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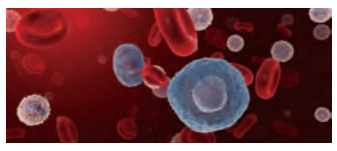

Why you should know your family's medical history

Creating knowledge that expands human possibilities

MEDIA PLANET

# PERSONALIZED MEDICINE

**WHY WE NEED TO START THE CONVERSATION ABOUT OUR HEALTH**

## THE RIGHT PERSON, THE RIGHT MEDICATION, THE RIGHT TIME

PHOTO: JASCO CHAN

How Canada is leading **the shift from "one-size-fits-all" medicine to more individualized care**

## Vision, unity of purpose, creativity, and agility

**Sir William Osler, considered the father of modern medicine, observed in regards to patient care that: "Variability is the law of life and as no two faces are the same, so no two bodies are alike and no individuals react alike and behave alike under the abnormal conditions which we know as disease."**

In contrast to Osler's theorem – the "individuality" of disease – contemporary medical diagnostics and treatment of disease are largely based on principles of commonalities. For example, all those presenting to their doctors with a particular combination of medical problems meeting the medical criteria for rheumatoid arthritis will be given this diagnosis and treated with the standard first-line medication.

### A personalized approach

Since our health is integrally influenced by our genetic make-up, we are indeed individual in our response to disease, our reaction to its treatment and in the types of diseases we develop. As Osler's words imply, we are not well served by a "one-size fits all" healthcare model.

Our medical care needs to be more customized such that all opportunities to predict and mitigate risk for disease are optimized across the population. Personalizing healthcare does not imply that each individual receive unique medical management but rather takes into account an individual's genetic and other relevant characteristics to improve the efficacy of healthcare decisions.

### Connecting the dots

This "personalized" approach, already successfully applied in a few areas of medicine, is illustrated by the use of Herceptin to treat breast cancer patients. Herceptin was designed to target a specific cancer gene mutation, HER2, found in some breast cancer patients.

While other examples of personalized healthcare are already in play, operationalizing this practice paradigm across the spectrum of medical care has until recently been impeded by the high costs inherent in obtaining a person's complete genetic profile (a.k.a. "whole genome sequencing").

### Increasing accessibility

This barrier is now vanishing as a virtual freefall in gene sequencing costs has made determination of an individual's whole genome sequence increasingly affordable and available.

While potentially transformative to the practice of medicine, connecting population-wide genome sequencing to personalized and more effective healthcare will be no small challenge. As it happens so often in medicine, technology has radically outpaced the understanding of the knowledge it produces. The scientific and medical communities face a virtual tsunami of personal genetic information that is only in the early stages of interpretation.

As evidenced by the poor state of health informatics across this country, the healthcare system does not respond well to demands for rapid change.

But change it must. The healthcare system needs to define its own VUCA: the Vision, Unity of purpose, Creativity and Agility that has driven the extraordinary advances in information and, for that matter, genetic technologies. Only then can we deliver the personalized healthcare that Osler envisioned and Canadians deserve.

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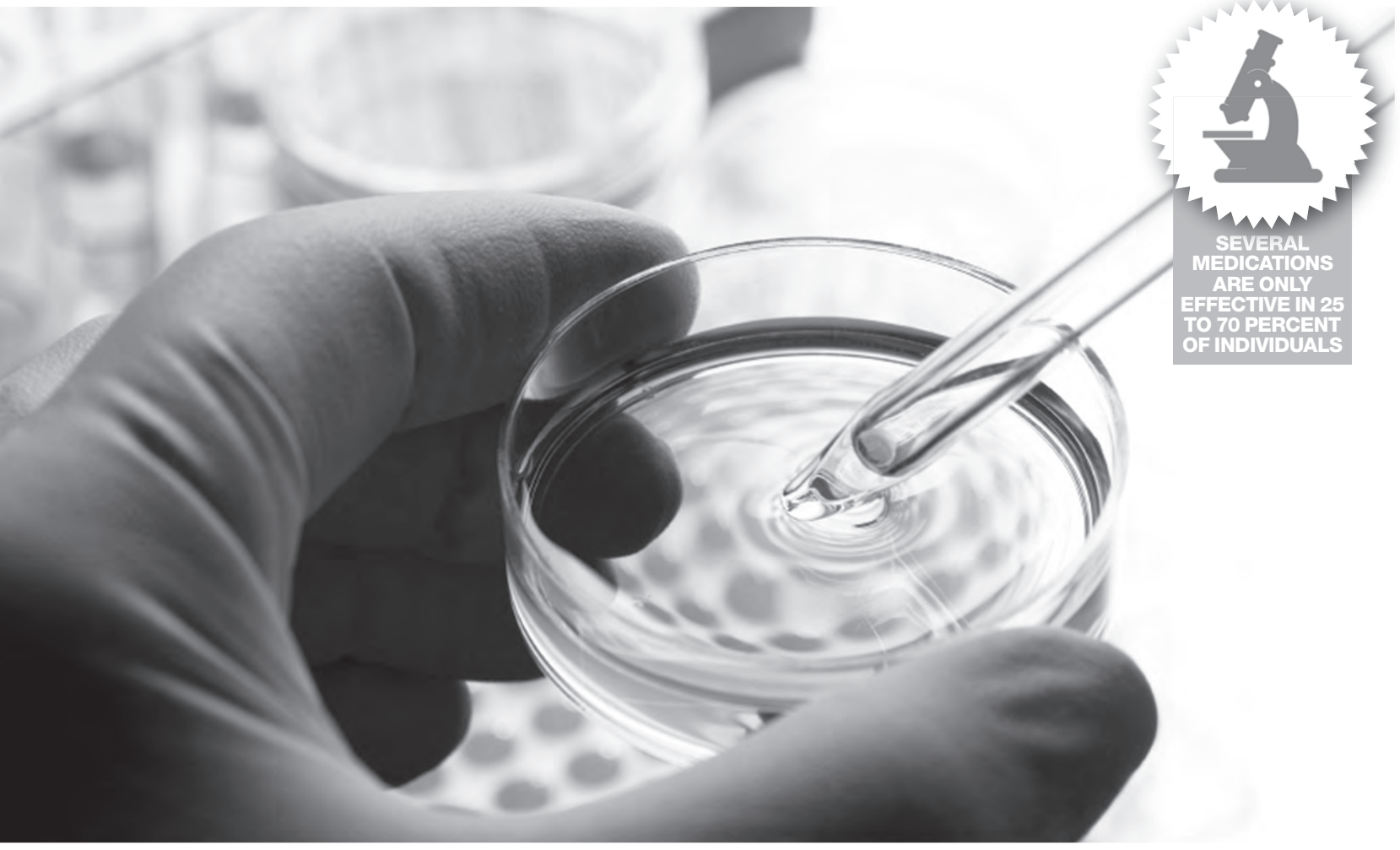
# CHALLENGES



**SEVERAL MEDICATIONS ARE ONLY EFFECTIVE IN 25 TO 70 PERCENT OF INDIVIDUALS**

Across Canada, leaders within the fields of research, diagnostics, biotechnology, and pharmaceuticals, along with government agencies, are **striving for excellence and advocating for patient health.**

## The next generation of healthcare

Personalized medicine refers to the tailoring of healthcare according to the personal characteristics of a patient through the use of genetic and/or other information. It is meant to move away from the "one size fits all" paradigm, to administer with greater confidence and predictability the right medication to the right patient, at the right dose and at the right time.

