



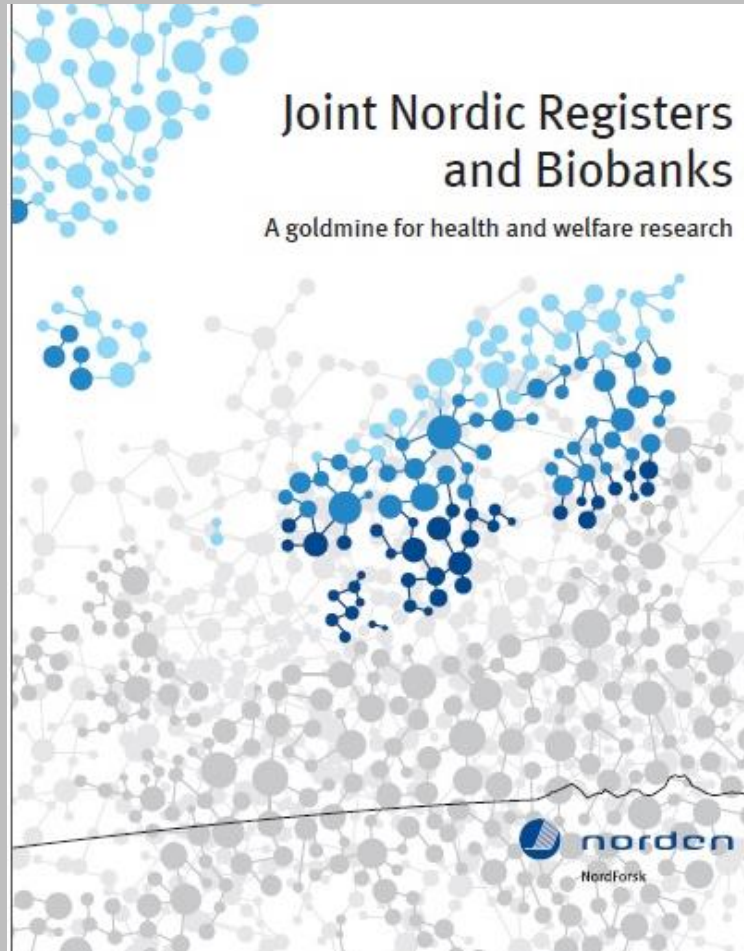
BIOBANKS AND NORDIC COLLABORATION IN HEALTH RESEARCH

NTA Ethics

Oslo, January 30, 2017

L.L.M Sirpa Soini

NORDIC GOLDMINE — REGISTRIES AND BIOBANKS



Church records and land property registry since 1600s

Health records and sample collections since decades

Register-based research tradition

Personal IDs since 1960s'

Pro bioscience (Eurobarometre-survey 2010, Gaskell et al)

Trust on research & public governance

OPPORTUNITIES IN THE NORDIC COUNTRIES FOR SUCCESSFUL HEALTH RESEARCH

- Nordic welfare model; universal access to health-care
- Right to good quality health-care
- Harmonised care models at the national level
- Improvement of care and services based on research and innovations
- Favourable legislation, good quality registers and biobanks
- Digitalisation of everything; electronic health records

