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HAS THE BIOBANK BUBBLE BURST? A TRANSLATIONAL CHALLENGE

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Has the Biobank Bubble Burst? A Translational Challenge

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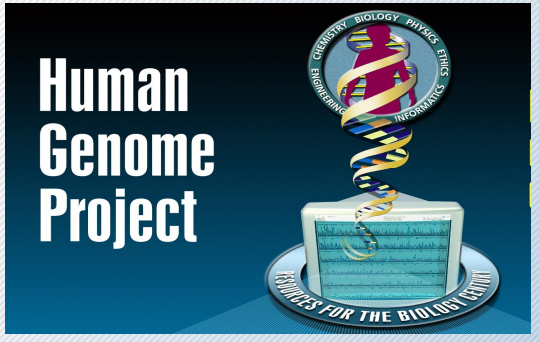
Outline –

1. The translational challenge and Biobanks
2. Nomenclature and Principles
3. Historical Phases in Biobank Development?
4. The Challenges ahead.

Acknowledgements of co-authors

1. Genome Era

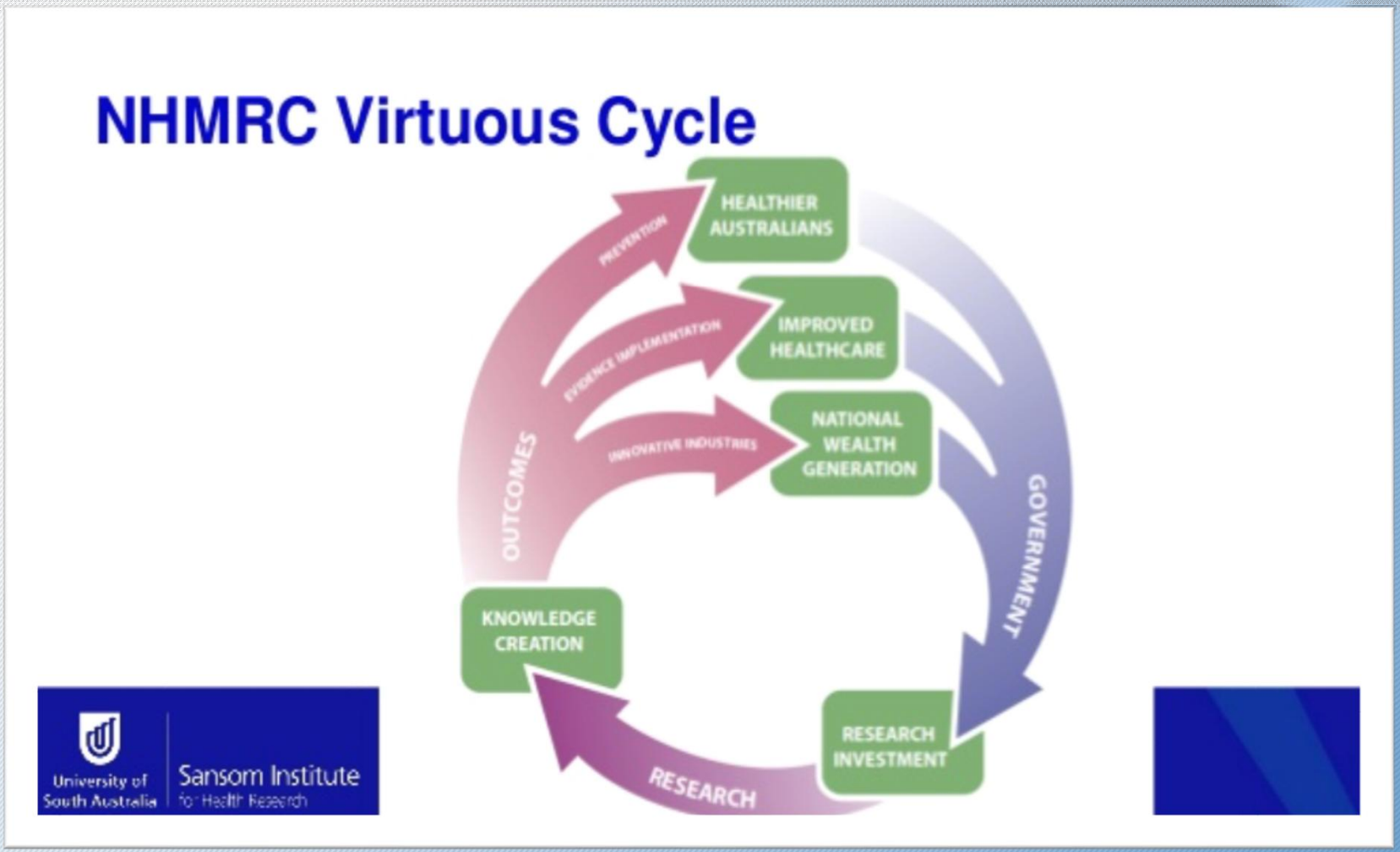
- Human Genome Project (HGP) 20 June 2000 –Optimism (working draft –NHGRI 14 April 2003)
- Francis Collins *The Genome Era* (1)