The importance of this approach lies in part in the following facts: 1) adverse effects of medications remain a major cause of hospitalizations, morbidities and deaths; and 2) several classes of medications are unfortunately only effective in 25 to 70 percent of individuals, which means that large numbers of patients do not derive benefits from such treatments.

Personalized medicine holds the potential of being more predictive, more precise and more proactive. Although physicians have always tried to personalize medical approaches, what is new about the time we are living in now is the potential to use an individual's genetic information or other "biomarkers" to inform and optimize disease evaluation and treatment.

### Behind the science

Since the completion of the Human Genome Project, related technologies have been developed and used to identify genes and variations in genes that are associated with diseases, efficacy responses or adverse reactions to medications.

Similarly, variations in non-genetic biomarkers (e.g., a protein) measured in blood, urine or tissues can contribute to the individualization of medical approaches. Emerging imaging methods (e.g., molecular imaging) also hold great potential in this context. Testing for genetic markers or other biomarkers can be used in posing the correct or more precise diagnosis, selecting the optimal treatment for an individual, or predicting responses to medications.

### Implementing our knowledge

The area in which personalized medicine has been mostly applied is within the treatment of cancers. Genetic changes that drive cancer development have been mapped in detail for many types of tumors. Currently, breast cancer is often screened for and treated based on genetic information.

Women who have inherited mutations in the BRCA1/BRCA2 genes have a higher risk of developing breast and ovarian cancer. Given this knowledge, patients can be screened on a more

**Dr. Jean-Claude Tardif**
Director, Montreal Heart Institute Research Center; Canada Research Chair in Personalized Medicine; Professor of Medicine, University of Montreal

frequent basis or may even undergo preventative surgical interventions.

Genetic tests are also being used to select the optimal treatments for breast cancer patients (e.g., evaluation of the HER-2 Neu gene before administration of the drug herceptin). These tests have had a major impact, enabling the development of more effective and safer treatments and significantly improving outcomes for patients.

In the field of cardiology, genetic information is already used in several circumstances, such as to identify and manage individuals who are at high risk of sudden death or heart failure when other family member(s) are affected or to treat specific cholesterol disorders.

### Looking to the future

With over 200 new personalized therapies currently in development, many more applications of personalized medicine are likely to soon emerge; not only in cancer and cardiovascular diseases but in dementia, depression and many other focus areas.

These breakthroughs will lead to unprecedented benefits in patient outcomes. We all have a responsibility in learning about personalized medicine, given that we will soon have the possibility of holding increasing amounts of our personal genetic information in electronic records at clinics, hospitals and pharmacies for use when needed.

Recognizing this enormous potential, it is important that patients, physicians, pharmacists, researchers, biotechnological and pharmaceutical companies and governments collaborate to realize these benefits. To enable this collaboration, the federal government, industry partners, Genome Quebec and the Montreal Heart Institute have created the Center of Excellence in Personalized Medicine (CEPMed).

**DR. JEAN-CLAUDE TARDIF**
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## Digitizing your personalized medical history

**Personalized healthcare relies on the ability to manage and mine large amounts of data.**

The healthcare and pharmaceutical industries have been buzzing with the promise of personalized healthcare since the inception of the human genome project, for good reason: knowledge gained through mapping the genetic make-up of the human species has and will continue to drive better preventive, diagnostic and therapeutic activities.

But it also gives rise to the problem of having too much information, a challenge that quickly replaces the problem of having too little. After all, knowledge only becomes knowledge if you derive insights from information. Otherwise, it's just information.

### Paperless records

This is true in all industries, but more so in healthcare. Every year, about a million articles are published in medical journals. Electronic patient records are continuously gathering petabytes of facts about symptoms, diagnoses, treatments and outcomes. The volume of data that constitutes medical information is doubling every five years; to make it useful to doctors and researchers — and beneficial to patients — new tools are required.

Enter big data analytics, an area of information technology that increasingly is underpinning the practice of biology today and driving personalized healthcare.

### Smart computers

To personalize treatment options for patients, the healthcare provider needs to crunch through large amounts of data — from personal genomics to known pathways on how drugs interact with genes. This task is ideally suited for computers like Watson, which in February 2011 competed in the TV quiz show "Jeopardy!" with human world champions. Watson won by first understanding the question, and then searching and analyzing about 200 million pages of text (about a million books) to find correct answers, all in about 3 seconds.

Some of the first commercial applica-

**Jeff Betts**
Business Development, Life Sciences IBM

tions of Watson's capabilities will be in healthcare, to help doctors make better, more accurate and more complete diagnoses. By analyzing the vast array of medical information, Watson will help physicians identify treatment options that balance the interactions of various drugs and narrow selection from among a large group of treatment choices, driving more effective treatment plans.

### Implementing the science

This year Memorial Sloan-Kettering Cancer Center announced they were building a powerful tool built on Watson to give clinicians a way to mine and extract knowledge from a wealth of clinical research, existing molecular and genomic data and cancer case histories and practices. The intent is to help doctors everywhere create individual cancer diagnostic and treatment recommendations for their patients based on the best current research and evidence.

Watson will never replace physicians or researchers, but it does demonstrate how big data analytics can enable doctors to use broader, deeper patient information and more complete clinical knowledge to promote personalized healthcare.

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WE RECOMMEND

**Christopher Needles**
Digital medical histories at our fingertips

PAGE 06

"Researchers are working to bring personalized medicine to cancer patients."



MEDIA PLANET

PERSONALIZED MEDICINE
1ST EDITION, JULY 2012

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**Distributed within:**
National Post, JULY 2012
This section was created by Mediaplanet and did not involve the National Post or its Editorial Departments.

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CHECK THIS OUT!

### Healthcare is beset with some of the most complex information challenges we face

- Medical information is doubling every 5 years, much of which is unstructured (unstructured is free text such as pathology and radiology reports, nursing documentation, e-mails, forms, surveys etc.)
- Data managed by hospitals and ambulatory providers will quadruple from 2010 to 2015
- 81 percent of physicians report spending 5 hours or less per month reading medical journals
- 1 in 5 diagnoses are estimated to be inaccurate or incomplete
- 50 percent of adverse drug reactions are caused by ineffective or inappropriate prescribing in Canada

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# CHALLENGES

# Small differences, big effects

**The vision that treatment choices, regardless of the disease being treated, will be based on a patient's genetic makeup and tailored to the biology of their disease, not just its symptoms.**

"It is much more important to know what sort of a patient has a disease than what sort of a disease the patient has," observed the late great Canadian scientist Sir William Osler.

As patients, physicians, funders, and society at large demand safer and more effective treatments, we continue to see the healthcare landscape undergo a shift. This shift is a direct result of our advanced understanding of diseases influenced by our ability to research and create more targeted therapies based on our genetic makeup.

By taking a predictive, preventive, personalized, and participatory approach to medicine, we have the opportunity to provide the highest level of care to patients that beforehand did not have access to the right treatments at the right time.

