

Canadian Institutes of Health Research Personalized Medicine Signature Initiative 2010-2013



Canadian Institutes of Health Research
Instituts de recherche en santé du Canada

Canada

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Contents

CIHR PERSONALIZED MEDICINE INITIATIVE	1
BUILDING EVIDENCE	2
ADDRESSING REGULATORY AND POLICY CHALLENGES	4
NATIONAL INFRASTRUCTURE AND SERVICES	5
DATA HANDLING	6
OUTREACH AND EDUCATION	7
GLOBAL REACH	9

CIHR Personalized Medicine Initiative

The **Canadian Institutes of Health Research (CIHR)** is the Government of Canada's health research investment agency. CIHR's mission is to create new scientific knowledge and to enable its translation into improved health, more effective health services and products, and a strengthened Canadian health care system. Composed of 13 Institutes, CIHR provides leadership and support to more than 14,100 health researchers and trainees across Canada.

It is widely recognized that the way we approach the understanding, diagnosis, and treatment of disease is rapidly changing. Emerging technologies in genomics, epigenomics, proteomics, nanotechnology, molecular diagnostics and imaging are enabling this rapid revolution. Consequently, it is clear that we will need to transform from a reactive, one-size-fits all approach to a more personalized system of predictive, preventive, and precision healthcare that is tailored to a population or an individual.

The overall goal of the CIHR Personalized Medicine Signature Initiative is to **enhance health outcomes** through patient stratification approaches by integrating evidence-based medicine and precision diagnostics into clinical practice.

This is initially accomplished by supporting the **development and translation of research discoveries**, including biomarkers, genomic signatures, diagnostics, and innovative devices for clinical use. It is also accomplished by **supporting the development of an evidence base** on how to assess and eventually integrate these discoveries and therapeutic approaches into **health policy and practice**.

To date, **over \$200 million** has been invested or committed by **CIHR and its partners** over a 5-year period to support personalized medicine research across Canada.

National Framework

Personalized medicine promises obvious benefits to medical practice as well as the healthcare system, including prevention and screening strategies targeting high-risk individuals, avoidance of serious adverse outcomes, and better matching of therapies to disease and individual profiles.

Components for a national framework that would support the successful integration of personalized medicine approaches in the Canadian context are grouped under five core headings:

- 1) **Building Evidence**
- 2) **Addressing Regulatory and Policy Challenges**
- 3) **National Infrastructure and Services**
- 4) **Data Handling**
- 5) **Outreach and Education**

Examples of current research funding opportunities, infrastructure, and engagement strategies that address and overcome the current health research gaps under each of these core headings are described throughout this document.

Building Evidence

A strong evidence base is required for the establishment of personalized medicine. Fortunately, the generation of this evidence base is strongly supported by research, and Canada has a very active research community. Canada is involved in national and international projects that have led to the discovery of numerous genes, mutations, biomarkers and molecular pathways that are associated with diseases. The next step will be to translate this knowledge into tangible health benefits. Below are a number of funding opportunities that support the building of this evidence base, while at the same time sustain the appropriate health services, policy, and economics research. A number of partners and CIHR Institutes have invested in these funding opportunities, including: **Institute of Cancer Research, Institute of Genetics, Institute of Health Services and Policy Research, Institute of Infection and Immunity, Institute of Musculoskeletal Health and Arthritis, Institute of Neurosciences Mental Health and Addiction, Institute of Circulatory and Respiratory Health, Institute of Nutrition Metabolism and Diabetes, and Institute of Aging.**

**Genomics and Personalized Health
Competition: Genome Canada-CIHR Partnership
Funding from 2013-2017
Total Investment with Genome Canada and Partners:
~ \$150 million**

The funded multidisciplinary projects will allow ‘omics-based research and technology to contribute to a more evidence-based approach to health and to improve the cost-effectiveness of the health-care system. Projects also demonstrate a high potential for improving health outcomes as well as practical applicability.

