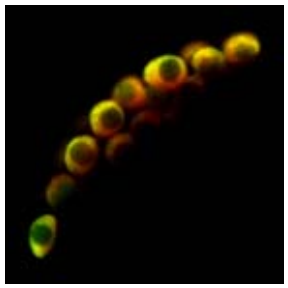

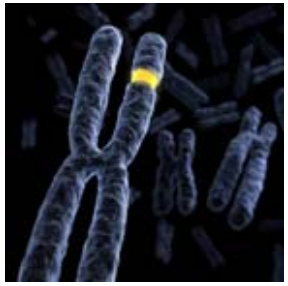

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CIHR and Precision Medicine: Personalized Health

Jane E. Aubin, Ph.D.

Chief Scientific Officer and

Vice-President, Research, Knowledge Translation and Ethics

Canadian Institutes of Health Research

CAG Symposium: 27 February 2016

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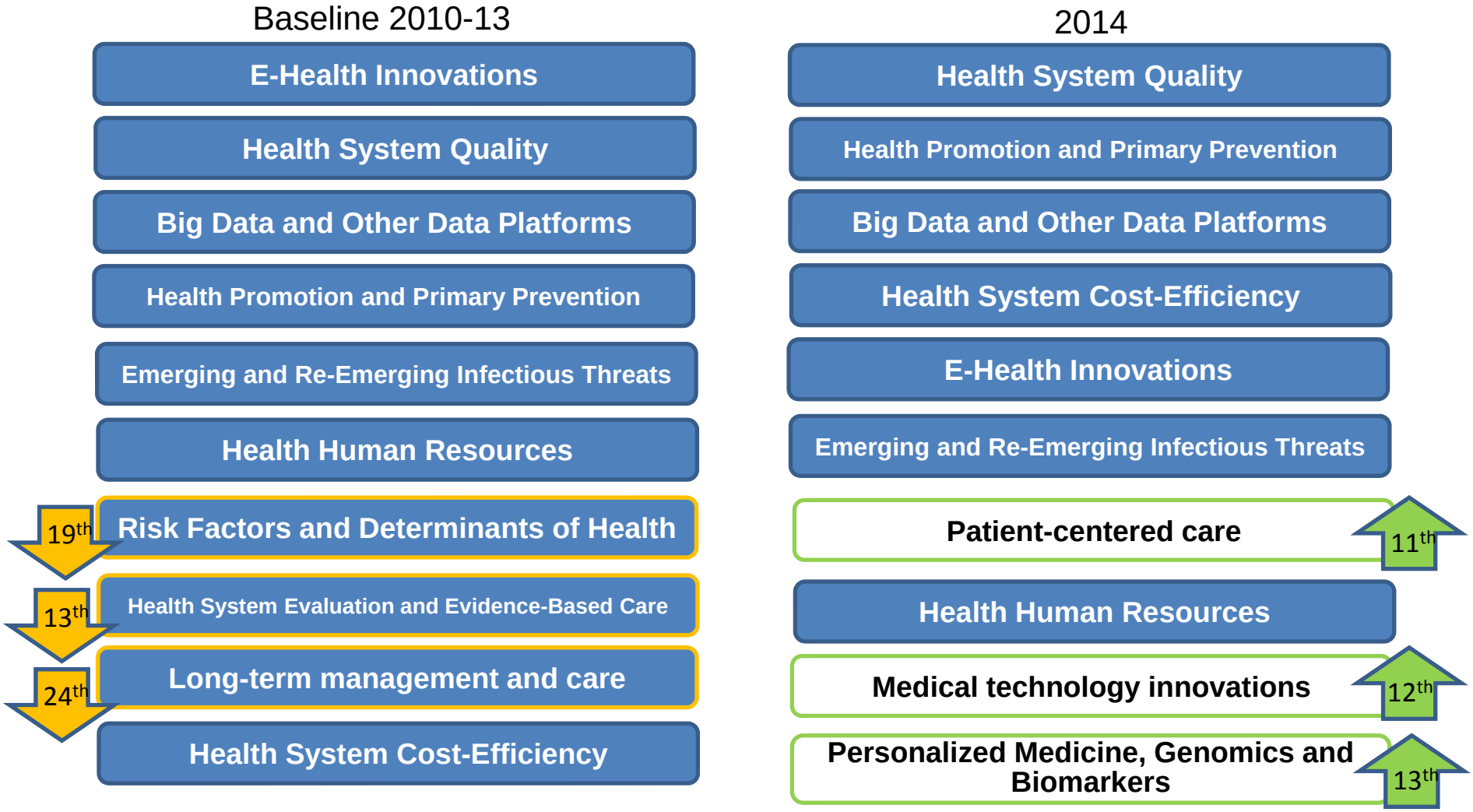
Health and Health Research Priorities
Top 10 Global Trends