## Matching the right medicine to the right patient

"Personalized medicine is the delivery of the right therapy to a specific group of patients at the right time. It uses the insights we have from a genetic and biological perspective," explains Roche Canada CEO Ronnie Miller. "The important thing about genetics right now is that it really gives us the ability to offer targeted treatment and that's really important in the field of cancer treatment, because in chemotherapy healthy cells get destroyed along with cancer cells," he adds.

At its heart, it provides hope for those individuals who suffer from life-altering conditions. The value of personalized medicine, through saving lives and improving the quality of life, is rooted in positive outcomes for the patient.

The providers, developers, and researchers of the health care community now have access to cutting-edge technologies. These technologies improve our understanding of disease diversity and subtypes, determine differences between patients, identify drug targets, improve the quality and efficiency of research and development results, and provide biomarker and diagnostic tests.

It is through these advancements that we can now better identify, diagnose, and treat specific conditions, including but not limited to melanoma, hepatitis, leukemia, and breast and lung cancer.

## Thinking pink

Organizations advocating for patient health have transformed genetic and biological discoveries into tests and treatments for serious, life-threatening diseases. Thanks to these discoveries, Herceptin has become one of the most well-known examples of personalized medicine. The drug is a treatment for HER2 positive breast cancer, targeted at women who have been found to have an overexpression of the HER2 gene.

On average, one in five breast cancer tumors displays an overproduction of HER2 receptors. HER2 tissue tests are crucial in identifying those patients who will benefit from targeted Herceptin therapy. Once administered, the targeted treatment homes in on these receptors and inhibits their growth and production. Its benefits include improved response rates, increased disease-free survival and overall survival in women with breast cancer.

Every year, approximately 1.4 million new cases of breast cancer are diagnosed worldwide. While advances in the treatment of breast cancer are continuously being made, 450,000 women still die of the disease each year. With an estimated 22,700 women expected to be diagnosed with breast cancer in Canada in 2012, access to treatments such as Herceptin could positively influence thousands of lives.

"The important thing about genetics right now is that it really gives us the ability to offer targeted treatment and that's really important in the field of cancer treatment."

**Ronnie Miller**
CEO and President,
Hoffmann-La Roche Ltd.

## Treatment that's skin deep

Among the disease areas benefiting from personalized medicine, Canadians are seeing major strides related to melanoma.

It is ironic that Canada, renowned for its long winters and short summers, is seeing a rise in the number of people suffering from melanoma, a deadly cancer closely linked to sun exposure. Melanoma is now the seventh most common disease in Canada, and is predicted to affect 5,800 Canadians this year. Of these, 970 will die from the disease. As a result, it is now often thought of as the most dangerous type of skin cancer.

The production of melanin within melanocytes, a type of skin cell, is the reason behind our ability to tan. However, it is these same cells which have the ability to turn cancerous if overexposed to ultraviolet radiation from sunlight.

Up to 75 percent of melanoma cases are caused by exposure to ultraviolet radiation from sunlight or radiation from tanning beds. "The increase in melanoma cases is strongly linked to the increased use of tanning beds," says Dr. Anthony Joshua, a medical oncologist at the Princess Margaret Hospital, University Health Network.

## Discovering new therapies

Previously, when a patient was diagnosed with metastatic melanoma, the only treatment option was surgery to excise the tumour. There were no effective drugs. "However, in the last two years treatment options for melanoma sufferers have significantly advanced," notes Dr. Joshua.

This year alone, Canada has made leaps and bounds in treatment discoveries with regards to personalized melanoma therapy. Two new treatments have been approved by Health Canada, Yervoy and Zelboraf.

"Canada's approval of Zelboraf is a significant advancement for patients living with metastatic melanoma," Dr. Joshua says. Zelboraf, a drug that has been shown to inhibit cancer growth in patients with a common type of metastatic melanoma associated with a BRAF mutation, has shown impressive results within clinical trials. Zelboraf specifically targets the BRAF mutation and offers high, predictable response rates, giving physicians and payers confidence in the likelihood of its therapeutic benefit.

Yervoy, a human monoclonal antibody, works as a treatment for melanoma by activating the immune system. The drug has been shown to double the chances of survival 1-2 years after diagnosis. "Having these two new treatments available to patients will revolutionize the treatment of metastatic melanoma," states Dr. Joshua.

"As a result of the cancer genome sequencing project, we now recognize critical gene mutations, and drugs are now available that can block these mutations," Dr Joshua explains. "Doctors now know that in 40 percent of patients with melanoma, there is a defect in the BRAF gene."

## Looking to the future

Growing demand for highly effective, impactful medicines is being driven by an aging population, health care concerns and economic pressures. However, an influx of new technologies has enabled leaders within the fields of research, diagnostics, pharmaceuticals and biotechnology to meet this need by offering innovative tests and medicines.

The 1980s and 1990s were the era of the big "blockbuster drugs", says Miller. These were developed with a "one-size-fits-all" approach. However, things are changing now, he points out and the industry is undergoing a paradigm shift.

"We will see more innovations now," he predicts. By 2016, it is estimated that 50% of pharmaceuticals will be biologic medicines. Regulatory authorities like the Food & Drug Administration in the US and Health Canada are also very receptive to this new approach of treatment. "Industry philosophy is changing," Miller says.

It is the passion, commitment, and drive for excellence from leaders within the industry that is setting the pace for the future of health care in Canada.

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# From struggle to survival

A PATIENT'S VIEW

In a lifetime, the likelihood that you or someone you know has suffered or will suffer from a life threatening ailment has become increasingly probable.

To counter-act these statistics there has been a shift from a one-size-fits-all system to a more individualized approach, an effort that is changing the future of health care in Canada and world-wide. The ability to determine early diagnosis, identify the effectiveness of a drug, and analyse collective genetic information continues to positively impact the lives of many.

## Lifting the veil on melanoma

Annette Cyr, founder of the Melanoma Network of Canada, was first diagnosed in 2001 with a low risk Melanoma that she was told was "very curable". Unfortunately, the cancer reappeared in 2007 and this time it was larger. In both instances the tumour was surgically excised as chemotherapy was not available for Melanoma sufferers at the time, she says.

"I was prescribed interferon and that was not very good," she observes wryly. Interferon is not a chemotherapy drug, and until very recently it was the only medication that was available for patients with high risk melanoma.

## Making a come-back

"I was melanoma-free for five years, but in May I again felt the tell-tale bump the size of a pea just under the skin on my right leg," confides Cyr. "It is extremely distressing and disconcerting to be diagnosed the third time with the disease, but I don't allow myself to dwell on the negatives."

"It's true that 'when you know better, you do better'", she says, quoting American poet Maya Angelou. "We do know better now. We know that ultra violet exposure or radiation in the sun causes cancer, and 90% of melanoma and skin cancer is preventable."

## Increasing the odds

Melanoma is the deadliest and most aggressive form of skin cancer, killing 80 to 85 per cent of stage IV patients within five years. Of the individuals diagnosed with melanoma, approximately half carry a genetic mutation in the BRAF gene. The B-Raf protein, which is a product of the BRAF gene, is involved in signalling pathways within cells. While a non-mutated BRAF gene is responsible for directing cell growth, when a mutation occurs within this gene cancer can occur.