1. The Translational Challenge

- **Genome Era**
  - International Collaborations – multi-centre projects
  - Open Access – data sharing (HGP Bermuda Principles, 1996).
  - Technology Cost of sequencing reducing- $1000 genome
  - ELSI Ethical, legal and social implications important
- **Economic** Vast increase funding of scientific/ medical research
- **The Translation Challenge** from research to clinical application to better health and healthcare to better funding
- **Vision** Australia, *Strategic Review of Health and Medical Research 2013* "overarching vision for health and medical research …fully embedded in ..healthcare to deliver Better Health Through Research"
- "virtuous cycle"(2).

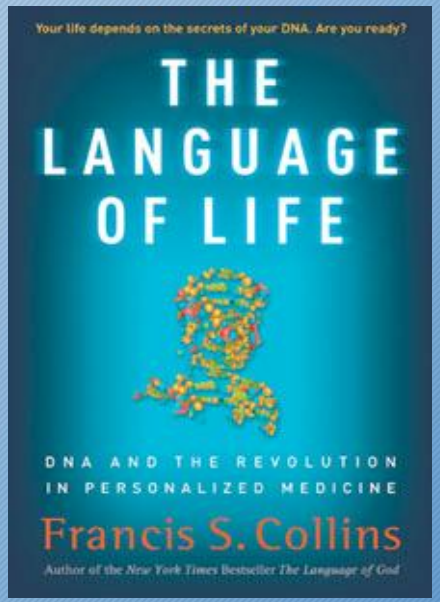
1. Translation and the “Virtuous cycle”



1. Translation to better health

Vision of the “virtuous cycle” to future translation to personalised medicine (Francis Collins)

- Hope (born 1-1-2000& most people) -DNA sequenced and integrated predictive models for diet, lifestyle, and treatments . Hope healthy 100+
- Alternative -dystopic health-care system w/o
- personalised medicine
- No trained doctors in genomics
- No payment for predictive and preventive tests
- Hope- genetic predisposition to heart attack
- Gardening at 50.



1. Personalised Medicine Era and Biobanks

- **Virtuous cycle** "If properly supported, medical research will create new jobs, catalyse sustained economic growth and help to restore public finances by improving health.. making the NHS.. more cost effective" AMS *Biomedical research-a platform for increasing health and wealth in the UK* (3)
- Biobanks – key flagships in the Virtuous cycle in Precision Medicine era
- Considerable public/ private investment in biobanking over last 20 years in
  - small –scale biobanks, often disease or project specific
  - international collaborative consortia with combined data sets.
- A *bcc Research Report* , June 2011 (4), estimated global biobanking market $141 billion in 2010, projected to increase by 30% to estimated $183 billion in 2015
- NCI estimated $50 million a year on basic biospecimen infrastructure.

2. Biobanks - Nomenclature

- Knoppers and Saginur (5) The Babel of genetic data terminology.

Bruegel (elder) 1563

Nomenclature OECD *Creation and Governance of Human Genetic Research Databases* 2007 by 2009 morphed to OECD *Guidelines on Human Biobanks and Genetic Research Databases* (HBGRD - acronym!)

2. Biobanks - Nomenclature

- **Nomenclature,** Estonia “Genome database”, Latvia “Genebank”
- French National Consultative Ethics Committee Opinion 77 collections of biological material and associated information data : “biobanks”, “biolibraries”
- UK Biobank, 2007 *Ethics and Governance Framework* -financial collapse of sub-prime mortgages, RBS and Lehman’s banks, housing and share markets in 2007-8 - use of term?
- Public Population Project in Genomics and Society (P3G) **“** compare and merge results from studies**, biobanks, research databases and other similar health and social research infrastructures** conducted around the world” (6)

2. Biobanks - Nomenclature

“Biobank” can include epidemiology studies, focus on data?