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CIHR's Personalized Medicine Roadmap Signature Initiative

Enhance health outcomes through patient stratification approaches by integrating evidence-based medicine & precision diagnostics into clinical practice

Develop & translate discoveries

- Biomarkers, targets & genomic signatures
- Diagnostics & innovative devices for clinical use

Support policy & practice

- Improve the evidence base on how to assess & integrate innovative diagnostics & therapeutic approaches into practice

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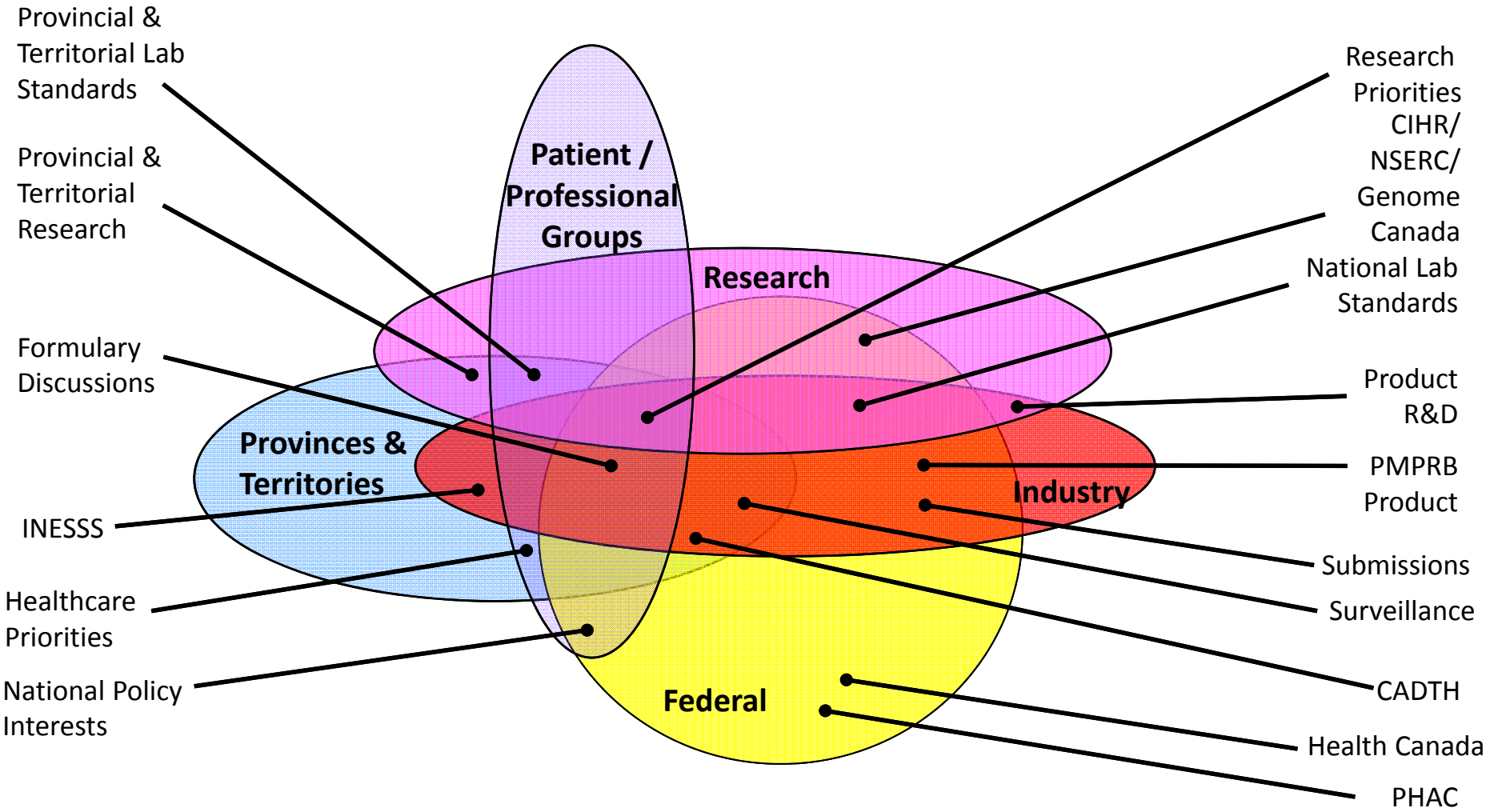
Canadian Personalized Medicine Stakeholder and Variable Map