As a result of a partnership between Hoffmann-La Roche and Plexxikon, the first and only personalized treatment for people with BRAF V600 mutation-positive metastatic melanoma was created. Zelboraf, a B-RAF inhibitor, is a drug that targets and inhibits the mutated BRAF protein. In layman's terms, this targeted therapy has the ability not only to reduce the pain associated with cancer but also to reduce the risk of mortality and having the disease progress further. As such, the clinical trials for Zelboraf offer the promise of great potential.

"Zelboraf offers BRAF-positive patients a chance to live; to raise their children, to spend time with loved ones and to continue to contribute to society," says Cyr. "For Canadians with metastatic melanoma, the approval of Zelboraf brings new hope."

## New perspectives

Cancer isn't the only type of disease that is treatable through personalized health care. Over 550 million people worldwide are infected with hepatitis B or C. Hepatitis, a disease caused by the hepatitis A, B, and C viruses respectively, attacks the liver. Similar to chronic hepatitis B, chronic hepatitis C is a "silent" disease. Often no symptoms appear until your liver is severely damaged.

Peginterferon alfa-2a, the medical name for an often used hepatitis therapy, is a once-a-week injection that works to reduce the amount of chronic hepatitis C or B virus in the body. With the right dosage, and the right timing, this specific medication has the ability to help the body's immune system fight the hepatitis virus.

## Enhancing quality of life

Our expanding knowledge and understanding of disease mechanisms combined with molecular biology and technology expertise has lead and continues to lead us to more targeted therapies. We have already applied world-class science across numerous fields all in the hopes of benefiting the patient.

Treatments and therapies for hepatitis B and C; as well as melanoma, breast, and gastric cancer; are early successes for a medical future that looks brighter by the day.

It is this ability, to enhancing a patient's quality of life and prolonging their life expectancy by ensuring a treatments success, that truly is the meaning of personalized medicine.

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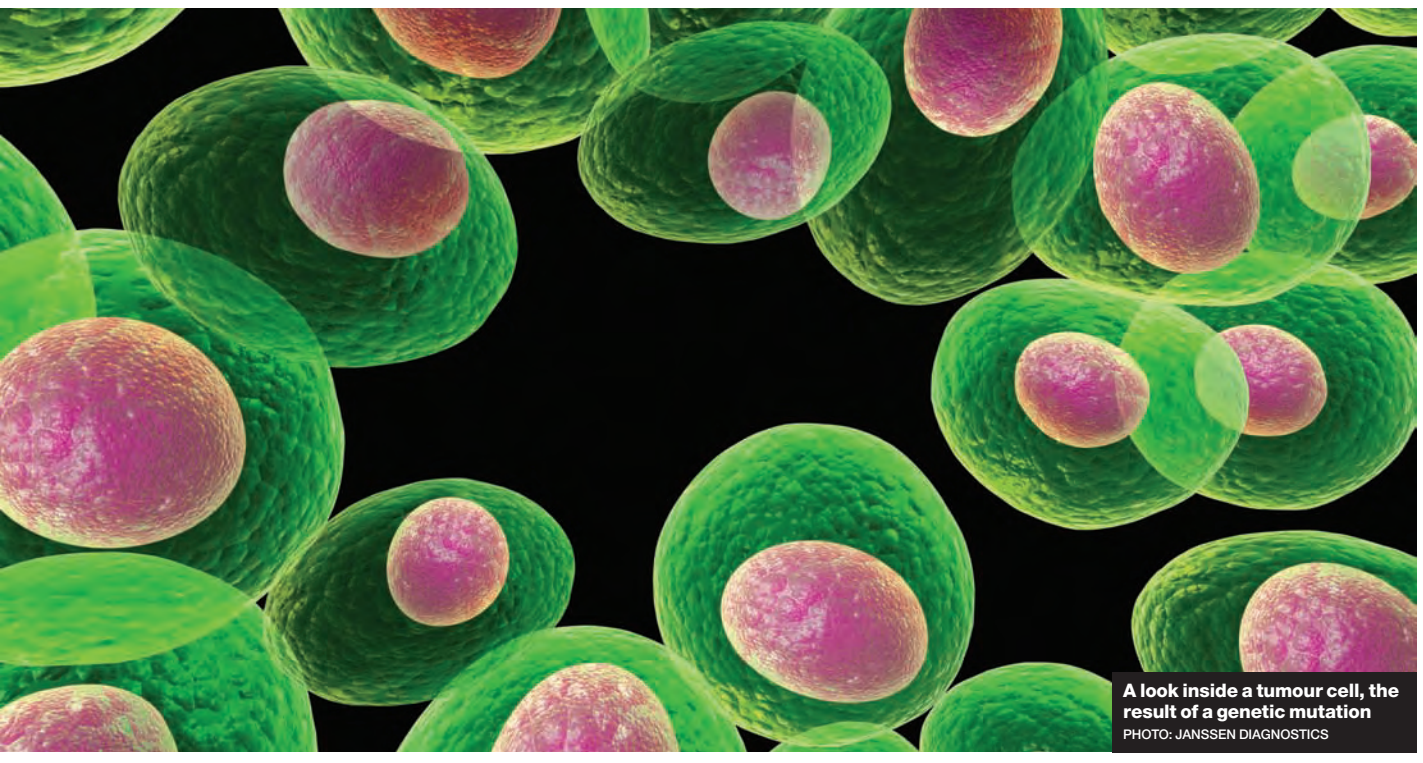
# INSPIRATION



**A look inside a tumour cell, the result of a genetic mutation**
PHOTO: JANSSEN DIAGNOSTICS

■ **"This technology can change the way we treat people facing a number of metastatic cancers."**
Vicki Vakiener, Global Business Leader, Janssen Oncology Diagnostics

■ "We are engaged and committed to understanding individual risk factors and enabled to take corrective action."
Daap Kooij, Global Business Leader, Infectious Diseases Diagnostics and Health Information Technology, Janssen Inc.

■ "At its heart, personalized medicine is about bringing the right drug to the right patient at the right time."
Kostas Trakas, Global Market Access Leader, Personalized Medicine, Janssen Inc.

# A focus on patient-centred care

■ **Question:** How has one of Canada's largest industries impacted the future of personalized medicine?

■ **Answer:** By targeting widespread diseases with precision, pharmaceutical companies such as Janssen Diagnostics are driving a change in how we look at healthcare.

Janssen Diagnostics is advancing a customized, patient-centric approach to improve the lives of people affected by some of the world's most serious and widespread diseases. Their R&D strategy recognizes that every patient is different and should be treated accordingly to identify which individuals will respond to certain medications.

Beyond patient support, Janssen Diagnostics (JDx) aims to make diagnostic information available to healthcare professionals to help them make more informed treatment decisions. "At its heart, personalized medicine is about bringing the right drug to the right patient at the right time. By pursuing this philosophy, we continue to deliver on our dedication to bring transformational and innovative products and services to patients," says Kostas Trakas, Global Market Access Leader, Personalized Medicine, Janssen Inc.