- UK Biobank (500,000) ; GenomEUtwin (Finland);); LifeGene (Sweden 500,000) “relationships among heredity, environment and lifestyle; LifeLines (Netherlands) 2006 “**one of the most valuable multidimensional cohort studies and biobanks in the world**..”; CARTaGENE (Quebec) **“biological samples and data”;**

Some of the variations in biobank terminology

- *Biobanks in Europe: Prospects for Harmonisation and Networking* JRC Scientific and Technical Report 2010 “. …. **trend to break down this sample/data dichotomy and to consider under "database" both** the **physical sample and the information** derived from it, but a deeper international understanding and agreement still needs to be reached. (at vi) (7)[Report includes biobanks around world].

P3G definition addresses biobank terminology challenge

- Fransson, Rial-Sebbag,, Brochhausen and Litton (D-G BBMRI) survey in 2015 support a “common terminology” …. “Creation of a global biobank data dictionary” -mainly targeted at members BBMRI, **favors the glossary of the P^{3}G consortium (8)**

3. The First Wave – Establishing Biobanks

- 2005 Biobanks "translating biomedical research into real improvements in health care" (9)
- Growth of national/regional biobanks and shifts in research ethics (10)
- Public good shift and benefit sharing. Public trust, particularly after deCODE debate and Autogen
- Consent shift to prospective, as yet unspecified, research projects
  - NIH Clinical Center's Department of Bioethics Workshop, 2015 concluded broad initial consent coupled with oversight and ongoing information to donors acceptable (11) and
  - UNESCO IBC October 2015, moral acceptability of a broad consent (ethical challenges of biobanking and recs for international registry of biobanks, and points for model governance.
- Longitudinal research projects shift from single projects to biobanks as platforms
- Governance models for dynamic accountability to research participants and public to maintain public trust
  - Regulatory layers – legislation, national ethical research codes, codes of practice and internal institutional governance arrangements on samples/data collection, storage, distribution and consent .
  - Best practice governance -oversight body with regular compliance reviews.

3. The First Wave – Establishing Biobanks

2000s expansion of biobanks

- **National** – deCODE pioneer ?; GenomEUtwin (Finland); Estonian Genome project (50,000); INMEGEN (Mexico) “genomic research for medical applications to improve health”; Estonian Genome database, Latvian Genbank, BioBank Japan (BBJ).
- **Regiona**l -European Strategy Forum on Research Infrastructures (ESFRI) Roadmap 2006- pan-European facility- BBMRI; Generation Scotland “for genetic and health related research” Karolinska Healthcare Research Biobank (KHRBB) 2010 upgrade decision; CARTaGENE (Quebec); Danubiobank; Centre for Integrated Genomic Medical Research (Manchester UK)
- **Australasian** Biospecimens Network (ABN) and guidelines *Biorepository Protocols*/NHMRC Enabling Grants (ABN-Oncology 2005, 7 Oncology biobanks awarded) WA Genetic Health project (Busselton);Victoria cancer consortium; and Chapter on Databanks, *National Statement on Ethical Conduct in Human Research* 2007 .

- **HUGO “**seismic shift in the values underlying genomic research”(Knoppers and Chadwick 12) Committee on Ethics, Law and Society (CELS) (13)

Statement on the Principled Conduct of Genetics Research, December 1995; Statement on Benefit Sharing, April 2000**; Statement on Human Genomic Database, December 2002;** International code of conduct for genomics and health-related data sharing, June 2014

3. Second Wave – Collaboration and Harmonisation

- **Time** 2009 “Ten ideas changing the world” – Biobanks No 8
- **Second wave?**
- **Homogeneity or variety?** *Biobanks in Europe:* JRC Report
  - “While biobanks are increasingly recognised as a crucial infrastructure for research, at the same time the **widely varied practices in biobanking regarding for example collection, storage and consent procedures** may also pose a barrier to cross-border research and collaboration by limiting access to samples and data”. (at *v*)
- Recognised biobanks needed more “**standardised”** technical procedures .