T. Ryan Sigouin, Health Canada adapted by Inga Murawski CIHR-ICR and Etienne Richer CIHR-IG

CIHR's Personalized Medicine Signature Initiative: Investment and Partnership Summary

Initial business case
$100,100,000
(2010-2011 – 2018-2019)

Current total and planned
$242,875,777
(2010-2011 – 2018-2019)

Partnerships

# of External Competition Partners: 39
# of External Applicant Partners: 76
# of Partnership Events: 5

Projected Commitments: $ 156,715,055
Projected Leverage Ratio: 1 : 1.82

Firm Partner Commitments: $ 147,215,05

Current Partner Leverage Ratio: 1: 1.78

(From funded opportunities only, incl. Applicant Partners)

Projected Leverage by Partner Type

Canada

Genomics and Personalized Health:
2012 Large-Scale Applied Research Project Competition

CIHR/Genome Canada partnership: One of the most significant public sector investments in Personalized Medicine

- Research projects span various areas including cancer, rare diseases, epilepsy, inflammation, HIV, cardiovascular disease and autism

Investment: over $165M

- $68.8M CIHR (IG, ICR, INMHA, III, INMD, IHSPR, and initiatives) /GC investment with more than 1:1 match from outside sources

Projects funded: 17

- 15 large-scale applied research projects with integrated GE3LS
- 2 large-scale GE3LS research projects
- E.g., Rioux, John D - IBD Genomic Medicine Consortium (iGenoMed): translating genetic discoveries into a personalized approach to treating the inflammatory bowel diseases

International Rare Diseases Research Consortium (IRDiRC)

Foster international collaboration in rare diseases research

- ✓ Deliver 200 new therapies for rare diseases and
  - ➢ 155 as of September 18th
- ✓ Means to diagnose most rare diseases by the year 2020
  - ➢ About 3500 as of September 18th

- 43 funding members (including E-Rare) & 3 invited patient advocacy groups
- Minimal commitment: US$10 million over five years in research projects contributing towards the goals of IRDiRC
- CIHR & Genome Canada joint commitment of $25 million to IRDiRC while the
- Total pledges of the consortium nearly $2 billion

Orphanet Canada

Mission

- To provide the community at large with a comprehensive set of information to contribute to the improvement of the diagnosis, care and treatment of patients with rare diseases.

National objectives are to

- Create a national entry site to communicate at the national level on activities of the national Orphanet team, rare disease events, and rare disease policies in the country
- Comprehensively document resources available in Canada: expert centers, medical laboratories, patient organisation, research projects, clinical trials, and registries and biobanks
- Outreach to all stakeholders of the Orphanet-Canada project and facilitate exchanges between group of stakeholders

Resource	Completed	Expected
Clinics	47	-
Diagnostic tests	487	25
Patient Organizations	78	135
Clinical Trials	27	34+
Registries	8	16
Research Projects	148	155

http://www.orpha.net

Rare Diseases Research Catalyst Network

Creation of a national network organized to:

- Identify Canadian model expertise relevant to newly discovered human disease genes
  - Funded research projects focus on functional validation
- Enhance clinical translation
  - Develop and implement innovative knowledge translation strategies/activities to link clinical genetics & model research communities

