Médecine moderne, Éthique moderne?

Journées d'étude des comités d'éthique de la recherche

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McGill

CGP Centre of Genomics and Policy
Centre de génomique et politiques

Médecine moderne, Éthique moderne?

INTRODUCTION

Multiples défis?

A. Restructuration de la recherche (“Learning health care system”)

B. Mega-données (“Big Data”)

CONCLUSION

Multiples avenues?

C. Reconnaissance mutuelle des CÉR?

D. Gouvernance: modèles nouveaux?

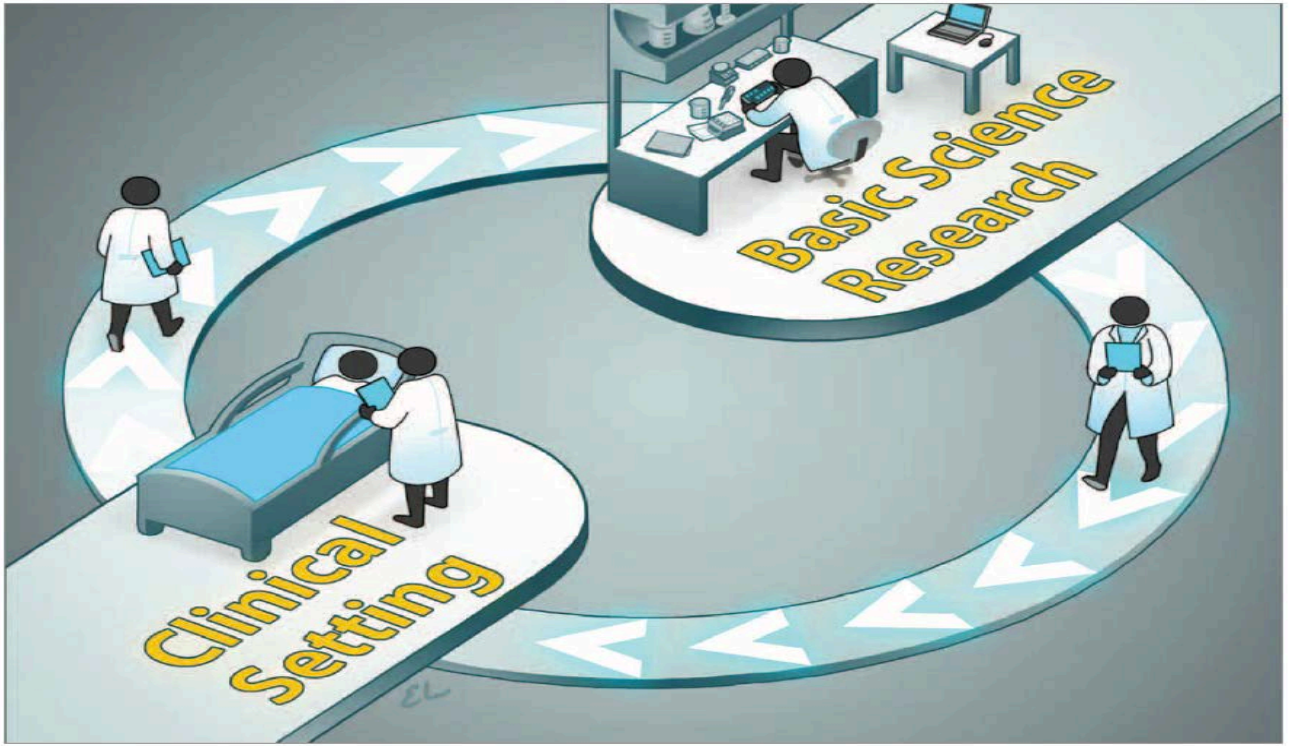
Multiples défis?

A. Restructuration de la recherche

(“Learning health care system”)