## Building strong partnerships

Janssen Diagnostics, through its Virco team, has actively collaborated with Canadian researchers and clinicians in the area of infectious diseases for more than a decade.

This has been a truly symbiotic relationship that has been made possible by world-class scientists in Canada. Dr. Julio Montaner, Director for the British Columbia Centre of Excellence, has developed a strong collaboration with Janssen Diagnostics, noting, "Our work with Janssen has enabled us to further our understanding of HIV resistance and its clinical consequences. This has been a critical component to advance our fight against HIV/AIDS."

## Unique technology making a difference

HIV/AIDS, once considered a death sentence, is now a lifelong treatable disease. One of the key drivers behind this change is scientists' increased understanding of the HIV virus' resistance to antiviral therapies.

In this regard, the Janssen Diagnostics VircoTYPE™ HIV-1 analysis service has impacted the industry immensely. This service analyzes the genetic information from the patient's HIV virus to provide physicians and people living with HIV/AIDS with accurate, personalized information about their virus's susceptibility, resistance to antiretroviral drugs, and available drug options.

"Together with the clinical community we are engaged and committed to understanding individual risk factors and enable to take corrective action", states Daap Kooij, Global Business Leader, Infectious Diseases Diagnostics and Health Information Technology. "The old concept of patient treatment is changing as we need to become smarter in the way we deploy drugs in clinical practice so we can treat patients with the highest level of confidence."

## Liquid biopsies improve care

In oncology, Janssen Diagnostics strives to transform cancer to a preventable, chronic or curable disease. To that end, their CELLSEARCH® platform, developed and marketed through their Veridex, LLC division, enables clinicians to perform non-invasive "liquid biopsies" via a routine blood test.

CELLSEARCH is indicated for patients with metastatic breast, prostate and colorectal cancers and is available in Canada, although not currently reimbursed. The test identifies circulating tumor cells (CTCs) - cells that have broken away from an existing tumor and entered the bloodstream. Clinicians can then use this information to determine their patients' prognoses.

Additionally, CTCs can be measured alongside other standard tests to gain a more complete picture of patients' statuses and allow oncologists to make more informed treatment decisions. The revolutionary technology has helped save many lives and is the first and only CTC test that is cleared for use as an in vitro diagnostic in Canada, the US, and a number of other countries globally. Most therapies given are trial and error.

Physicians try new combinations when one fails, but advances such as CELLSEARCH® prove that the future of oncology and personalized medicine is promising. "My vision is to tell patients that they're getting the right therapy. This technology can change the way we treat people facing a number of metastatic cancers," says Vicki Vakiener, Global Business Leader, Oncology Diagnostics.

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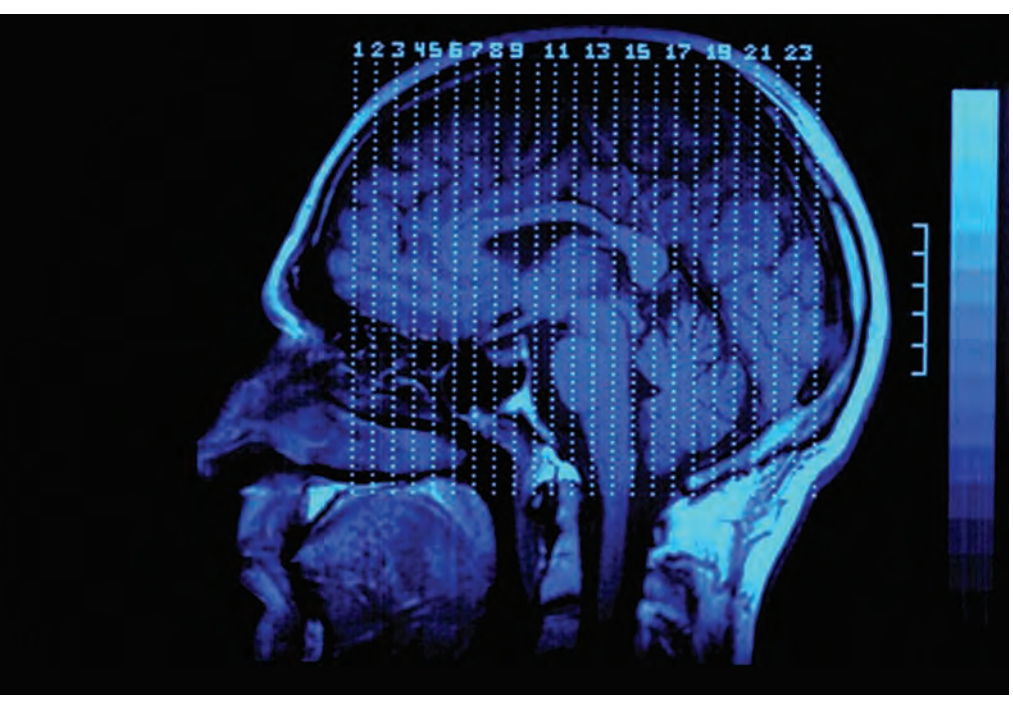

# Molecular imaging: Setting a precedent

**Now that particle physics has found its "God particle," what holy grail comes next? Personalized medicine, perhaps.**

Even though we are all human, our bodies, our diseases, and our cures are distinct. Personalized medicine is the (hope for a) platform that would truly individualize healthcare, tailored specifically to you at the moment when you are ill and want to be diagnosed, prognosed, and treated.

## Technology's role in the hunt

We often think of genetics or genomics as the key. But there is another side, one that speaks to the capacity of observation that couples powerfully with genetics to provide the best possible guidance to the clinician and the patient: molecular imaging. It represents the suite of technologies that can non-invasively reveal exactly what is happening inside you at the cellular level — at the location of the illness.

## Why does it matter?

It is the combination of genes and molecular imaging that might bring the holy grail of personalized medicine within reach. For instance, the BC Cancer Agency is already using PET/CT scans to monitor the effectiveness of chemotherapy in cancer treatment: checking to see if the cure is actually impacting the minute-by-minute biological and chemical pathology of the cancerous tumour.

Various groups ranging from CHUM in Montreal, UHN in Toronto, to BCCA and TRIUMF + AAPS, Inc. in Vancouver are pressing forward with the research to underpin this breakthrough. Using isotopes, dyes, fluoroscopies, spectroscopies and everything else, these teams are convinced that Canadians will soon have the ability to be mapped and understood individually and uniquely.

## Targeting your care

When you go in to see your doctor, he or she will combine your genetic data with up-to-date imaging of the area of your health concern to provide a diagnosis.

When the treatment regiment begins, the doctor will monitor your body's response to the protocol and you will know day-by-day how effective the cure or therapy is. So not only will you feel better faster, but precious healthcare resources will be more effective in targeting just what makes a difference for each patient.

So, let's welcome this bright, new future and take all the steps necessary to realize it. You and I will personally be better off as a result.