Investment: $2.3 M CIHR-IG in partnership with GC

Principal Investigators	Title of Project
Philip A. Hieter (UBC) Kym Boycott (CHEO) Janet Rossant (SickKids)	Canadian "Rare Diseases: Models & Mechanisms" Network (RDMM)

http://webapps.cihr-irsc.gc.ca/cfdd/db_search?p_language=E&p_competition=201404RCN

Canada

Drug Repurposing Initiative

Repurposing Research in Rare Diseases: Cures Within Reach/CIHR Collaborative Funding Program

- **Goal**: to support efforts on proof of concept clinical trials repurposing human approved drugs for new disease indications
- **Proposal requirements**:
  - generate clear deliverables with immediate applications, including off-label use, for rare diseases management;
  - propose novel (evaluation criteria to lower projects that have been done) proof of concept clinical trials involving, multiple clinical sites in Canada and the United States of America, and;
  - propose an adequate development plan to ensure the realization of the expected benefits.
- **Budget**: $1.5M USD (CIHR and CWR)/3 years

Canada

Personalized Medicine cuts across Roadmap II's Four Strategic Research Priorities

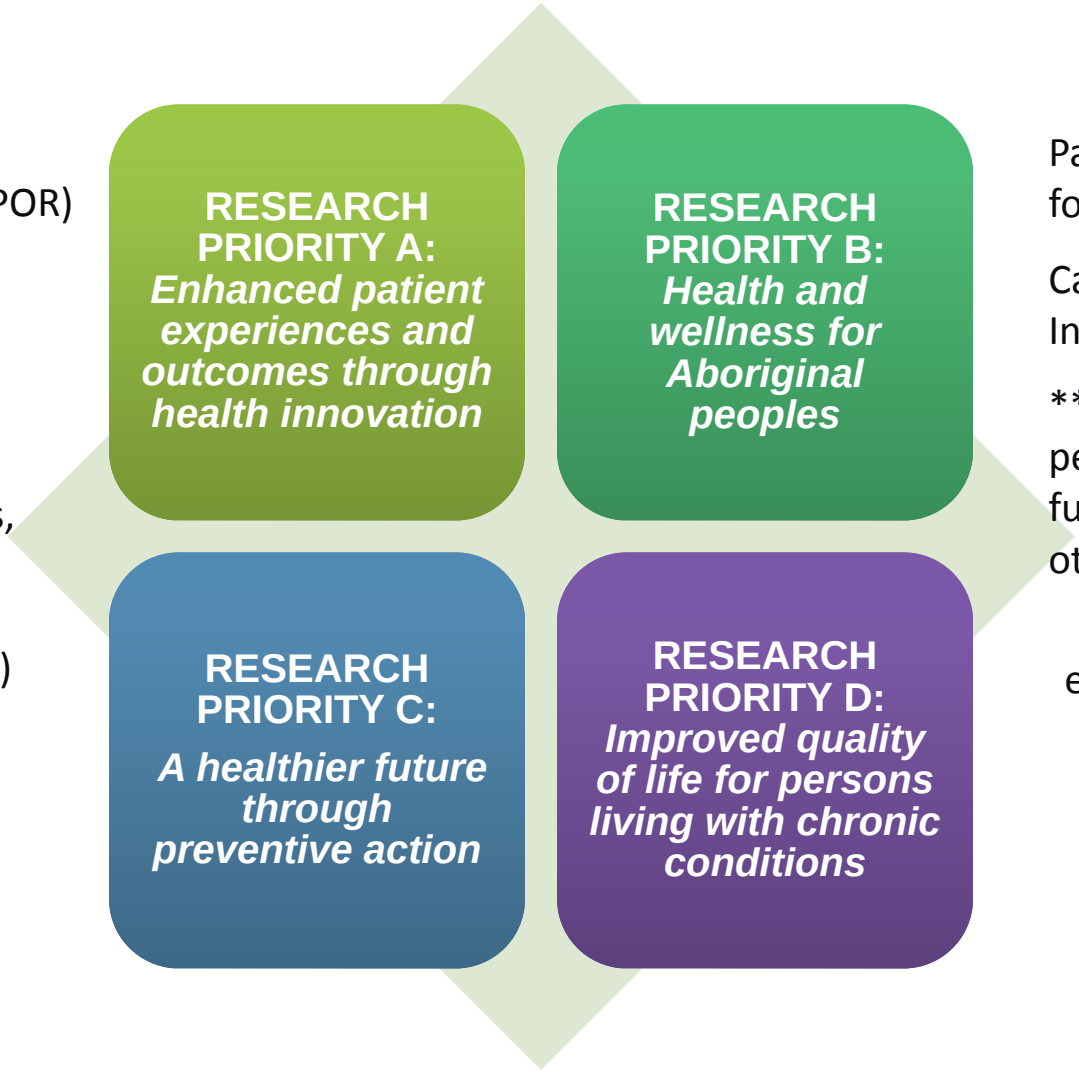
Strategy for Patient-Oriented Research (SPOR)