Bench to Bedside and Back Again May Be Key to Clinical Breakthroughs

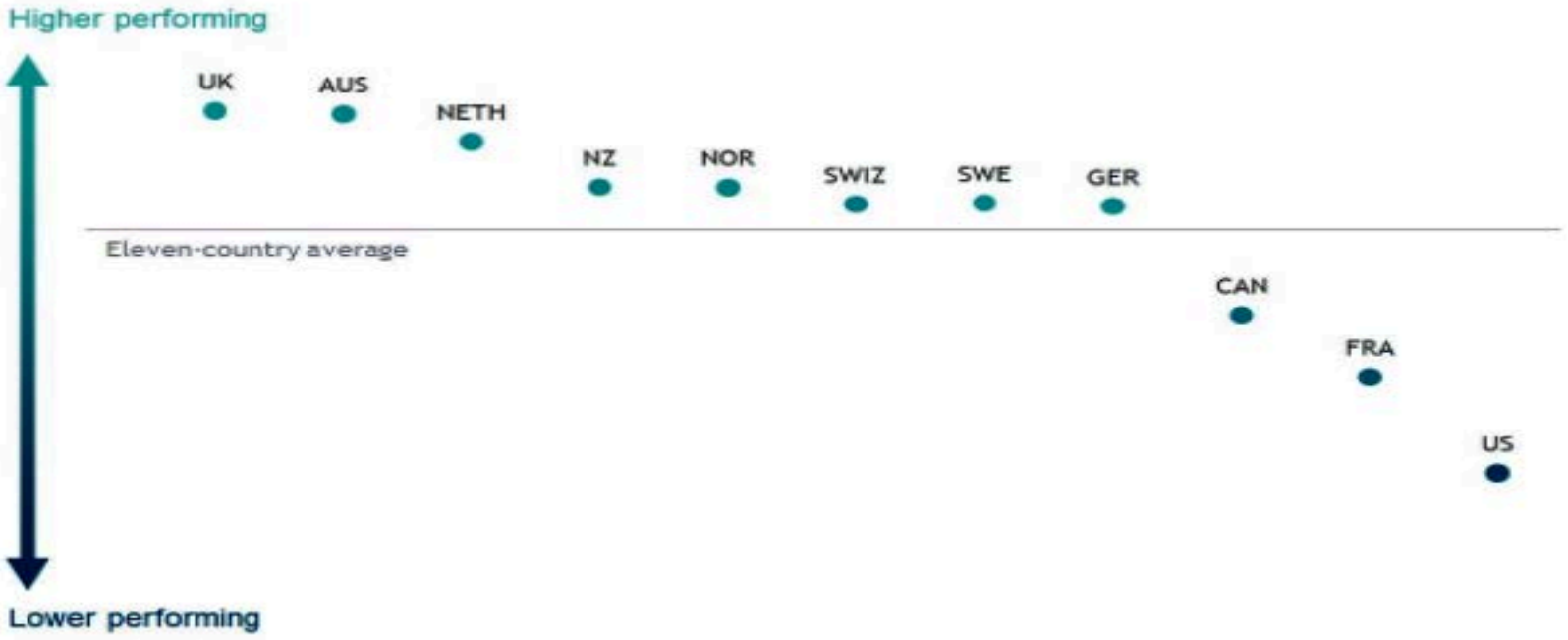
A.1



JAMA July 4, 2017 Volume 318, Number 1

A.2

Reactions to international health care rankings



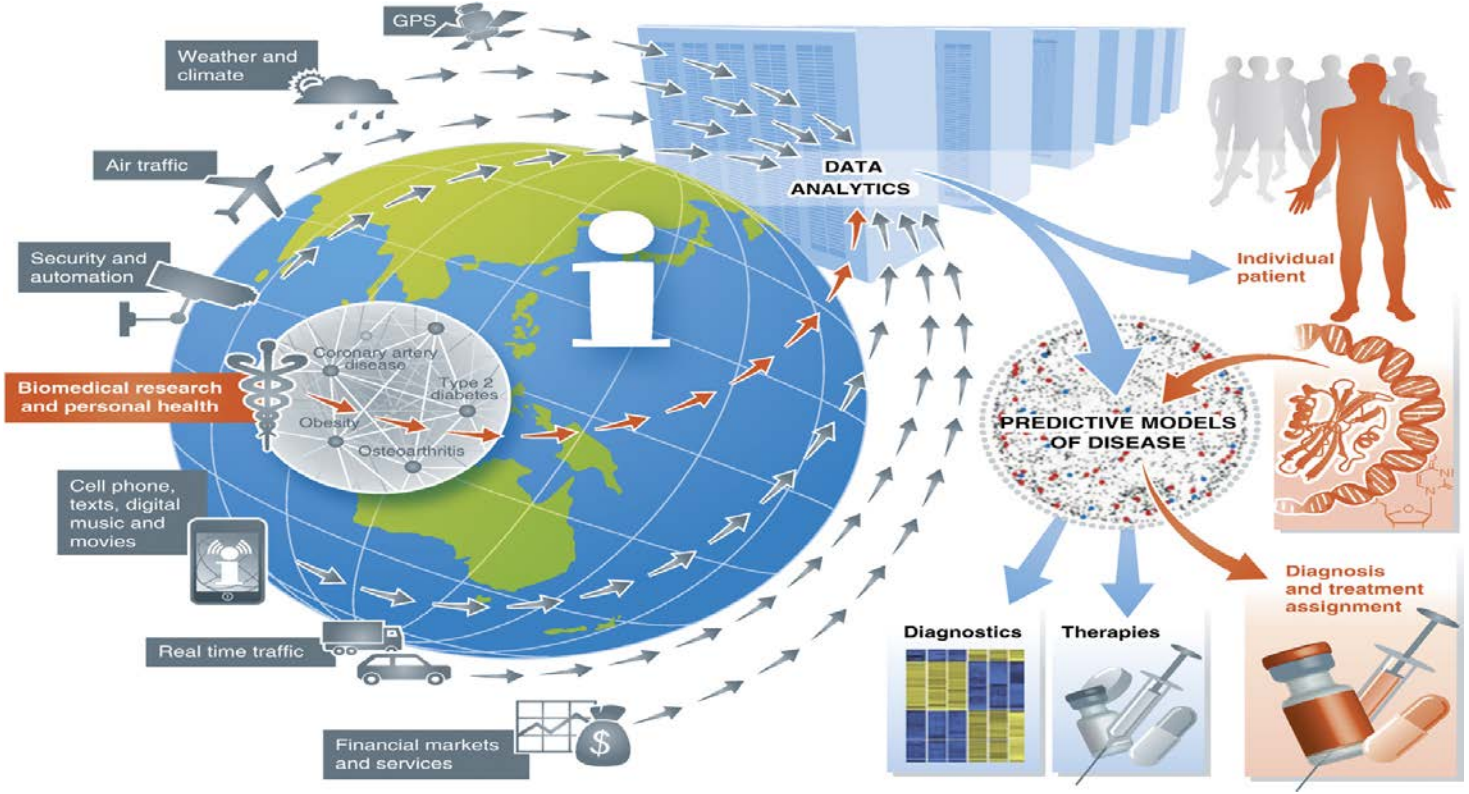
Roger Collier | CMAJ | July 18, 2017

A.3

Art. 22 CCQ

Une partie du corps, qu'il s'agisse d'organes, de tissus ou d'autres substances, prélevée sur une personne dans le cadre de soins qui lui sont prodigués, peut être utilisée aux fins de recherche, avec le consentement de la personne concernée ou de celle habilitée à consentir pour elle ou, si la personne concernée est décédée, de la personne qui pouvait ou aurait pu consentir aux soins requis par son état de santé.