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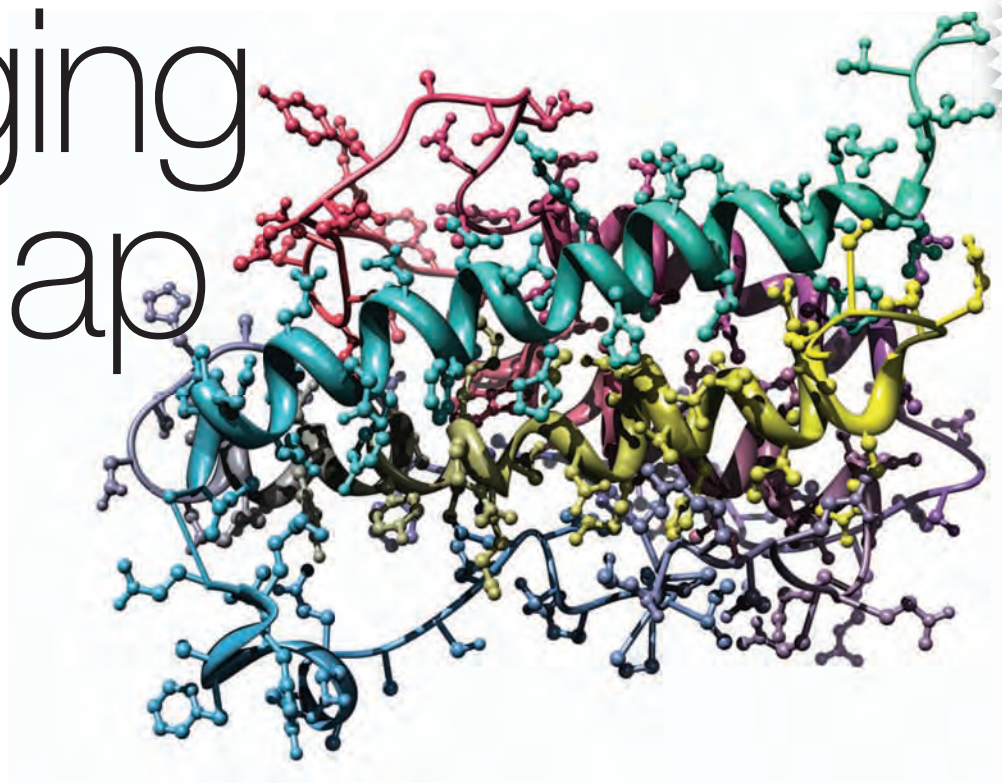
CHALLENGES

# Bridging the gap



CANADIAN LEADERS IN HEALTHCARE ARE LEADING THE CHARGE ON INNOVATION

Rapid progress in genomics, proteomics, diagnostic device technologies and information technology now enable the use of patients' genomic information in drug development and clinical decision making for more effective and safer individualized health care.

As a result traditional 'blockbuster' drug development models and 'one-size fits all' drug therapy are being displaced by more innovative approaches. Personalized medicine aligns the interests of patients and health care systems with those of pharmaceutical and diagnostic companies: each striving to provide the optimal treatment for each patient.

These changes affect the interests of many, from individual patients to multi-national pharmaceutical companies, and can be leveraged to provide clinical, social, commercial and economic benefits.

## Strategic alliances

Cepmed is a Centre of Excellence for Commercialization and Research (CECR) funded by the Canadian Government, Genome Quebec and industry partners, including Pfizer, Roche, AstraZeneca, Novartis and Merck. At Cepmed our mission is to develop and co-invest in public-private partnerships in research that: (1) enable synergies that accelerate innovation in personalized medicine and (2) generate commercial opportunities for multiple industry partners.

## Leading by example

Founded by the Montreal Heart Institute and Genome Quebec, Cepmed makes use of the Beaulieu-Saucier Pharmacogenomics Centre and the Montreal Heart Institute Coordinating Centre (MHICC) in its projects. Since 2008, Cepmed has attracted millions of dollars in foreign investment through public-private partnerships in translational medicine that incorporate pharmacogenetic testing into Phase III clinical trials and studies of marketed drugs.

Cepmed's priorities also include developing business models that are attractive to its partners and leverage Canadian assets. Importantly, Cepmed has built a Canadian and international network of experts and industry partners in personalized medicine, which can be used in positioning Canada as a leader in personalized medicine.

**Manon Decelles, CPA, CGA**
President & CEO, Center of Excellence in Personalized Medicine

Cepmed plays an important role as an integrator in the development and implementation of personalized medicine. As a non-profit organization Cepmed can align and manage the interests and efforts of different stakeholders with overlapping or different interests (i.e. industry, physicians, researchers, health care organizations etc.) to create synergies that accelerate innovation. By doing so, Cepmed can reduce the significant risks and costs required for medical innovation while maximizing the clinical and commercial benefits derived from partnerships. This risk and cost sharing strategy will speed the development of business models needed for the sustainable growth of Canadian biopharmaceutical, biotechnology and telecommunications companies in personalized medicine.

## A support system

To support the development of a Canadian environment that is favorable to the adoption of targeted drugs, molecular tests and decision making tools, Cepmed engages and works with physicians, health care system decision makers and policy makers. Working together with its partners, Cepmed can play a key role in transforming health care, health care systems and the role each of us plays in it, as a user, a provider or a payor.

**MANON DECELLES, CPA, CGA**
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CHECK THIS OUT!

## Pharmacogenomics as an aid in personalized medicine

Pharmacogenomics is the utilization of genetic information to predict how an individual will metabolize medicines. For example, genetic differences can cause some people's bodies to break down a medication too quickly, making the treatment much less effective, or too slowly, allowing the medicine to accumulate to toxic levels in the blood.

Knowing what these genetic factors are in a particular patient allows a doctor to prescribe the right dose or to use a different medication to avoid problems. Pharmacogenomics will not only allow physicians to choose the most effective drug for each patient but will also help reduce the large number of adverse drug reactions (ADRs) that currently occur.

ADRs, which are harmful effects of a medication used at the recommended dose, represent a significant health concern for patients and a tremendous drain in health care resources. Through pharmacogenomics, physicians will be able to personalize medical treatments to provide safer, more effective and thus less costly therapy for every individual.

- Genetics may account for up to 95 percent of the variability in drug responses
- Fatal ADRs represent the fourth to sixth leading cause of death in the United States
- ADRs are responsible for between 5 and 7 percent of hospital admissions

**COURTESY OF THE BC CLINICAL GENOMICS NETWORK**
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NEWS

# Mapping your genes

**Question:** How has Ontario influenced the future of personalized medicine?

**Answer:** The Ontario Institute for Cancer Research is shaping the way we look at cancer treatment by helping patients gain access to superior care.

Recent breakthroughs in research have shown that every patient's cancer is different. This means we need new tools to better diagnose and treat patients based on mutations and other features unique to their specific cancer. This is called personalized medicine. It will offer patients treatments that are more likely to work, have fewer side effects and help them to live longer, healthier lives.

**Christopher Needles**
Ontario Institute for Cancer Research

Researchers are working to bring personalized medicine to cancer patients. Scientists at the Ontario Institute for Cancer Research (OICR) and the University Health Network's Princess Margaret Hospital (PMH) in Toronto are collaborating on the Genomics Pathway Strategy (GPS).The GPS is a new initiative that connects scientists in different disciplines, including genomics, bioinformatics and clinical trials. They are conducting clinical trials to develop new ways to treat patients based on mutations found in the cancers.