Big Data-Health Data initiatives

Canadian Epigenetics, Environment and Health Research Consortium (CEEHRC)

***Personalized Medicine**

Environments and Health



Pathways to Health Equity for Aboriginal Peoples

Canadian HeLTI cohort – Indigenous Peoples

**Targeted indigenous peoples' health research funding pools in many other initiatives

e-Health Innovations

Enablers for Precision Medicine: Strategy for Patient-Oriented Research (SPOR)

- Coalition of federal, provincial and territorial partners (patients, researchers, health care providers, provincial health authorities, academic health centres, charities, pharmaceutical sector, etc) dedicated to the integration of research into care

- Fostering evidence-informed health care by bringing innovative diagnostic and therapeutic approaches to the point-of-care

- Effecting changes to health care policies and practices

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SPOR - Critical Elements to enhance Integration of Research and Care

Patient-Oriented Research and Knowledge Translation Networks

Support for People and Patient-Oriented Research and Trials (SUPPORT) Units

Training and Career Development

Improving the Environment for Clinical Research

Patient /Consumer Involvement and Engagement

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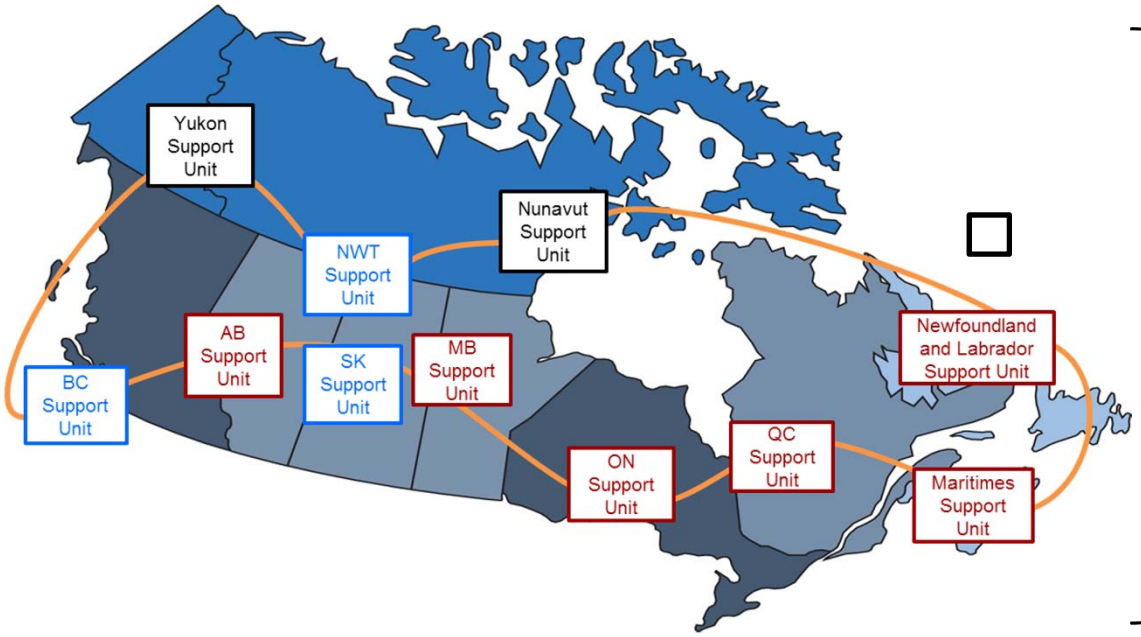
SPOR: SUPPORT Units and Networks