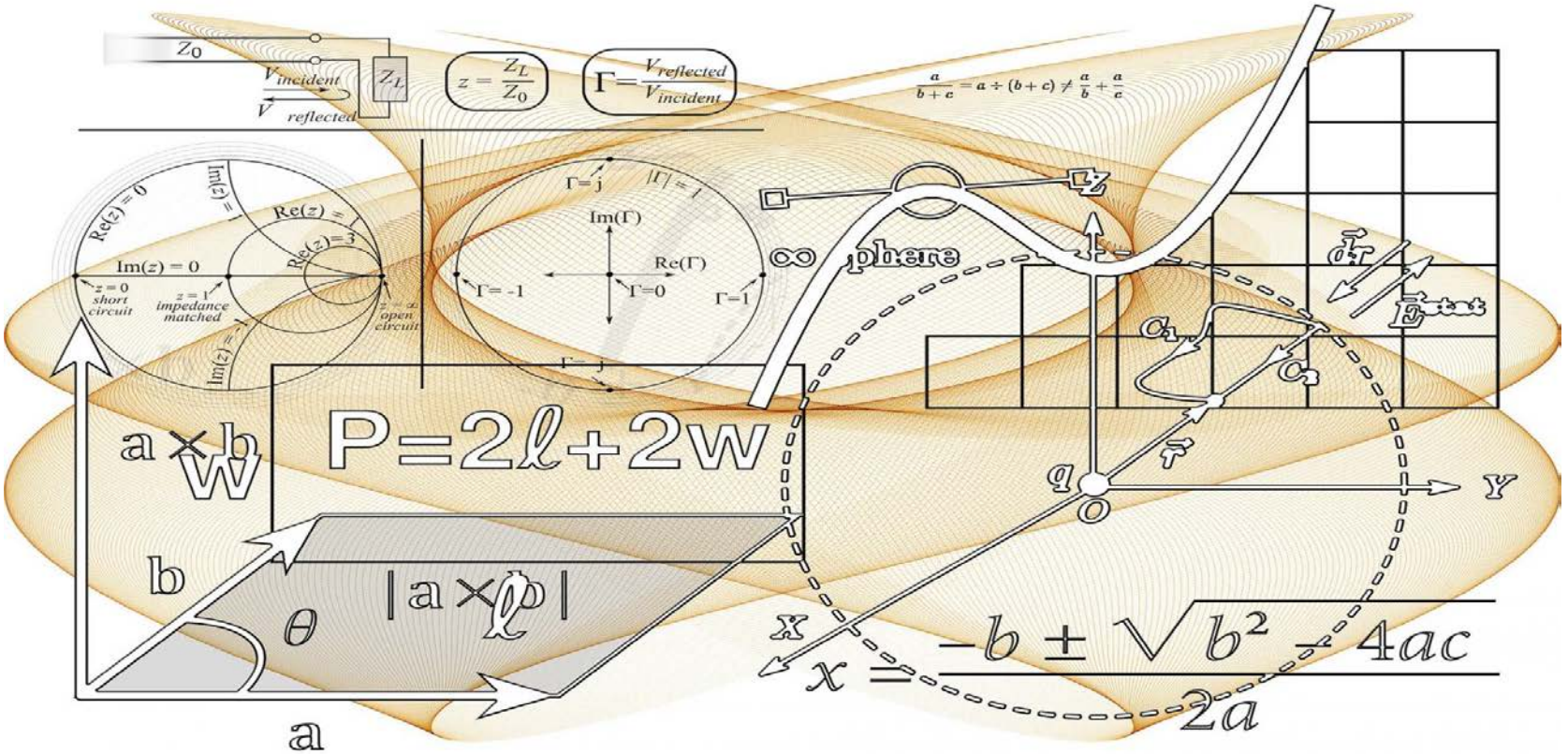
B. Mega-données



Eric E. Schadt, The Changing Privacy Landscape in the Era of Big Data, *Molecular Systems Biology* 8, 612 (2012).

Croissance fulgurante de la collaboration scientifique internationale

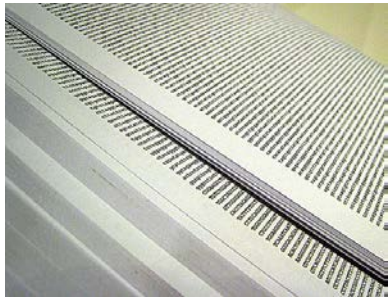
B.2



Le défi

B.3

Création sans précédent de données génétiques humaines



Comment accéder au potentiel offert pour la santé?

De façon à permettre le partage international des données

En favorisant de nouvelles connaissances, nouveaux diagnostics, et nouvelles thérapies pour les patients et la population

Published by Oxford University Press on behalf of the International Epidemiological Association

International Journal of Epidemiology 2009;**38**:263–2
doi:10.1093/ije/dyn1

B.4

THEORY AND METHODS

Size matters: just how big is BIG?

Quantifying realistic sample size requirements for human genome epidemiology

Paul R Burton,[1,2,3*,†] Anna L Hansell,[4,†] Isabel Fortier,[3,5] Teri A Manolio,[6] Muin J Khoury,[3,7] Julian Little[3,8] and Paul Elliott[4]

Accepted 8 June 2008

Background Despite earlier doubts, a string of recent successes indicates that if sample sizes are large enough, it is possible—both in theory and in practice—to identify and replicate genetic associations with common complex diseases. But human genome epidemiology is expensive and, from a strategic perspective, it is still unclear what *'large enough'* really means. This question has critical implications for governments, funding agencies, bioscientists and the tax-paying public. Difficult strategic decisions with imposing price tags and important opportunity costs must be taken.

Methods Conventional power calculations for case–control studies disregard many basic elements of analytic complexity—e.g. errors in clinical assessment, and the impact of unmeasured aetiological determinants—and can seriously underestimate true sample size

B.5

Medical mystery solved in record time

April 17, 2017

Dr. Daryl A. Scott is an associate professor ofMolecular and Human GeneticsBaylor College of Medicine. Credit: Baylor College of Medicine

In a study published today in *PLoS ONE*, a team of researchers reports solving a medical mystery in a day's work. In record-time detective work, the scientists narrowed down the genetic cause of intellectual disability in four male patients to a deletion of a small section of the X chromosome that had not been previously linked to a medical condition.