## The future is affordable

Genome sequencing, which can find mutations in all cancer related genes, is currently prohibitively expensive for widespread use in the clinic. But the costs of sequencing and analysis have dropped rapidly over the past decade, and are continuing to decrease. Soon genome sequencing could be no more or less expensive than currently used tests. This will present new opportunities to diagnose and treat patients by sequencing their DNA.

Currently, a GPS study is looking at the feasibility of introducing gene sequencing into clinical care. Researchers are enrolling cancer patients in the study for whom standard treatment has not been successful. They are sequencing the genes both of the patient's healthy tissue and tumour tissue. This enables the scientists to find the genetic mutations that are driving the growth of the tumour.

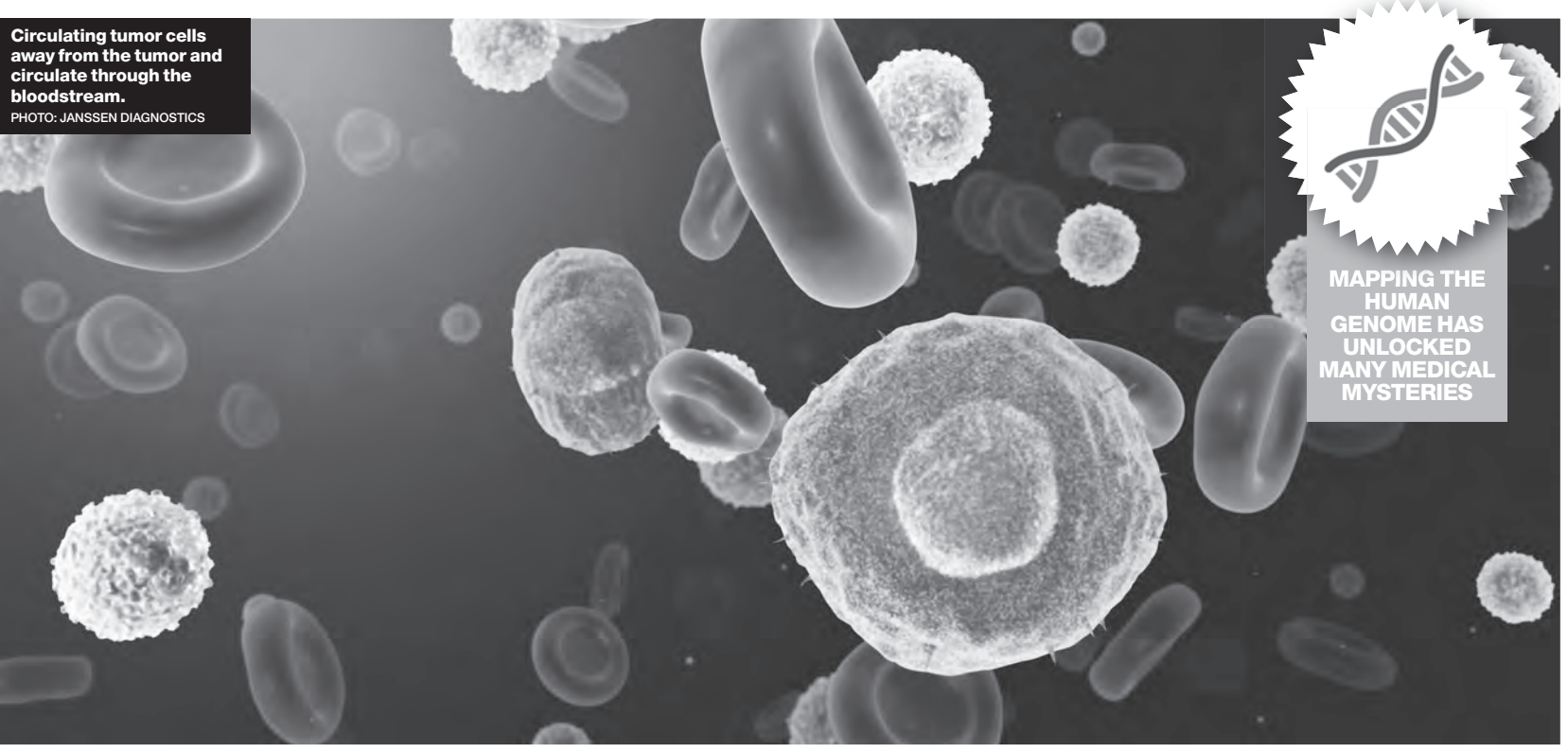
## Seeing the bigger picture

The information provided by the gene sequencing can then be used by an oncologist to select a treatment that may be effective against a particular mutation and may be more successful in stopping the growth of the tumour. The feasibility study was initiated at PMH and expanded to Hamilton, London, Ottawa and Thunder Bay.

GPS researchers are using the information from this trial and other trials to build a framework for integrating genomics into everyday clinical practice. The GPS shows we are starting to move personalized medicine based on the cancer genes from the lab to the clinic. We are at the frontier of a new era in health care where advances in research can become new tools for clinicians to use to better treat their patients.

**CHRISTOPHER NEEDLES**
**Ontario Institute for Cancer Research**
editorial@mediaplanet.com

NEWS



Circulating tumor cells away from the tumor and circulate through the bloodstream.
PHOTO: JANSSEN DIAGNOSTICS

MAPPING THE HUMAN GENOME HAS UNLOCKED MANY MEDICAL MYSTERIES

# Finding the answers within our DNA

■ **Question:** How has science really helped us identify whether or not we have or will develop life altering conditions?

■ **Answer:** The discovery of genetic mapping has opened up a whole new world of possibilities with regards to identification, diagnosis, and treatment.

Molecular biology is driving major change in medical practice and transforming how physicians manage patient health.

Traditional approaches to health care are shifting at a furious pace. Medical care that was once ruled by stethoscopes and x-rays has evolved into a hunting expedition inside the body's own cells for the underlying mechanisms of disease.

Research and advanced technology have brought us to a new era in health care that's more preventive in nature, with treatment backed by strong scientific data and early diagnosis.

## New discoveries

Our modern revolutionary wave in medicine began with the discovery of DNA's molecular structure and surged forward again with the sequencing of the human genome. Advances in science, specifically related to genomics, are dominating medicine and health care now and will continue onwards into the future.

Medical research facilities in hospitals, universities and innovation centres across the country are dedicating their efforts in molecular medicine to investigate underlying risk factors and causes of many health conditions.

## From reactive to predictive

Early results are appearing in laboratories and medical centres throughout Canada. Health care is moving away from a reactive model where patients are admitted to hospitals or visit their physicians with an illness that requires diagnosis then treatment through surgery or drug therapy.

"Medicine needs demonstration projects to show how genomics and personalized health will work and to help allay fears about what lies ahead."

**Pierre Meulien**
CEO and President,
Genome Canada

Instead, we are heading towards a medical practice that is more preventive, predictive and tailored to a person's own molecular biology. This is the essence of personalized medicine.

## Creating a new language

We are already witnessing some early indicators of how molecular biology as a base for personalized medicine is reshaping health care and recreating our knowledge of medical science.

An entirely new vocabulary has been spawned to produce a language of molecular medicine related to patient care. Specialties such as immunogenetics and pharmacogenetics enable physicians and researchers to peer into the human body and investigate the root cause of disease.