Genomics and Personalized Health

Since the launch of the Personalized Medicine Signature Initiative, CIHR’s partnership with Genome Canada on the Genomics and Personalized Health competition represents one of the most important and significant opportunities to date dedicated to advancing the personalized medicine health research agenda.

**Advancing Technology Innovation through
Discovery Program
Funding from 2011-2013**

Total Investment with Genome Canada and Partners: \$2.8 million

Two disease consortia were supported: one focused on rare childhood diseases and the other focused on pediatric cancers. Next-generation sequencing technologies are being used to identify disease-causing genes with great success. By themselves, these studies show great promise in terms of patient stratification and characterization and for the development of therapeutic protocols based on patients’ characteristics.

**Multidisciplinary Teams Focused on Late Effects and Rare Diseases
Funding from 2011-2017**

Total investment with partners: Over \$29 million

Four multidisciplinary cancer, and nine rare diseases, teams are supported. The cancer teams will advance the field in order to prevent or mitigate late effects of childhood cancer treatments, while the rare diseases teams will help transform fundamental biological research into medical practice and treatments. Projects will also focus on the ethical, legal and social aspects surrounding these issues.

Collaborative Health Research Projects (CHRP)

Funding from 2012-2016

Total Investment with Partners: Over \$1.9 million

The CHRP program supports innovative, interdisciplinary, collaborative research projects requiring participation from the natural sciences or engineering community together with the health sciences sector. It helps enhance the development of biomarkers, screening technologies and nanotechnologies to further develop molecular diagnostics and point of care devices.

Alternative Radiopharmaceuticals for Medical Imaging

Funding from 2009-2011

Total Investment with Partners: Over \$6 million

CIHR took the lead in organizing a research response to the health crisis caused by a Tc99m shortage following the closure of Canada's Chalk River nuclear reactor. Seven projects are researching viable alternatives to the nuclear reactor production of medical isotopes necessary for routine clinical practice.

Medical Imaging Clinical Trials Network (MITNEC)

Funding from 2010-2013

Total Investment: \$9.4 million

As part of the 2010 federal "Isotope Supply Initiative", CIHR helped establish a medical imaging clinical trials network. The objective is to establish a national, sustainable, imaging clinical trials network that will provide a clinical platform for imaging research in Canada.