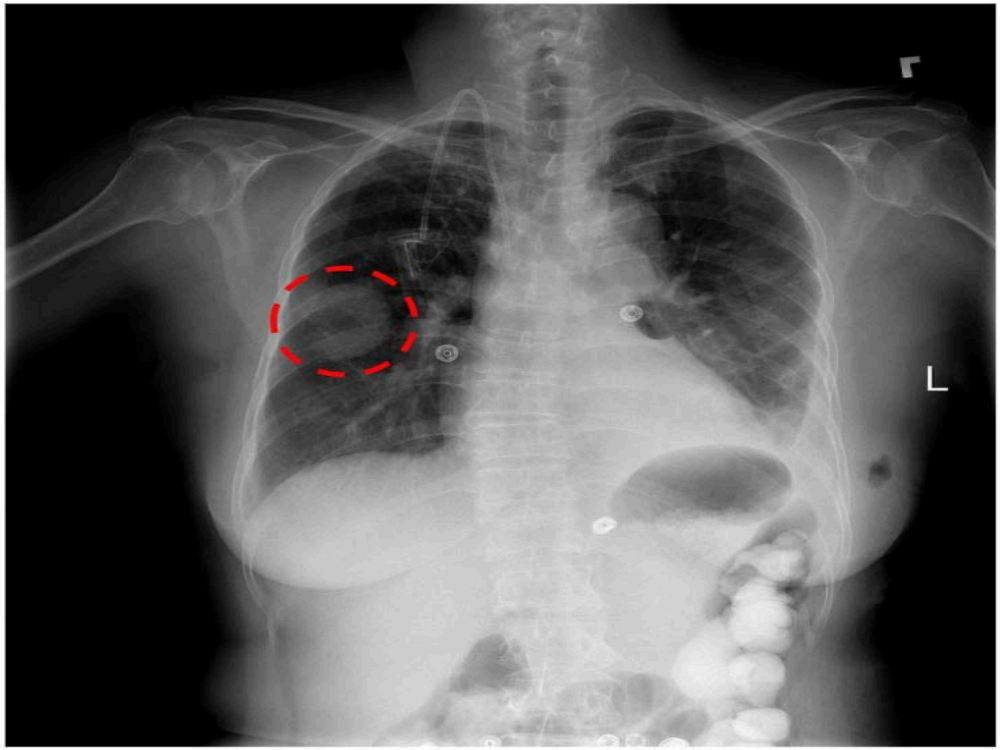
Even with the current technological advances, solving medical mysteries such as this one usually entails a much longer period of research. "We found it very interesting how fast we went from knowing nothing about the genetic cause of one patient's condition, to discovering the cause and finding three more individuals with the same problems," said senior author Dr. Daryl A. Scott, associate professor of molecular and human genetics at Baylor College of Medicine. "It took us a year to get all the documentation for writing and publishing the report, but the actual discovery was within hours. It was essential to our discovery that we had at our disposal technology to find and search genomic databases, and to connect electronically and exchange information with other researchers around the world."

Modern day medical detective work

NIH Clinical Center: largest publicly available chest x-ray datasets

B.6

The dataset of scans is from more than **30,000** patients, including many with advanced lung disease.



A chest x-ray identifies a lung mass.

Wang X, Peng Y, Lu L, Lu Z, Bagheri M, Summers RM. ChestX-ray8: Hospital-scale Chest X-ray Database and Benchmarks on Weakly-Supervised Classification and Localization of Common Thorax Diseases. IEEE CVPR 2017

Multiples avenues?

C. Reconnaissance mutuelle des CÉR?

Framework For The Responsible Sharing Of Genomic And Health Related Data—
FRENCH TRANSLATION

C.1

Global Alliance
for Genomics & Health

Version: 10 septembre 2014

!

Cadre!pour!un!partage!responsable!des!données!génomiques!et!des!données!de!santé!

(English is the official version of the Framework. La version officielle de ce document est en langue anglaise.)

Traduction: Stephanie Dyke (Centre de génomique et politiques, Université McGill)

Validation: Emmanuelle Lévesque (Centre de génomique et politiques, Université McGill)

RESEARCH ETHICS REVIEW AND DATA SHARING

C.2

Kosseim *et al. Genome Biology* 2014, **15**:430
http://genomebiology.com/2014/15/8/430

OPINION

Building a data sharing model for global genomic research

Patricia Kosseim[1], Edward S Dove[2], Carman Baggaley[1], Eric M Meslin[3,4], Fred H Cate[4,5], Jane Kaye[6], Jennifer R Harris[7] and Bartha M Knoppers[2*]

Abstract

Data sharing models designed to facilitate global business provide insights for improving transborder genomic data sharing. We argue that a flexible, externally endorsed, multilateral arrangement, combined with an objective third-party assurance mechanism, can effectively balance privacy with the need to share genomic data globally.

A flexible, externally endorsed, multilateral arrangement, combined with an objective third-party assurance mechanism can effectively balance privacy with the need to share genomic

The opportunities presented by data sharing models

One of the great opportunities in the genomics era is exploring how human genes influence health, disease and biologic pathways, and how the knowledge gained can contribute to better health through both prevention and therapy. Researchers collaborating globally can gather sufficiently granular data to discover gene-environment-disease correlations for translational research and clinical application. Conducting scalable projects has been aided by the convergence of two key developments: vast improvements in, and access to, low-cost sequencing technology, and the increased power and sophistication of data analytics, driven by what has become termed 'Big Data' [1]. Big Data provides a new generation of data ana

Published in final edited form as:
Science. 2016 March 25; 351(6280): 1399–1400. doi:10.1126/science.aad5269.