3. Second Wave – Collaboration and Harmonisation

OECD Governance and management frameworks-OECD
Guidelines for Human Biobanks and Genetic Research Databases 2009 (*Creation and Governance of Human Genetic Research Databases* 2007) (14)

Part I. Guidelines on HBGRDs
1. General elements
2. Establishment of HBGRDs
3. Governance, management, and oversight
4. Terms of participation
5. Contents of HBGRDs
6. Protection of human biological materials an data
7. Access
8. Qualifications, education and training
9. Custodianship, benefit sharing& intellectual property
10. Discontinuation of the HBGRD and disposal of materials and data

Part II. Annotations

3. Second Wave – Collaboration and Harmonisation

Second wave Collaboration

- **BBMRI** Biobanking and Biomolecular resources Research Infrastructure initiatives EU biobank infrastructure project for information tech, exchange of data and material quality management. –BBMRI-EPIC and BBMRI-LPC
- **EuroBioBank** 18 collaborating centres on DNA/Tissue, 2005 (Wave 1?) EuroBioBank is a **unique network of biobanks** s for scientists conducting **research** on **rare diseases**.
- **German Biobank Registry** (GBR) central IT infrastructure, publicly accessible information f medical biomaterial banks, policies, probands, materials, collections, funding and phenotypes.
- **Spanish National Biobank Network** (CNIO) Spanish Law 14/2007 on Biomedical Research
- **Coriell Personalized Medicine Collaborative** (CPMC) 2007 better understanding genome-informed medicine by combining biobank facility with microarray technology.
- **Australia** ABN support for biobanks. NHMRC *Information Paper on Biobanks* in 2010; NHMRC WGs cancer and brain biobanking and *Draft National Biobanking Strategic Plans;* 2011, Commonwealth Department of Industry, Innovation, Science and Research *Strategic Roadmap for Australian Research Infrastructure*

3. Second Wave – Collaboration and Harmonisation

Collaborative networks - cancer research

- **International Cancer Genome Consortium** (ICGC) (15) EU+16 country data exchange for 200 large scale projects in ***open*** **and** ***controlled***-access data sets.
- **USA** The Cancer Genome Atlas (**TCGA)** and the Cancer Human Biobank (caHUB)" infrastructure for collaborative biospecimen research and the production of evidence-based biospecimen standard operating procedures
- **Canada** Tumour Repository Network.
- **German** Cancer Consortium Center in Heidelberg, seven partner sites..
- **Taiwan** Lung Cancer Clinical Trial Consortium (TALCC) under umbrella scheme Taiwan Clinical Trials Consortium (TCTC) to promote Clinical data sharing
- **Australia**, Aust Breast Cancer Biospecimen Resource, National Leukaemia and Lymphoma Tissue Bank, kConFab, Aust Prostate Cancer Collaboration BioResource, Aust Ovarian Cancer Study (AOCS) and Vic Cancer Biobank.

3. Second Wave – Collaboration and Harmonisation

Cohort epidemiology Collaborations

- **BioSHaRE EU (**15 cohort studies) to ensure development of harmonized measures& standardized computing infrastructures;
- **PHOEBE** Promoting Harmonisation of Epidemiological Biobanks in Europe collaboration promoting harmonisation of epidemiological biobanks.
- **ENGAGE (European Network for Genetic and Genomic Epidemiology**, 2008 to **translate** wealth of data from large-genetic and genomic epidemiology research from European (and other) population for future clinical applications.
  - Dataset of more than 80,000 GWAS and 600,000 DNA/serum/plasma samples.
  - Why people differ in responses to treatment?

3. Second Wave – Collaboration and Harmonisation

Organisations and "hyperdemocracy" (J. Attali)

- **ISBER** International Society of Biological Environmental Repositories generic standards for information technology networking, quality management, responsibilities towards the public, advising biobanks, education and training and ethical, legal and social issues.
- **P3G** CHARTER OF FUNDAMENTAL PRINCIPLES (2007) highest standards of ethical comportment and research integrity.
  - PROMOTION OF THE COMMON GOOD optimise the benefits of ..research for… all.
  - RESPONSIBILITY Protection of the interests of all affected stakeholders -families, groups, populations, researchers and research sponsors.
  - MUTUAL RESPECT ..responsibility, collaboration, co-operation, trust and mutual respect for others, includes recognition of cultural diversity and the scientific specificity of projects.
  - ACCOUNTABILITY All standards, processes and procedures will be transparent and clear, developed [by]consensus, and aim to create best practice
  - PROPORTIONALITY All research materials (such as data and samples) must be protected to the **highest standards of privacy and propriety, while at the same time allowing and promoting the free exchange of ideas, datasharing and openness for the benefit of all.*****