Research in Action

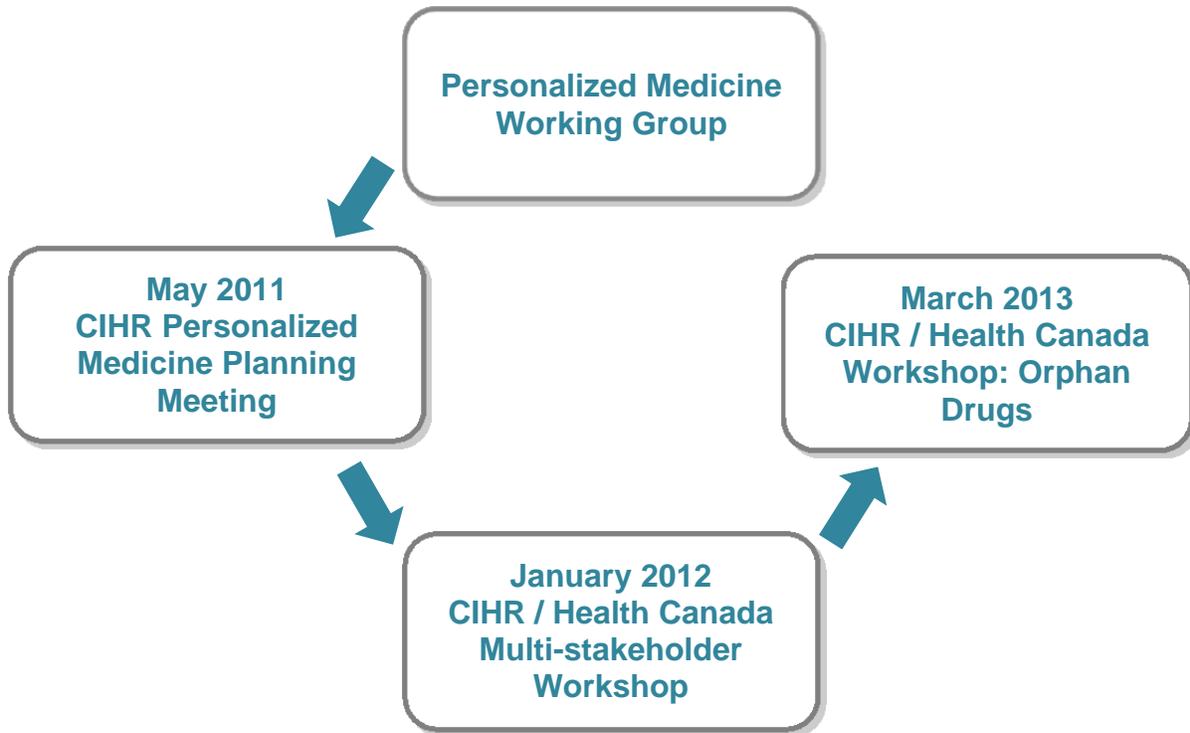
Medical imaging is one of the fastest growing fields in medicine and is a priority of CIHR Institute of Cancer Research. With the implementation of personalized medicine in the clinic, the demand to use imaging technologies for screening, diagnosis, real-time monitoring of health status and treatment efficacy is increasing significantly.

Knowledge Uptake

While many projects must demonstrate how 'omics-based research and technology can contribute to a more evidence-based approach to health, they must also demonstrate high potential for attaining eventual clinical utility, including improved health outcomes, and practical applicability.

Addressing Regulatory and Policy Challenges

In order to guarantee that new diagnostics and therapies will actually benefit Canadian patients the appropriate regulatory and governance frameworks need to be adapted and reinforced. Regulatory reforms must be influenced by all stakeholders and also be open to the development of new models in the changing landscape in the era of personalized medicine. CIHR has been involved in a number of consultations to promote a dialogue in this area.