Ethics review for international data-intensive research*

Edward S. Dove[1,*], David Townend[2], Eric M. Meslin[3], Martin Bobrow[4,5], Katherine Littler[6], Dianne Nicol[7], Jantina de Vries[8], Anne Junker[9], Chiara Garattini[10], Jasper Bovenberg[11], Mahsa Shabani[12], Emmanuelle Lévesque[13], and Bartha M. Knoppers[13]

[1]J. Kenyon Mason Institute for Medicine, Life S
Edinburgh, United Kingdom [2]Department of H
School, Maastricht University, The Netherland
University School of Medicine, Indianapolis, In
Trust Sanger Institute, Hinxton, United Kingd
Cambridge, United Kingdom [6]Wellcome T
Genetics, Faculty of Law, University of Tasma
Health Sciences, University of Cape Town, So
Medicine, University of British Columbia, Vanc
Corporation, Health and Life Sciences, Londo
The Netherlands [12]Centre for Biomedical Ethi
of Genomics and Policy, Faculty of Medicine,

In addition to moving toward common ethics review standards and procedural alignment, common conditions for exchanging data should be developed, which we believe would make RECs more inclined to mutual

Historically, research ethics commit
regarding human experimentation i
to provide assurance as to their inte
aggregate data sets, possibly includi
individuals, may require different assessments. As the scale of international
data-sharing collaborations adds stress to a system already under fire for subjecting multisite
research to replicate ethics reviews, which can inhibit research without improving the quality
of human subjects' protections (1, 2).

"Top-down" national regulatory approaches exist for ethics review across multiple sites in domestic research projects [e.g., United States (3, 4), Canada (5), United Kingdom, (6), Australia (7)], but their applicability for data-intensive international research has not been considered. Stakeholders around the world have thus been developing "bottom-up" solutions. We scrutinize five such efforts involving multiple countries around the world, including resource-poor settings (table S1), to identify models that could inform a framework for mutual recognition of international ethics review (i.e., the acceptance by RECs of the outcome of each other's review).

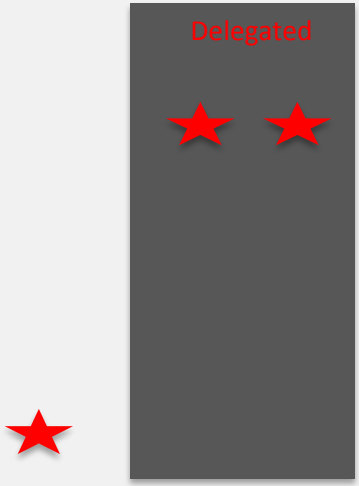
*Correspondence to: Edward S. Dove, edward.dove@ed.ac.uk.

C.3

ETHICS REVIEW

MUTUAL RECOGNITION

Comparative analysis of ethics review mutual recognition models across Canada, USA, UK & Australia



Rahimzadeh V, Knoppers BM (2016) How mutually recognizable is mutual recognition? An international terminology index of research ethics review policies in the USA, Canada, UK and Australia. Personalized Med; pp 102

2017 REVISIONS TO THE COMMON RULE

- **Mandated single ethics review of multisite collaborative protocols involving humans beginning January 2018**
- **Limited tools to guide and support the operation of sIRB review ahead of its 2018 implementation date (e.g. SMART IRB Reliance Tools, National Center for Advancing Translational Science (NIH)) https://smartirb.org/join/**

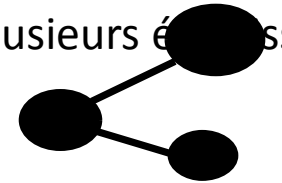
Federal Policy for the Protection of Human Subjects (45 CFR Part 46)

C.4

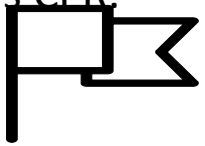
Article 8.1 Mécanismes d'évaluation d'un projet de recherche impliquant plusieurs établissements et CER

La recherche contemporaine comporte souvent une collaboration établie au sein de partenariats entre des chercheurs de plusieurs établissements ou de plusieurs pays. La section 8.1 porte principalement sur les modalités d'évaluation éthique d'un projet de recherche faisant intervenir plusieurs établissements ou plusieurs CER.

RÉCIPROQUE



DÉLÉGATION



INDÉPENDANTE

Énoncé de politique des trois Conseils : Éthique de la recherche avec des êtres humains, 2014.

C.5

Global Alliance for Genomics & Health

ETHICS REVIEW RECOGNITION POLICY

Version: 13 February 2017

Global Alliance for Genomics and He
Ethics Review Recognition Polic

Preamble

The Global Alliance for Genomics and Health ("GA4GH") is an internati
coalition of individuals and organizations working in healthcare, research
sciences, and information technologies dedicated to improving human hea
potential of genomic medicine through effective and responsible data shar
accelerate progress in human health by helping to establish a common fra
approaches to enable effective and responsible sharing of genomic and cli
catalyzing data sharing projects that drive and demonstrate the value of da

In 2014, the GA4GH adopted the *Framework for Responsible Sharing of*
Related Data (the "*Framework*"), which sets forth a harmonized and hum
responsible data sharing in accordance with Foundational Principles and
Elaborating on the general principles and guidance offered in the *Framew*
committed to creating policies that will provide specific guidance for its a
on ethics review recognition provides specific guidance to enhance both t
"Dissemination" Core Elements of the *Framework*. Building on the relate
organizations, such as the Council for International Organizations of Med
Organisation for Economic Co-operation and Development, and the Worl
the purpose of this Policy is to provide Essential Elements of ethics revie
jurisdictional research projects involving health-related data (including g
derived from samples). The two express goals of the Policy are: to both fo
extra-jurisdictional ethics reviews and improve the consistency thereof, as
efficient and responsible health-related data sharing for human health and

This Policy will be elaborated by subsequent more detailed Practical Gui
ethical and research governance issues. The Policy and subsequent Practical Guidance should be used in projects around the world (whether Global Alliance "inspired" or not) such that they become the tools to turn or refer to for guidance. Recognizing diversity of legal and ethical approaches and being responsive to emerging issues, both this Policy and subsequent Practical Guidance are intended to provide leadership in this domain for wider discussion.