Legislation on biotechnology in the Nordic countries – an overview 2014



norden

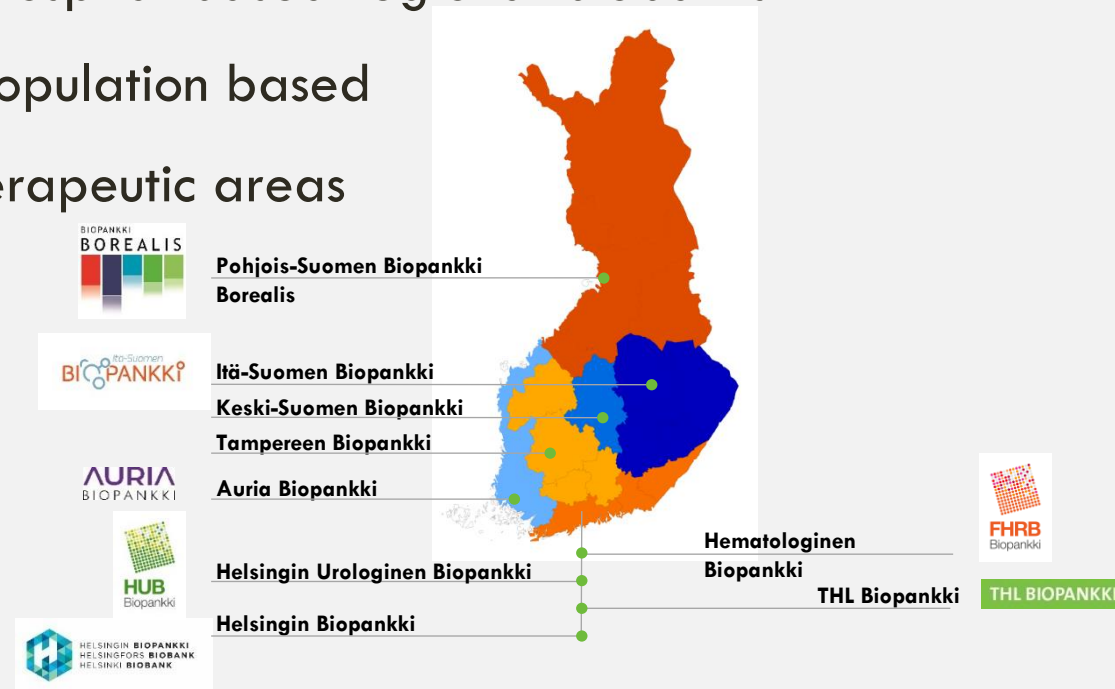
NordForsk

FINNISH BIOBANKS — BBMRI.FI

5 university hospital based regional biobanks

1 national population based

2 special therapeutic areas



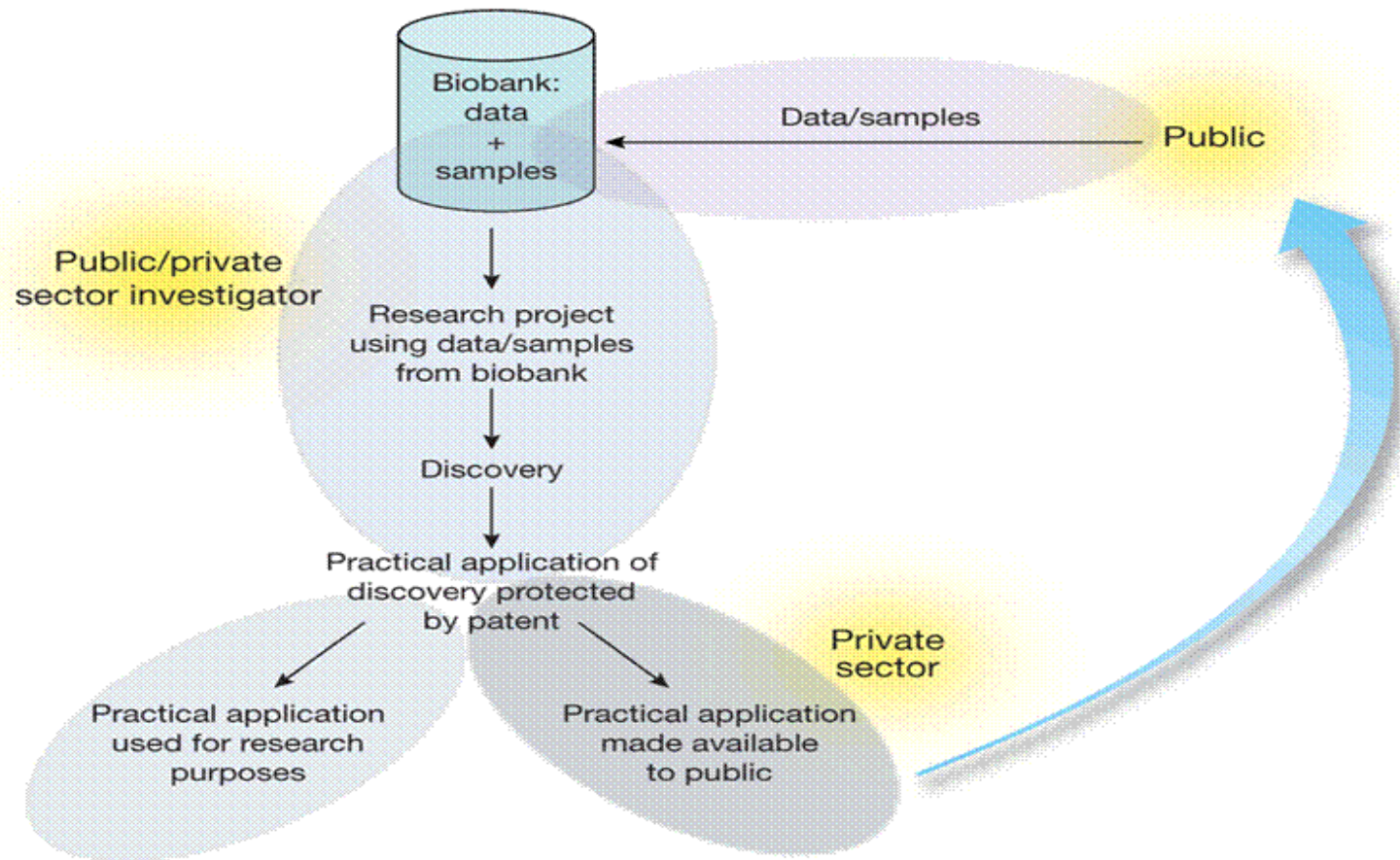
KEY FEATURES OF FINNISH BIOBANK ACT

(IN FORCE SINCE SEPT 1, 2013)

- Broad consent for future research purposes
- Transfer of old samples via public/personal notification and opt-out
- Overall ethical review of biobanks' procedures by National Medical Research Ethics Committee (TUKIJA) at the time of establishment
- Continuous supervision under Valvira (National Supervisory Authority for Health and Welfare) – mandatory licensing
- Metadatabase for preliminary info about available samples and data
- Professional high-quality collections
- Equal access for all researchers that meet the access criteria (*open science, sharing*)
- Return of analysis results to biobank
- Can be combined with patient records and national health registers
- People have right to check their information at biobank (incl. health)
- Data cannot be used against the individual (work, forensic, administration, insurance)

INNOVATION CYCLE IN PUBLICLY FUNDED BIOBANKS

PATHAMASIRI ET AL., NAT BIOTECH 2011;29:321.



FINNISH HEALTH ECOSYSTEM & STRATEGIES

- Health sector growth strategy 2014, (2016)
- Genome strategy 2015, government funding to establish a Genome Centre 2016-19
- Health and welfare data – effective use for secondary purposes 2018
- Political push for a joint biobank operator 2017 (Expert Centre –concept)
- Collaboration with many ministries
- Health system reform effective by 2019
- Key approaches: *digitalisation, mydata, open science, sharing*

FINNISH DRAFT LAW PROPOSAL ON SECONDARY USE OF SOCIAL AND HEALTH CARE DATA

- Aim is to establish legal ground to process personal data for secondary purposes
- Primary purpose: collection of (sensitive) data for the provisions of social and health care and services
- Secondary purposes
 - statistics, scientific research, development & innovations, education, knowledge based leadership; guidance, monitoring, planning of authorities
- Harmonisation of procedures - one-stop-shop, e-applications, ethics review when needed
- Data linkages from various registries in a data secure environment
- Basic principle: data is anonymised, or pseudonymised for secondary purposes (code keys stored)