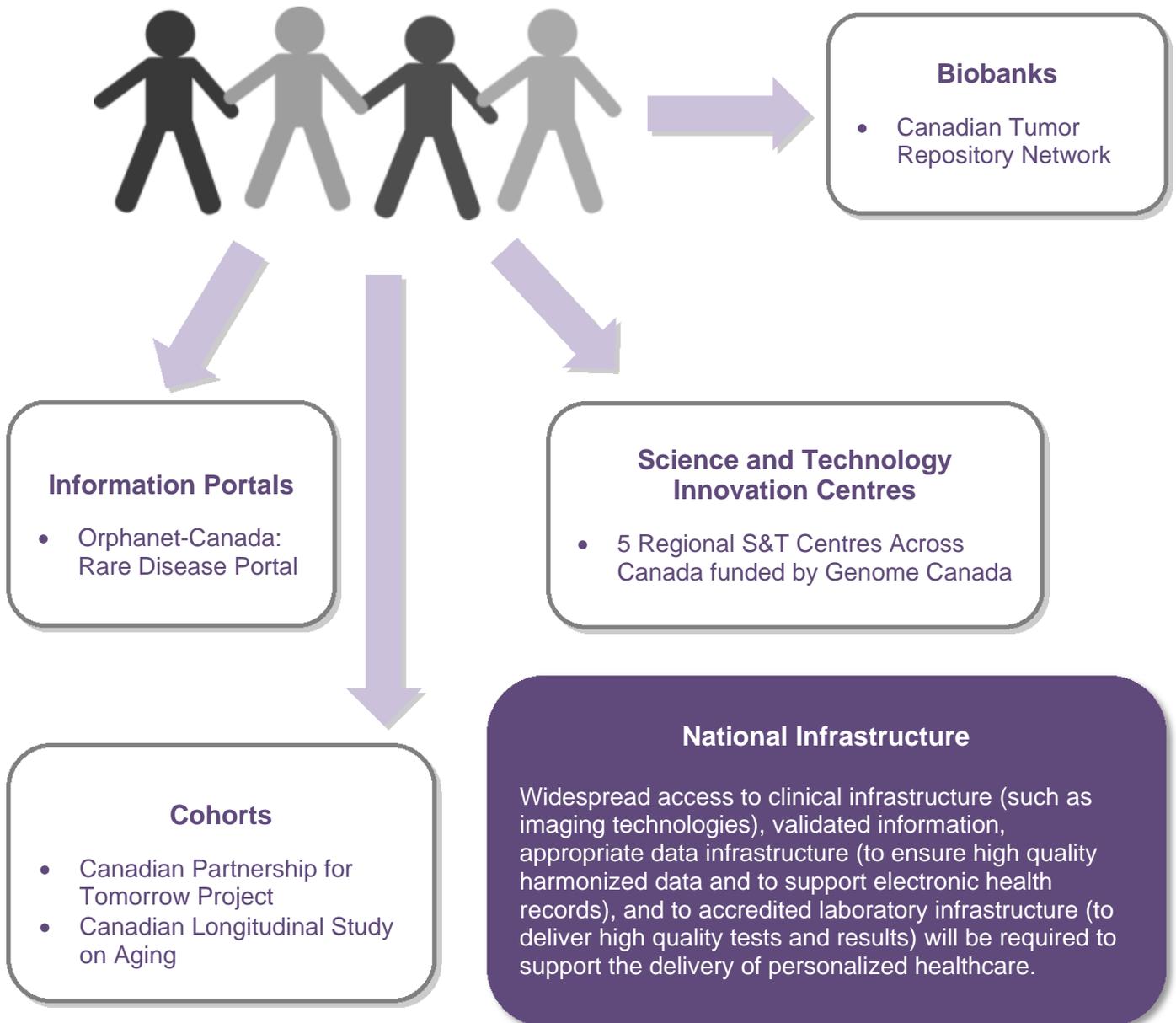
A Personalized Medicine Working Group, of which CIHR was a member, was convened by the Deputy Heads to coordinate an integrated policy response to emerging issues related to personalized medicine. Workshops were organized to support the development of a framework that would optimize the successful integration of personalized medicine approaches in the Canadian context. Themes addressed at these workshops included **research, regulatory and policy**, as well as **implementation** challenges.

Stakeholder Engagement

The engagement of all stakeholders is essential for the efficient implementation of personalized medicine. This engagement is meant to mobilize and coordinate the actions of federal and provincial governments/agencies, research communities, voluntary health organizations, and the public.

National Infrastructure and Services

The appropriate infrastructure and resources are necessary to support the uptake of personalized medicine approaches. Fortunately, Canada already has a strong existing research infrastructure. This includes Science and Technology Innovation Centers with advanced genome sequencing and proteomic technologies, large-scale cohort studies, and extensive biobanks.



Data Handling

Our ability to generate genetic, epigenetic, and imaging data has increased exponentially. This has created a need to translate data into useable clinical information, as well as to harmonize protocols for data collection, storage, and handling. The following examples demonstrate some of the efforts made to address this data challenge within the Personalized Medicine Signature Initiative.

2011 Data Harmonization Workshop

National and international experts in population research, data standardization, data archiving and data integration across a variety of disciplines, participated in a roundtable discussion designed to develop a vision for data harmonization in Canada and to identify the essential elements for a harmonization initiative.