This Policy is intended for research involving health-related data collection, production, access

Ethics review

mutual RECOG-NITION

policy

C.6

Essential Elements of Ethics Review to Foster Recognition

(Ethics Review Recognition Policy, ERE Task Team (Global Alliance for Genomics and Health https://genomicsandhealth.org/files/public/GA4GH%20Ethics%20Review%20Recognition%20Policy_FINAL_0.pdf)

- Norms, authority and independence
- Resources
- Competence
- Diligence
- Procedures and Forms
- Proportionate Scrutiny
- Transparency
- Natural Justice and Equity
- Research Oversight
- Accountability of RECs
- Vulnerable Populations

Global Alliance for Genomics & Health

ETHICS REVIEW RECOGNITION POLICY

Version: 13 February 2017

Global Alliance for Genomics and Health: Ethics Review Recognition Policy

Preamble

The Global Alliance for Genomics and Health ("GA4GH") is an international, non-profit coalition of individuals and organizations working in healthcare, research, disease advocacy, life sciences, and information technologies dedicated to improving human health by maximizing the potential of genomic medicine through effective and responsible data sharing. Its mission is "to accelerate progress in human health by helping to establish a common framework of harmonized approaches to enable effective and responsible sharing of genomic and clinical data, and by catalyzing data sharing projects that drive and demonstrate the value of data sharing."

In 2014, the GA4GH adopted the *Framework for Responsible Sharing of Genomic and Health-Related Data* (the "*Framework*"), which sets forth a harmonized and human rights approach to responsible data sharing in accordance with Foundational Principles and Core Elements. Elaborating on the general principles and guidance offered in the *Framework*, the GA4GH is committed to creating policies that will provide specific guidance for its application. This Policy on ethics review recognition provides specific guidance to enhance both the "Accessibility" and "Dissemination" Core Elements of the *Framework*. Building on the related work of other organizations, such as the Council for International Organizations of Medical Sciences, the Organisation for Economic Co-operation and Development, and the World Health Organization, the purpose of this Policy is to provide Essential Elements of ethics review recognition for *multi-jurisdictional research projects involving health-related data* (including genomic data and data derived from samples). The two express goals of the Policy are: to both foster recognition of extra-jurisdictional ethics reviews and improve the consistency thereof, as well as to promote efficient and responsible health-related data sharing for human health and wellbeing.

This Policy will be elaborated by subsequent more detailed Practical Guidance on particular ethical and research governance issues. The Policy and subsequent Practical Guidance should be used in projects around the world (whether Global Alliance "inspired" or not) such that they become the tools to turn or refer to for guidance. Recognizing diversity of legal and ethical approaches and being responsive to emerging issues, both this Policy and subsequent Practical Guidance are intended to provide leadership in this domain for wider discussion.

This Policy is intended for research involving health-related data collection, production, access

Multiples avenues?

D. Gouvernance: modéles nouveaux?

D.1

La gouvernance anticipée, ou l'approche prospective de la gouvernance

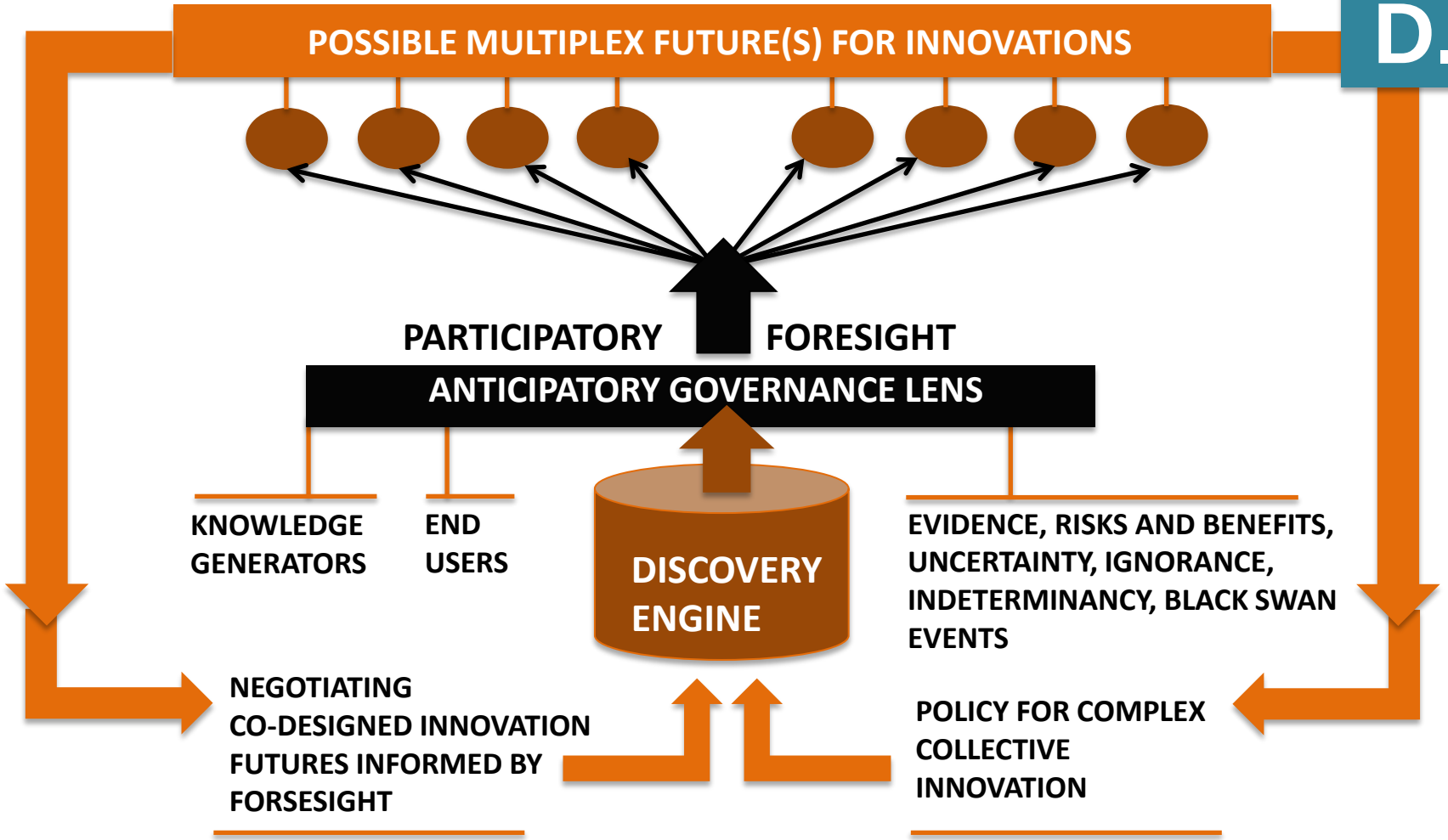
"la capacité large et étendue de la société de contribuer, au moyen d'une variété d'apports, à la gestion des technologies du savoir émergentes - pendant qu'un tel type de gestion est encore possible."