3. Second Wave – Collaboration and Harmonisation

- **Global Alliance for Genomics and Health** to help accelerate the potential of genomic medicine to advance human health via a common framework of standards to enabl6 the responsible, voluntary, and secure **sharing of genomic and clinical data** (16).**- Four working Groups**
- **Clinical Working Group-** clinical data quality and exchange
- **Data Working Group-** data representation, storage, and analysis, working with platform development partners and industry to develop standards to facilitate interoperability.
- **Regulatory and Ethics Working Group** – ethics, legal and social implications, including harmonizing policies and standards, developing *forward-looking consent*, privacy.., and best-practices in data governance and transparency.
  - ***International Code of Conduct for Genomic & Clinical Data Sharing***
- **Security Working Group-** technology of data security, user access control, and audit functions to develop/adopt standards for data security, privacy, and user/owner access control.
- **Second wave Report Card ?** *Biobanks in Europe:* JRC Report (8) "To help promote networking of biobanks, at least some degree of harmonisation must be achieved. Whether ..solely at the level of legal/regulatory requirements... Experts suggested the establishment of an **international (rather than just a European) umbrella (or network) organization, which would establish common operating procedure**s" (at *vii*)





3. Second Wave – Collaboration and Harmonisation

Harmonisation not only national and international but **Institutional**

- **Challenge of sample storage and retrieval; data management/integration; common platforms**
- **Biobank Landscape at Duke University Biobanking** (17)
  - Biospecimen Repository Processing Core
  - Biofluids Shared Resource
  - Duke Human Heart Repository
  - Center for Applied Genomics & Precision Medicine
  - LabCorp Biobanking
  - Alzheimer's Disease Research Center.
  - (and the Duke Translational Medicine Institute; Duke Surgery; Duke Clinical Research Unit; Murdock Study; Duke Molecular Physiology Institute; and, Preston Robert Tisch Brain Tumor Center)
- Goal of Biorepository Task Force "to develop and implement systematic approaches that support a regulatory-compliant, comprehensive, and sustainable Network-wide biorepository" to serve. National Patient-Centered Clinical Research Network (PCORnet) within Patient-Centered Outcomes Research Institute (PCORI) (18)
- **LabVantage** - Study, Consent and Sample Management; Biospecimens Processing Workflows; Storage and Inventory Management; Package Tracking and Handling; and, Analytics and Reporting

3. Third Wave – the Sustainability Challenge

Sustainability concerns

- At biobank establishment stage, long-term viability, discontinuance, not at forefront,
- increasing focus on sustainability in constrained funding environment (Toyotism and the three “Es”)
- Decade ago, Hank Greely observed biobanks could be “staggeringly expensive.”
- *Biobanks in Europe:*JRC Report “ need for assuring sustainability of biobanks. Most funding resources do not accept requests ..project .. exceeding 3 to 5 years. However, biobanks ..must be run for at least 20 years, … need for a 'salvation fund' for saving ..European collections .. (at 147)
- Vaught and colleagues (19) , the “[t]ight economic realities ..have spurred the need to re-examine financial models ..of biobanking … but this model is not often achieved”
- Biobanks in **Australia a**nd a “levelling off phase”
  - Continued funding and sustainability -national issue.
  - NHMRC funding, once-only basis and not after 2012.
  - NHMRC Biobank Strategy Committee –W/t more funding, many biobanks (cancer) cannot continue.
  - Recommended introduction of fee-for-service cost recovery system

3. Third Wave – the Sustainability Challenge

Sustainability – challenge for some biobanks and collaborations.

- Australian Breast Cancer Tissue Bank and Canadian biorepositories recover negligible amounts and smaller biobanks tend to have few requests for access (20)
- Singapore Tissue Network (STN) 2002 to collecting bio-specimens from tissue repositories for population-based epidemiological/translational research. Name changed to Singapore Bio-Bank (SBB) closed by government in 2011.
- German Biobank annual Symposium, 2013 focus on business/financial models for biobanking noted need long-term sustainability plan also for well established, financially sound biobanks
- Promoting Harmonisation of Epidemiological Biobanks in Europe (PHOEBE) established 2006 wound up in 2009.
- Danubiobank final report 2011
- Taiwan Ministry of Health and Welfare (MOHW) secured funding for Taiwan Biobank for next decade but action by Human rights groups objections to use of records
- Biobank Japan has had its budget cut for the third 5 year period