Bioinformatics and Computational Biology

Funding from 2013-2016

Total Investment with Genome Canada and Partners: \$6.5 million

The massive influx of data from "omics" research underscores the need for new computational and theoretical tools in modern biology. These tools are essential for analyzing and integrating complex data sets and to better understand the associated biology. The goal of this funding opportunity is to support the creation and evolution of enhanced bioinformatics and computational biology tools and methodologies, which will be key to enabling the development of novel translational research applications in medicine.

Bioinformatics Approaches to Cancer Research Catalyst Grant

Funding from 2009-2010

Total Investment: Over \$550,000

The intent of this funding opportunity was to bring together experts working in the field of bioinformatics with cancer researchers to identify and address key research questions in cancer. Remarkably, bioinformatic approaches have contributed significantly to our understanding of cancer and have led to improved prevention, diagnosis, management and treatment of cancer.

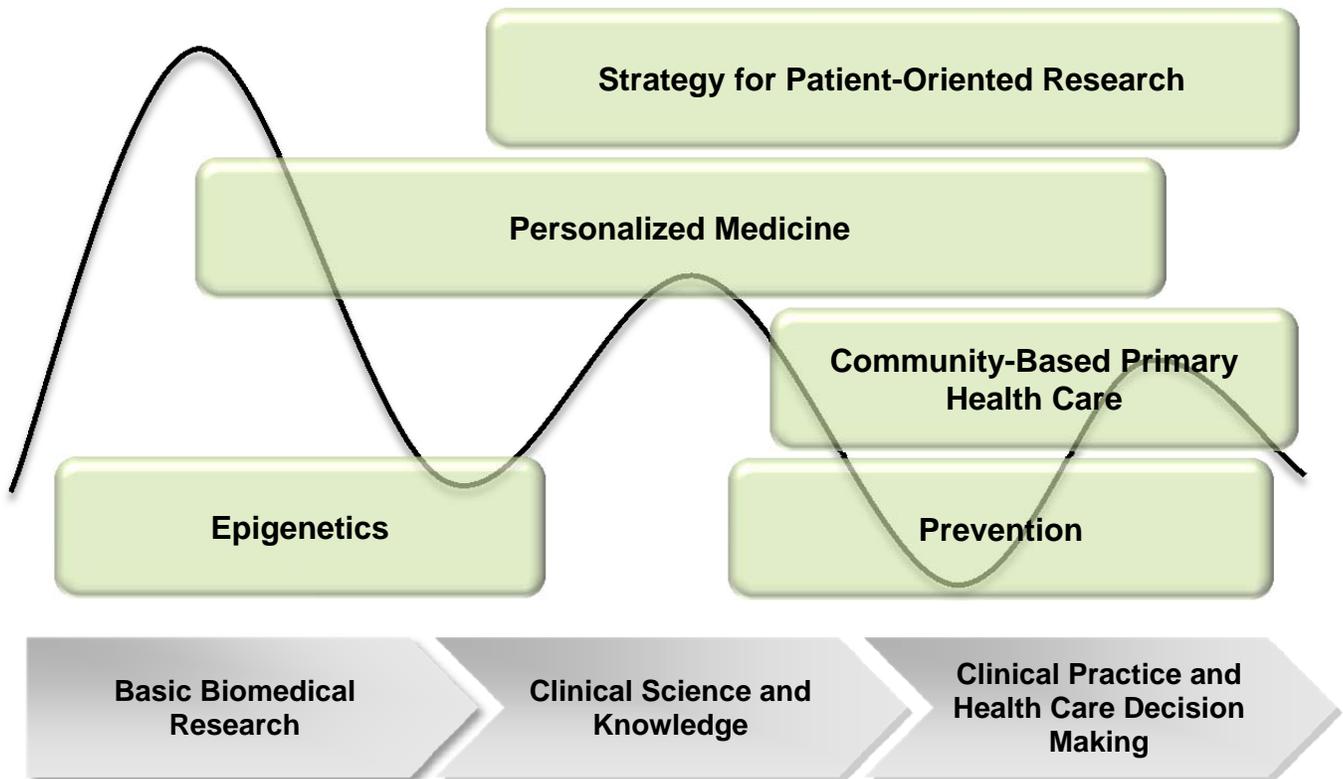
Research in Action

In this era, personalized medicine is driven by data from genomics and other 'omics technologies, imaging technologies and environmental and lifestyle data. Securing Canada's leadership in data harmonization and handling will require a common vision and will maximize the national return on research investments.