Anticipatory Governance

"a broad-based capacity extended through society that can act on a variety of inputs to manage emerging knowledge-based technologies while such management is still possible"

Guston, D. H. Understanding 'anticipatory governance'. *Social Studies of Science 44.*

D.2



Vural Ozdemir, Samer A. Faraj, and Bartha M. Knoppers, OMICS A Journal of Integrative Biology Volume 15, Number 9, 2011 ª Mary Ann Liebert, Inc. DOI: 10.1089/omi.2011.0087

D.3

Half of Canadians can expect cancer diagnosis during lifetime

Cite as: *CMAJ* 2017 July 10;189:E920. doi: 10.1503/cmaj.1095447

Nearly half of Canadians will get cancer during their lifetime, according to *Canadian Cancer Statistics 2017*. The risk is 49% for men and 45% for women, states the report by the Canadian Cancer Society. Cancer is the leading cause of death in Canada, responsible for one in four deaths.

"These numbers are an important reminder of the challenge we continue to face with cancer, despite the progress we've made," said Leah Smith, an epidemiologist with the Canadian Cancer Society. "Cancer takes a huge toll, not only on health care resources, but on Canadians and their loved ones. We have to take action to reduce this risk. Prevention, support and research are key."

These figures are relatively the same as last year, when the society reported that "almost half of all Canadians will develop cancer in their lifetime, and one quarter of Canadians are expected to die of the disease."

Cancer rates expected to continue rising as population ages.

According to the new report, about 206 200 people are expected to be diagnosed with cancer in 2017, up from the 202 400 diagnoses expected last year. Nearly 90% of cases will be among people age 50 and older (similar to last year's figure of 89%). About 80 800 Canadians will die from the disease, compared to 78 800 in 2016. The number of cases is expected to rise as Canada's population continues to age.

The two most common types of cancer diagnosed overall are colorectal (13%) and lung cancer (14%). Breast cancer is the most common among women, affecting one in eight. Prostate cancer is the most common among men, affecting one in seven. Lung, breast, colorectal and prostate cancers accounted for half of all cancer cases in 2016.

One worrying finding, according to Smith, is that pancreatic cancer may soon become the third-leading cause of cancer death in the country. There will be an estimated 5500 diagnoses of this cancer in 2017 and 4800 deaths.

"Many of us are surprised to learn that because pancreatic cancer isn't a cancer we hear about a lot," said Smith. "The reality is pancreatic cancer has the lowest survival rate of the 23 cancers we reported on, and we've made very little progress with this disease, especially relative to the other major cancers. Since little is known about preventing pancreatic cancer and detecting it early, research is key to making a difference with this disease."

Overall, however, advances in cancer research have improved survival rates considerably, according to the report. In the 1940s, the five-year survival rate was only 25%. It has increased to 60%. An estimated 179 000 cancer deaths have been avoided since 1988 thanks to improvements in cancer prevention and control.

Canadian Cancer Statistics 2017 was produced by the Canadian Cancer Society, the Public Health Agency of Canada and Statistics Canada.

Roger Collier, *CMAJ*

D.4

Chapter 16

Ethics and the social contract for genomics in the NHS

Chapter leads
Prof Anneke Lucassen[1], Prof Jonathan Montgomery[2] and Prof Michael Parker[3]

Authors contributed equally

1 Faculty of Medicine, University of Southampton
2 Faculty of Laws, University College London
3 Ethox, Oxford University

UK seeks to make DNA testing standard in cancer care
UK chief medical officer wants whole-genome sequencing for all cancer patients (2017)

Dr. Sally Davies noted that more than 300 000 cases of cancer are diagnosed in the UK every year. According to the report, whole-genome sequencing could reduce time delays in choosing the appropriate treatments for patients, while also reducing adverse events.