3. Third Wave – the Sustainability Challenge

- Some Biobanks clearly surviving, prospering and sustainable
- European Strategy Forum on Research Infrastructures (ESFRI) Roadmap 2006- pan-European facilities including BBMRI.
- **The Preparatory Phase: 2008-2011,** In 2008, BBMRI was one of the first of the ESFRI Roadmap for Research Infrastructures.
- **The Interim Phase: 2011-2013** BBMRI-LPC to enabe scientists to access large prospective study sets with the vision to integrate in BBMRI-ERIC (European Research Infrastructure Consortium). –
- **Awarded EU Legal Status: 3 December 2013**. The ERIC status allows pulling together biobanks and biomolecular resources into a pan-European facility and providing access to collections of partner biobanks and biomolecular resources, their expertise and services on a **non-economic basis**.

3. Third Wave – the Sustainability Challenge

Sustainability

- Watson and colleagues . . “underlying belief that at some point, [biobanks] should be capable of becoming ‘self-sustaining.’” (21)
- Similarly, Henderson and colleagues (22). “Many biobanks …initiated ..based on a public or private grant or “one-shot” institutional funding… spent creating the biobank …for the first several years. Unfortunately, very few biobanking efforts have fully developed a robust plan to support their costs once the initial funding has been exhausted”.
- Vaught proposed„The true costs of developing and maintaining operations, ..must be better understood”. Biobank's "value chain,”? And “a Total Life Cycle Cost of Ownership (TLCO) model ..to estimate all costs arising from .. biobank”
- Many biobanks need to focus on developing sustainable business plans
- Any shift to “business” may raise concerns about public trust (23)
- Biobanks must balance values and rights of participants with any long-term sustainability plan (24)

3. Third Wave – the Sustainability Challenge

A need for new sustainability/ business models?

- **Cost-recovery** as solution -minimal fee for academic researchers, higher fee for commercial entities. Reports on cost-recovery not encouraging
  - Singapore government closed Singapore Bio-bank (SBB) in 2011 cost-recovery model failed and under-utilisation.
  - NHMRC Australia
- **Developing measures** of biobank success - “value”.
  - Number of requests -number of outgoing samples.
  - Metrics elements for sustainability - “financial value”; “operational efficiency”; “social acceptability”; “discoveries”.
  - Creation of knowledge/publications (for public good?)- “knowledge-value”.
  - Metrics should include public trust? - “price of everything and the value of nothing” (*pace* Wilde)
- **Accreditation** schemes are being debated by international groups like ISBER and national groups (25)
- **ISO** standards (26) for biobanks - ISO/TC 276?WG 2 *Biobanks and Bioresources (*ISO 9001, Quality Management Systems and ISO 27001, Information Security Management)
- Unlikely that a single business/operational biobank model a desirable goal.

4. Concluding Comments

- Virtuous cycle Research-translation- better health to funding increase
- Biobanks -considerable investment over past 20 years and key part of cycle
- PCAST (27) USA Three Priority Areas *Policy Recommendations 1: Technology and Tools* (*2: Regulation Challenges 3: Reimbursement Challenges)*
- Public trust and confidence in precision medicine will depend on the maintenance of high ethical and legal standards

- Sustainability challenge Some biobanks have long-term sustainability challenges.
- What happens if a biobank closes or even goes bankrupt? Note OECD *Guidelines*
-
- Francis Collins "Pharmacogenomics [Biobanks?]…..one of the most promising areas of personalized medicine, has also turned out to be extremely complicated, not that we shouldn't have known that" (28)

- If biobanks are the flagships, perhaps some may have to trim their sails

- Future Fourth phase – harmonious data sharing, including international and national biobanks

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- Has the biobank bubble burst? Withstanding the challenges for sustainable biobanking in the digital era (under review) Authors: Don Chalmers[a], Dianne Nicol[a], Jane Kaye[b], Jessica Bell[b], Alastair V Campbell[c], Calvin W L Ho[c], Kazuto Kato[d], Jusaku Minarid[d], Colin Mitchel[b], Fruzsina Molnár-Gábor[e], Margaret Otlowski[a], Daniel Thiel[f] , Stephanie M. Fullerton[g] and Tess Whitton[a].

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