PHARMA - SOME TRENDS

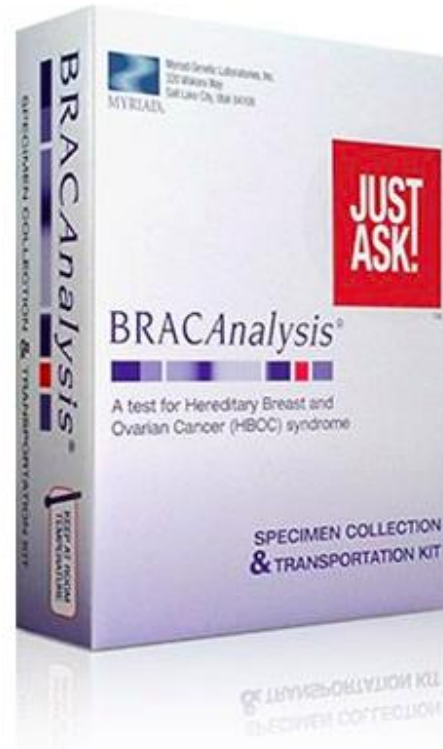
- **Great interest to Real World Data/Evidence, e.g, for**
 - Adaptive licensing
 - Optimising clinical trials (recruitment, stratification)
 - Post-market surveillance
- **In connection with clinical trials, attempts to get material for their own biobanks or stores (use of residual or extra samples for "any future research")**
 - E.g. Astra Zeneca's 2M genomes project (Science, April 2016).
 - Is such a consent legal?
- **Proprietary databases and repositories, however,**
 - Contradict with the idea of Open Science that the public sector is building and
 - Transfer collaboration outside the original sites

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The question asked by
healthcare providers:

**Is My Patient
At Risk?**

Predictive Medicine



Myriad's product
that brings the answers:

BRACAnalysis®

A test for Hereditary Breast and Ovarian Cancer (HBOC)
syndrome

MYRIAD POLICY ON GENETIC INFORMATION: Consistent with this regulatory oversight, **we are not allowed to release our variant databases** because they may only be used to interpret clinical test results for patients tested in our laboratories.

CHALLENGES FROM THE SUSTAINABILITY PERSPECTIVE

- Value in combining and enriching data & resources; and sharing them
- New funding & new partners common
- New analyses and revisits to the data may be needed
- Difficult to anticipate in advance, but reconsenting not often possible or helpful
- Broad consent solves some issues, but (global) sharing difficult or almost impossible due to information requirements
 - Case : Long-standing high-quality research collaboration between Finnish & US institutes almost ended due to data protection rules and their strict interpretation
 - Case: Finnish biobank consent is not enough for data authorities
- Reconsenting not often possible
- Respect of research participants (ethics) & law may contradict - is extreme data protection even ethical or socially justifiable?

ECOSYSTEMS DEVELOPING & CHANGING

- Big Data, Quality of Data & Tools
 - Data Ethics
- IBM, Microsoft, Google and other big ICT-companies are investing heavily and seeking collaboration
- Start ups, new partners & new ways of doing things
- Do the current structures enable "disruptive innovations"? Thinking creatively; combining various research sources in a new way?
- Agility and understanding needed also among the authorities
 - a) not to block progress (enabler)
 - b) to know when precaution is needed (gatekeeper)

COMPETITIVE NORDIC R&D LIFE SCIENCE AREA – TOGETHER

- Similar traditions & values – why not harmonise regulations and ethical evaluations?
Now many bureaucratic ways for the same end.
- Together still only ca. 30 million people
- Enhance R&D, support environment for innovations (see BCG Nordic Agenda report 2017)
- Need political will and concrete actions in the Nordic Council and national ministers

BCG

THE BOSTON CONSULTING GROUP

NORDIC AGENDA 2017

AS THEIR LEAD SLIPS, NORDICS LOOK TO REVITALIZE GROWTH

The changes that are needed aren't small; in many cases they are transformative. However, we believe it's better to start now, when the alarm bells are just becoming audible and the bigger danger is still several economic cycles off. A lot can be accomplished if businesses and governments undertake the transformation jointly. And they should want to: they are in this together.