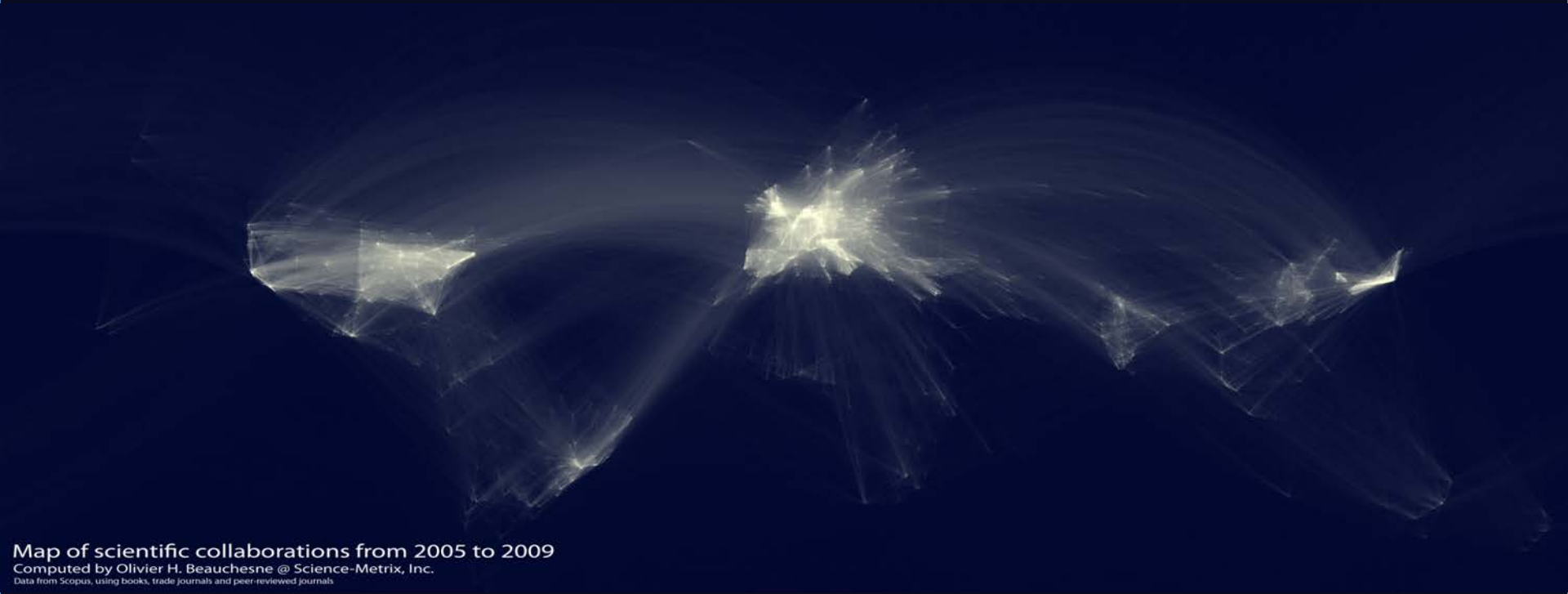
"The UK is almost uniquely placed, with its single point-of-care health care system, extensive genomics expertise and strong history of clinical trials, to develop a unified platform and use genomics to transform clinical practice and clinical trials."

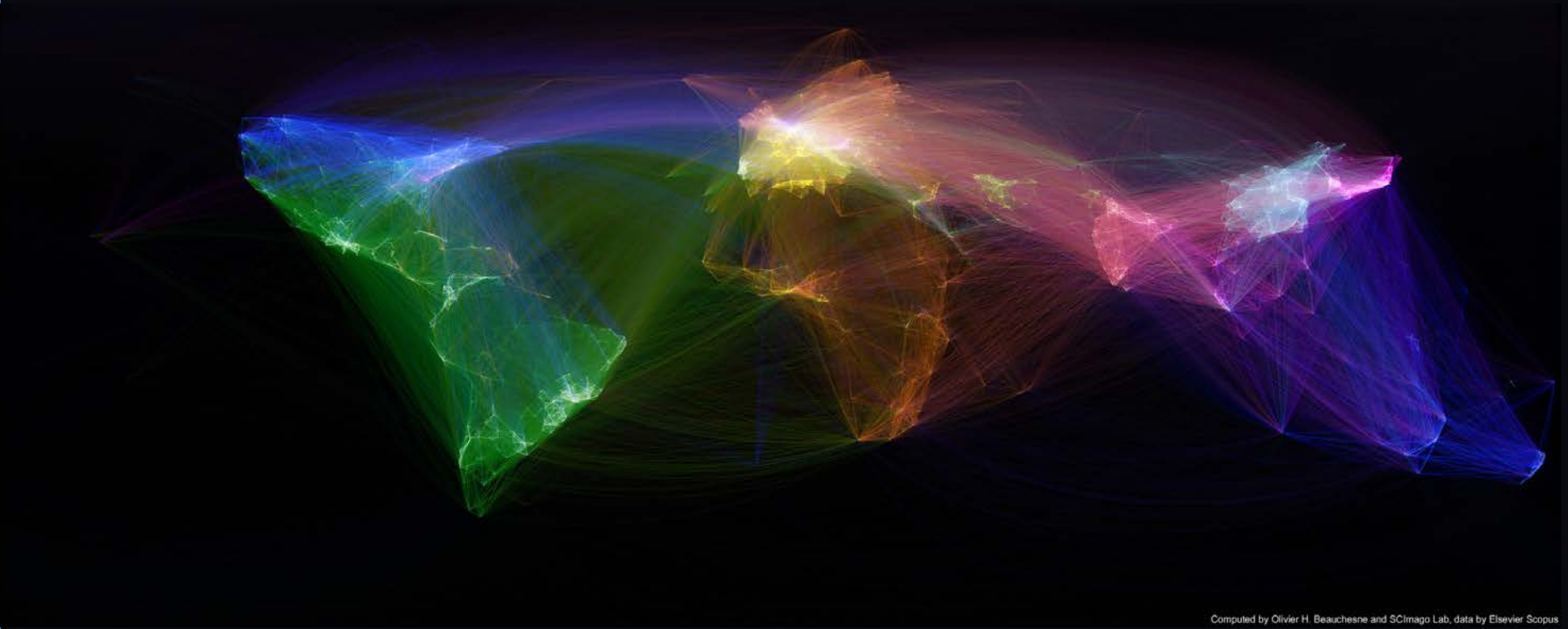
Collecting genomic data from "the totality" of cancer patients in routine care would also allow the UK to create a large clinical dataset that would not only contain the molecular features of different cancers but also track treatments and outcomes.

CMJA 2017 July 31; 189:E1001-2 doi:10.1503/cmaj.1095456

CONCLUSION

Il s’agit d’une approche réellement innovante, mais je crains qu’on ne puisse l’envisager. Cela n’a jamais été fait avant.


Map of scientific collaborations from 2005 to 2009
Computed by Olivier H. Beauchesne @ Science-Metrix, Inc.
Data from Scopus, using books, trade journals and peer-reviewed journals


Computed by Olivier H. Beauchesne and SCImago Lab, data by Elsevier Scopus