Newly discovered genomic variations associated with cholesterol levels, high blood pressure, diabetes and other risk factors or cardiovascular disease- a leading killer in North America and around the world - are slowly making their way to patients at the bedside.

## Same conditions, new outlooks

We are learning, for instance, how inflammation at the cellular level leads to arteries clogged by plaque, which in turn can rupture causing heart attack and stroke.

Heart attack patients are being saved by a bedside genetic test that shows whether they carry a gene that reacts to a popular clot-busting drug during treatment.

Medical science continues to investigate human genomics to uncover the mysteries of childhood neurological disorders, such as autism.

Genomics tools are used to identify drug toxicity and adverse drug reactions. Cancer patients are being classified and treated according to the molecular nature of their tumors.

These are but a few examples of personalized medicine.

## Looking to the future

We know how environment, behaviour and lifestyle can influence the progression of disease. Now we are proceeding swiftly along a new path of personalized medicine using the tools, technology and knowledge of genomics to learn how to identify and provide treatment.

**PIERRE MEULIEN**
editorial@mediaplanet.com

### FACTS

**More than $130 million in funds have been set aside for Canadian researchers to demonstrate the effectiveness of personalized medicine.**

The research must deliver tangible results showing the medical value or practical applications, and lead to economic or social benefits for Canada. These results could include:

- new technologies
- changes in clinical practice
- new uses of existing drugs, or
- reduction in adverse drug reactions

At least 13 large-scale projects are expected to be funded, with work commencing in 2013.

Personalized health is especially promising for infectious and autoimmune diseases, cancer, cardiovascular and neuro-degenerative diseases, psychiatric disorders, diabetes and obesity, arthritis, pain, inflammation, Alzheimer's and rare diseases.

"This competition is significant because we will understand which technologies can be integrated into the health system in an economically viable manner," says Meulien.

Typical of Genome Canada-funded projects, researchers must also incorporate ethical, environmental, economic, legal and social aspects of their work.

# TREATMENT WITHOUT SIDE EFFECTS

## A new approach to cancer therapy

Alpha Cancer Technologies Inc. (ACT) has created an innovative approach to the advancement of cancer care. Increasing the quality of life is one of the key advantages of a new chemotherapy delivery system that the company is advancing.

Alpha-Fetoprotein (AFP) is a unique delivery platform which allows chemotherapy drugs to kill cancer cells exclusively without damaging normal cells. This targeted cancer therapy uses a human protein that is produced by the embryo as it grows which means that every human being has been exposed to AFP. This protein is not considered by the immune system as foreign and does not cause an immune reaction that is often a problem with biologic drugs. Upon birth the protein is no longer found, however, it sometimes shows up again when there is cancer in the body. More importantly, the receptor for AFP is not present on normal adult cells but appears on most cancer cells. When chemotherapy is attached to AFP and then delivered to the patient the AFP molecule binds to the receptor and enters the cancer cell where it unloads the chemotherapy. Because AFP cannot enter normal cells that lack the receptor toxicity is greatly reduced and the targeted killing of cancer cells is significantly increased. Lower toxicity also offers the desirable ability to treat the patient more frequently killing cancer cells even in chemotherapy resistant tumors.

"Once our drug is on the market, we expect it to become a new standard of care for the majority of cancer patients"

**Igor Sherman**
CEO,
Alpha Cancer Technologies Inc

## Looking ahead

"Results to date show that AFP itself is very safe and AFP-chemotherapy drug combination should be much safer and more effective than chemotherapy drug alone. "Simply put, this could be a significant game changer in the treatment of cancer," says Richard Potts, Chairman of Alpha Cancer Technologies Inc. Most cancers can potentially be treated by using this approach as most cancer cells express the receptor for AFP. One of the major problems with some of the widely used chemotherapy drugs is nerve damage, loss of sensitivity and chronic pain. But ACT has started a series of experiments to show that the AFP delivery technology does not have these side effects. "Once our drug is on the market, we expect it to become a new standard of care for the majority of cancer patients," Dr. Igor Sherman, CEO of Alpha Cancer Technologies Inc. (ACT) says.

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DON'T MISS!

**Roberto Lara**
**SoCRA Certified Clinical Research Professional**
Director of Business Development, Scimega Research Inc

### What is a CRO?

A Contract Research Organization, also known as a Clinical Research Organization (CRO), is a service organization that provides support and/or services to pharmaceutical, biotech and medical device industries as well as foundations, research institutions, and universities. There are over 1,100 CROs in the world. What separates Scimega Research Inc from the rest is our dedication to exclusively providing expert oncology clinical research services in Canada for 15 years.

### What is a clinical trial?

When the term clinical trial is mentioned many automatically assume one refers to paid healthy volunteer studies. The truth is that clinical trials are much more. They play a crucial role in understanding how our body reacts to the drugs that devoted researchers develop to treat everything from seasonal allergies to the flu and even the most challenging of diseases like heart disease and cancer. There are several reasons why patients volunteer for clinical trials but for most, it is the possibility to help themselves and to help others who may benefit from developing a new medication or treatment.

### How has Scimega contributed to the advancements made in oncology thanks to clinical trials?

Scimega's two-pronged approach includes attracting cutting edge oncology clinical research and facilitating sponsor access to pertinent data, thereby accelerating our clients "go/no-go" decision making ability. Since 1997, we have invested much effort and marketing dollars promoting Canada's oncology clinical research potential. In 2008, we introduced the Reverse Feasibility Program – bringing biotech sponsors and Canadian investigators together to facilitate recruitment and accelerate study start-up times while meeting the needs of Canada's cancer patients.

### What are common misconceptions regarding clinical trials?

The most frequently mentioned concern as to why people do not participate in clinical trials is the fear of receiving placebo instead of the active drug. However, for a life-threatening condition such as cancer all participants will receive the standard of care treatment at the very least, for practical and ethical reasons.

### How has science and personalized medicine benefited from the use of clinical trials?

Personalized medicine has the potential to optimize targeted delivery and dosing of treatments so patients can receive the most benefit with the least amount of risk, cutting out the difficulties of the current trial-and-error process many patients endure to find the correct drug and dose to treat a condition.

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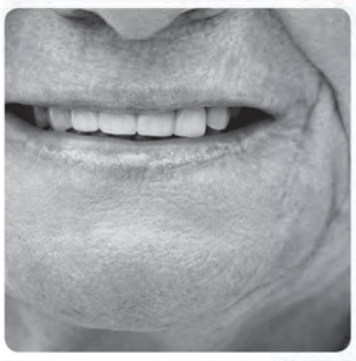
patient
targeting

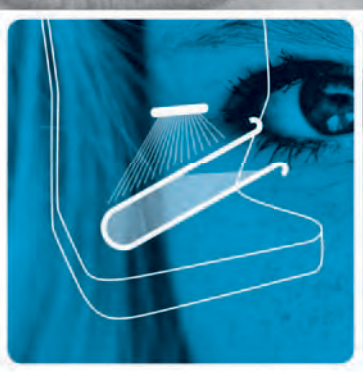


early
diagnosis

personalized
medicine



expert
test
platforms



# We take your health **personally**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