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Genomics and Personalized Health

NHGRI - Global Leaders in Genomic Medicine Meeting
Washington DC January 8-9, 2014

Pierre Meulien
President and CEO, Genome Canada

Presentation Today

- Introduction to the Canadian healthcare environment
- Genomics in Canada
- New program design in Canada for large-scale applied research projects in *Genomics and Personalized Health* (launched in January 2012)
- Some conclusions and looking ahead

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Canadian Environment

- Publically funded health care system
- Provincially delivered (Regional Health Authorities)
- Costs the country around $200 billion per year
- Growth in cost is around 3% annually (NOT sustainable)
- Biomedical research very strong in Canada
- Canada spends about 2% of government funded global research but produces 4% of the highest impact factor publications
- Strong clinical networks across the country and - for some diseases - has among the best outcomes in the world

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Challenges

- Our ability to move the latest technology into healthcare system is traditionally low and the way technology is assessed across the country is heterogeneous

- New technologies are often seen as just an added cost and economic analyses performed are not convincing enough for the payers

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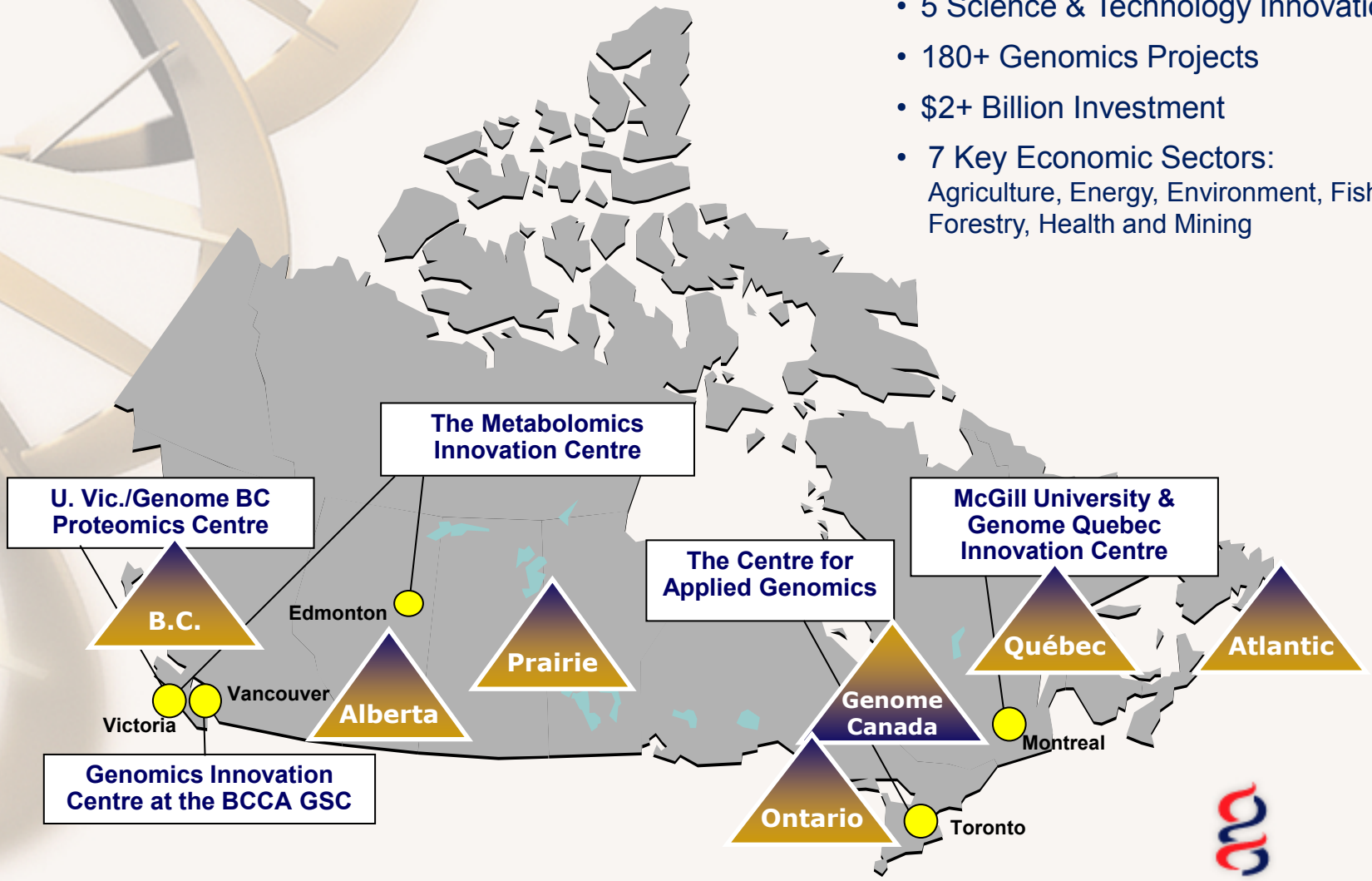
Genomics in Canada