Outreach and Education

Synergies with Other Initiatives at CIHR

The success of the Personalized Medicine Signature Initiative relies on the coordinated effort and expertise of other CIHR initiatives. Each initiative tackles an important part of the research continuum, thus supporting translational research such that discoveries are successfully integrated into clinical practice after rigorous and informed health care decision-making.



Linking with the Private Sector

The development of partnerships between the academic, pharmaceutical and biotechnology sectors plays a key role in the promotion of the translation of information into useful knowledge, products and services. These public-private partnerships in research and development allow for the implementation of research outcomes into practice to ensure optimal impact for patients and concerned stakeholders.



Professional Training and Education

The goal of partnering on the Community-based Primary Health Care Signature Initiative is to support professional training and education. This will enable the development of educational and engagement tools, guidelines and tools for risk assessment, and referral and management for genetic and genomic screening and testing. In addition to this, CIHR is supporting a number of postdoctoral fellowships in the area of personalized medicine.

Public and Media Outreach

The engagement of the public and patients is critical for the successful uptake of any personalized medicine approach. Public values and concerns need to be respected, and the public must be empowered to understand the changing health landscape in the era of personalized medicine. CIHR is engaged in various outreach activities all with the goal of improving awareness and understanding of personalized medicine.



Café Scientifiques are informal gatherings held at cafés, bookstores, or other public locations to discuss health-related issues of popular interest to the public. To date, CIHR has hosted five

cafés focused on personalized medicine. Each event resulted in lively discussions between leading researchers and the public.

Journalist Workshops bring together health and science reporters with leading researchers and clinicians as they discuss the latest developments in health research. Outcomes include researcher highlights, book publications, and newspaper articles. CIHR hosted a journalist workshop on innovations in cancer research, and highlighted how cancer research drives innovations, which leads to better diagnosis, prevention, and personalized treatments, and ultimately better care and survivorship.

Engagement through Social Media, such as Twitter, Facebook, YouTube and a blog for the Café Scientifique program, has been used to feature the Personalized Medicine Signature Initiative and its research outcomes.



Outreach and Education in Action

The engagement of the appropriate stakeholders, healthcare professionals, and the public is critical for the successful uptake of personalized medicine approaches. This is essential to promote the translation of information into useful knowledge and to empower others to use this knowledge to improve health outcomes.

Global Reach

The successful engagement of multiple partners within Canada and beyond will be a key element to the success of the Personalized Medicine Signature Initiative. CIHR has engaged in various international research partnerships, research consortia, consultations and workshops.

International Research Partnerships



2013 E-RARE-2 Joint Transnational Call on Rare Diseases

Funding from 2014-2017

Total CIHR Investment with Canadian Partners: \$2 million

CIHR has joined the ERA-Net "E-Rare 2" research program on rare diseases to further help coordinate and support collaborative research projects that will focus on patient-oriented research, 'omics research, and research on diagnosis and therapies.

International Memberships and Partnerships

International Agency for Research on Cancer



IRDIRC

INTERNATIONAL
RARE DISEASES RESEARCH
CONSORTIUM



International
Cancer Genome
Consortium

International Conferences and Workshops Attended

CIHR has participated and presented the Personalized Medicine Signature Initiative at a number of international workshops. At each of these meetings, the Canadian funding perspective on personalized medicine and the development of a Canadian personalized medicine national framework has been presented.

Global Reach in Action

Each of these activities signifies the global reach of the Personalized Medicine Signature Initiative, but also highlights the growing landscape of personalized health.