SUPPORT Units: provincial, territorial or regional centres providing support and expertise on data access, methodological and research services, knowledge translation, clinical trials and capacity development

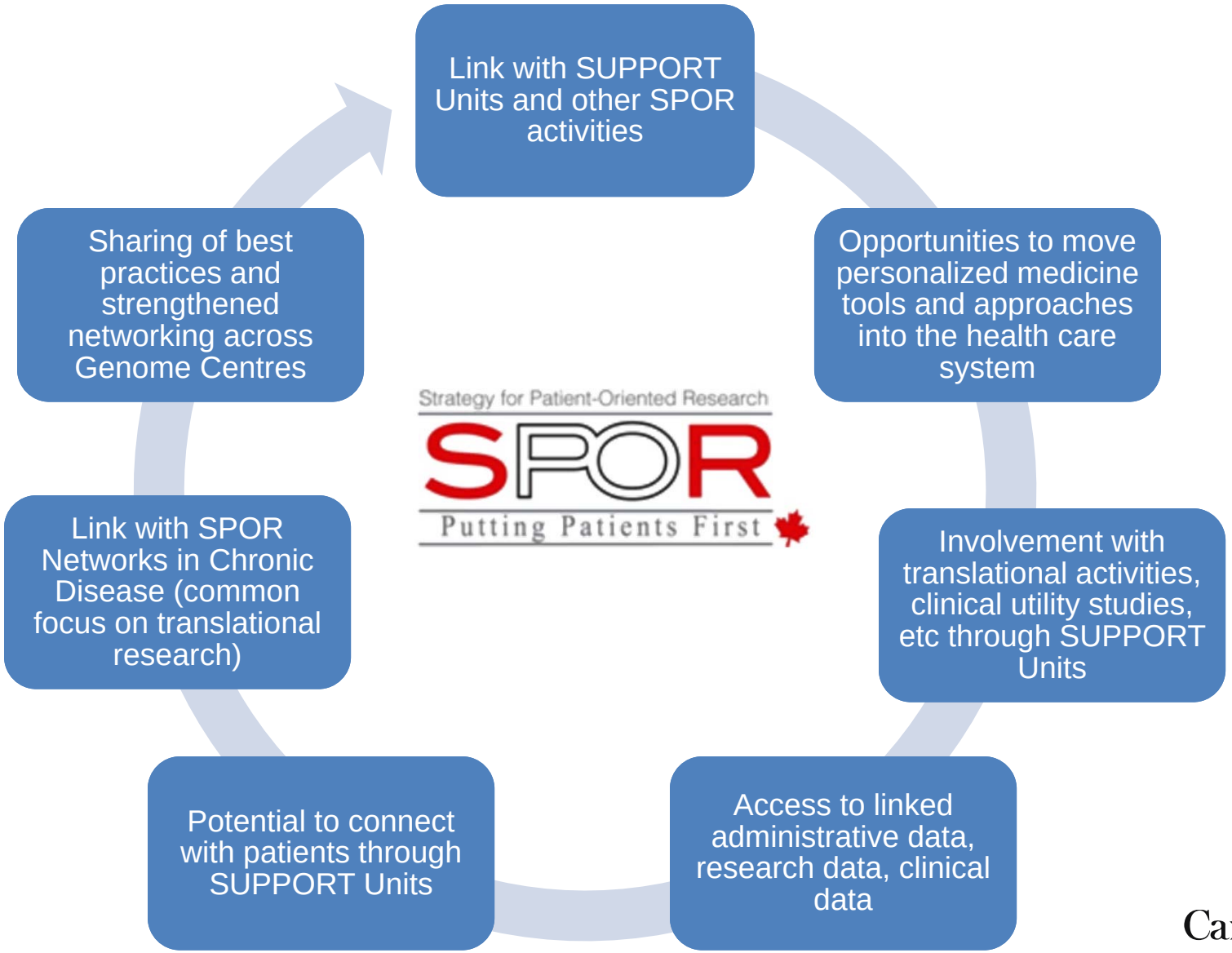


- specialized and multidisciplinary methodological expertise
- biostatistical analyses
- linked administrative databases, patient and treatment registries, drug information systems, electronic health records, and other data