- 6 Regional Genome Centres
- 5 Science & Technology Innovation Centres
- 180+ Genomics Projects
- $2+ Billion Investment
- 7 Key Economic Sectors:
  Agriculture, Energy, Environment, Fisheries, Forestry, Health and Mining



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How do we translate when we need to consider a lot of complex issues?

- How good is the technology? (clinical validation)
- In a fast moving field, when do we decide that “now is the time for transfer”?
- Is it easy to adapt existing clinical laboratory structures?
- Who will make these decisions? (and based on what criteria?)
  - Technology assessment based on sound economics and clinical benefit?
- Who will pay?

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What We Need Now

Demonstrations that:

- the technology can deliver real value to patients, and
- integrating the technology within the healthcare system will be cost effective

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New Program Design - Role of Funders

- **How do we ensure:**
  - The right team is formed?
  - The right deliverables are achieved (timely impact on patients)?
  - That true demonstrations of value are obtained?

- **Importance of the peer review process.**

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Genome Canada - CIHR
2012 Large Scale Applied Research Competition
Genomics and Personalized Health

- Major partnership between Genome Canada and the Canadian Institutes of Health Research (CIHR)
- $65 million from Genome Canada/CIHR leveraged to $150 million through partnerships (regional Genome Centres, provinces, industry, health authorities, international organizations, etc)

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

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Genomics and Personalized Health Competition - Deliverables

Outcomes of the research had to include concrete deliverables with clinical utility or other applications that will allow for subsequent translation into the healthcare system.

Projects had to demonstrate their potential to:

- contribute to a more evidence-based approach to decision making with regards to both health maintenance and disease interventions, and
- improve the cost-effectiveness of the healthcare system.

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Genomics and Personalized Health Competition – Key Features

- A rationale and economic analysis for why the particular application will add value to the healthcare system
- Importance of assembling the right team
- A detailed development plan for integration into the healthcare system, including:
  - demonstration of engagement by the end-user(s)
  - consideration of the regulatory frameworks existing in Canada
  - consideration of the challenges and barriers to translation – GE^{3}LS

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GE³LS - Genomics and its Ethical, Environmental, Economic, Legal and Social Aspects

- Genomics-related research undertaken from the perspective of the social sciences and humanities

- In the context of this RFA it was extended to cover researchers in the fields of health administration, health management, health services research, health technology assessment, evaluation and comparative effectiveness studies.

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Genomics and Personalized Health Competition – Review Process

- Review was in two phases:
  - Pre-application (146 submissions)
  - Full proposals (40 submissions)
- Full proposals were reviewed by ~40 international translational researchers, social scientists and **health economists**
- Panel Chair: Raju Kucherlapati (HMS)
- Review of full proposals took place over 3 days with face to face meetings between members of the review panel and project team applicants
- Review criteria: research merit; socio-economic benefits; finance & management
- 17 projects are now launched (average $8.8 million)

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Post Award Management

- GC funds milestone-driven projects that are closely monitored
- GC has introduced new project specific Research Oversight Committees (ROCs) for each project
- The ROCs report to the Genome Centres and GC on progress, provide advice to project teams, and help ensure the teams focus on reaching project milestones and objectives

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Examples of Approved Projects

Molecular stratification of patient populations to inform decision making re: effectiveness of drugs, adverse drug reactions, intervention strategies and disease management:

- Epilepsy
- Autism
- Lymphoma, Breast Cancer, Glioblastoma, and other cancers
- Rare diseases
- Stroke
- HIV
- Inflammatory Bowel Disease
- Cardiovascular disease
- Prenatal diagnosis

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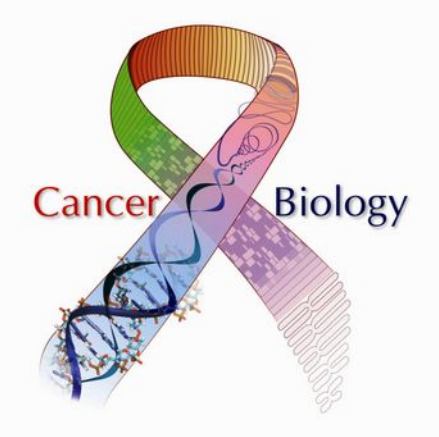
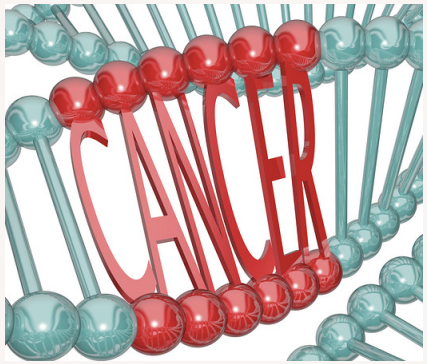
Personalized Treatment of Lymphoid Cancer: British Columbia as Model Province

Joseph Connors, BC Cancer Agency; Marco Marra, Randy Gascoyne

To demonstrate the use of genomics in diagnosis of lymphoid cancers in a large population (province), with potential for scale up nationally and internationally.





Personalized Genomics for Prenatal Aneuploidy Screening Using Maternal Blood – PEGASUS

François Rousseau, Université Laval; Sylvie Langlois

To provide Canada with evidence to make informed decisions about implementation of genomics-based non-invasive prenatal testing (NIPT) for aneuploidies

Enhanced CARE for RARE Genetic Diseases

Kym Boycott, Children's Hospital of Eastern Ontario; Alex Mackenzie

To improve clinical care for patients and families affected by rare diseases by developing efficient and cost-effective molecular diagnoses and a platform to identify therapeutic opportunities for rare diseases.

<u>1 Story…</u> Undiagnosed Neurodegeneration

PACE – ‘Omics: Personalized, Accessible, Cost-Effective Applications of “Omics Technologies

Christopher McCabe, University of Alberta; Tanya Bubela

To enhance the adoption of high value PM treatments and services in Canada and allow the public to receive the PM interventions that will most increase their health, faster, and at a lower cost by bridging informational gaps between researchers, developers, regulators, payers and patients.

Conclusions and Future Challenges

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Integration of Genomics into the Healthcare System

- Develop receptor capacity for technology pull (capacity for clinical and translational research)
- Involvement of the private sector
- Educate and train healthcare professionals to be proficient users of the technology
- Ensure information systems are state of the art and harmonize e-patient records
- Increase the role of patients and advocacy groups in demanding evidence based medicine
- Apply robust technology assessments focused on improvement of clinical outcomes and economic benefit analyses

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AN IMPORTANT STEPPING STONE TOWARDS PERSONALIZED MEDICINE

Bearing in mind that over 80% of genetic diseases are diagnosed in childhood or adolescence…

Creation of a unique partnership between Sainte-Justine UHC and Génome Québec:

- ✓ Develop new solutions to diagnostic challenges in childhood rare diseases
- ✓ Focus on prevention
- ✓ Pave the way for future initiatives in pediatric and adult cancers

One of the first pediatric clinical genomics centres in the world. The first in Canada!

GenomeQuébec

The Future…..?

- This is the beginning of something not the end
- Knowledge base will be totally different in 5 years (again!)
- We will be layering proteomics, epigenomics and microbiome data on top of our personal genome sequence data
- In ten years technology will allow us to do things unimaginable today

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ACKNOWLEDGEMENTS

GenomeAtlantic

GenomeQuébec

OntarioGenomicsInstitute

GenomePrairie

GenomeAlberta

GenomeBritishColumbia

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