SPOR Networks

1) Youth and Adolescent Mental Health
2) Primary and Integrated Health Care Innovations
3) Chronic Disease (5 awarded in February 2016)

SPOR: Enabling Personalized Medicine



Data Strategies and Policies: Enabling Personalized Medicine

CIHR is leading and contributing to many open science/open data activities…

Examples	Strategic Opportunities
- Open Government / Open Science - National Strategy for Bioinformatics & Computational Biology	Focus on increasing and enhancing: Better data attributes Data management Data access Data linkage Infrastructure and tools Digital skills Collaborations and partnerships
- Tri-Agency Open Access Policy on Publications - Tri-Agency Statement of Principles on Digital Data Management - Acting upon the CCA report on Timely Access to Health Data	
- Data components within CIHR Signature Initiatives (e.g., eHealth, Environments & Health, CLSA, CCNA, SPOR SUPPORT Units, Epigenetics, Personalized Medicine)	
- Canadian Research Data Centre Network - Global Alliance for Genomics and Health - Advancing Big Data Science in Genomics Research - Cancer Genome Collaboratory - Sharing Big Data for Biomedical Discovery	

However, translational bioinformatics requires a cohesive, consistent and coordinated approach

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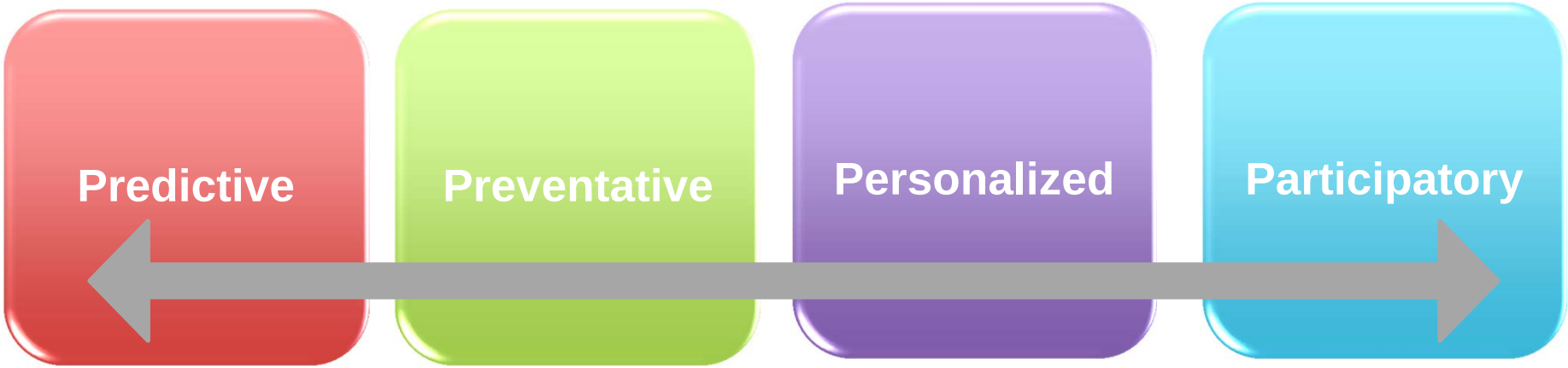
Transition from Reactive Medicine to P4 Medicine or Precision Health



Predictive	Preventative	Personalized	Participatory
Susceptibility factors (genetic and epigenetic) Predictive biomarkers Opportunities/limitations of NGS Ethical issues/genetic counselling	Enhance accuracy/range of screening programs Implement preventative activities/programs Develop Public Health policies/program, e.g., targeting epigenetic influences	Stratification of diseases Stratification of treatments Improved quality of care (better targeted-reduced invasiveness) Reduced side effects Reduced adverse drug reactions	E-apps - patients monitor own health-treatment responses Self-management of EHRs Awareness of personal genetic profile Patient education0empowerment

- Shifting emphasis from reaction to prevention, and from disease to wellness
- Personalized medicine – focus on stratified treatment, but also prevention, prediction and care
- Integrative, interdisciplinary, cross-sectoral approaches

Canada