Sustainable biobanks

- challenges and future perspectives

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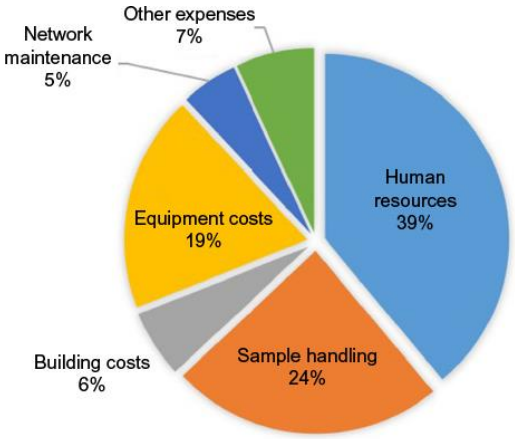
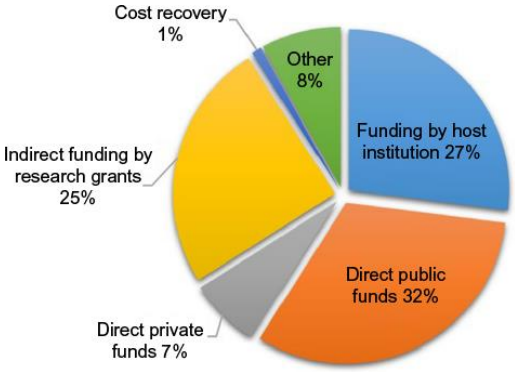




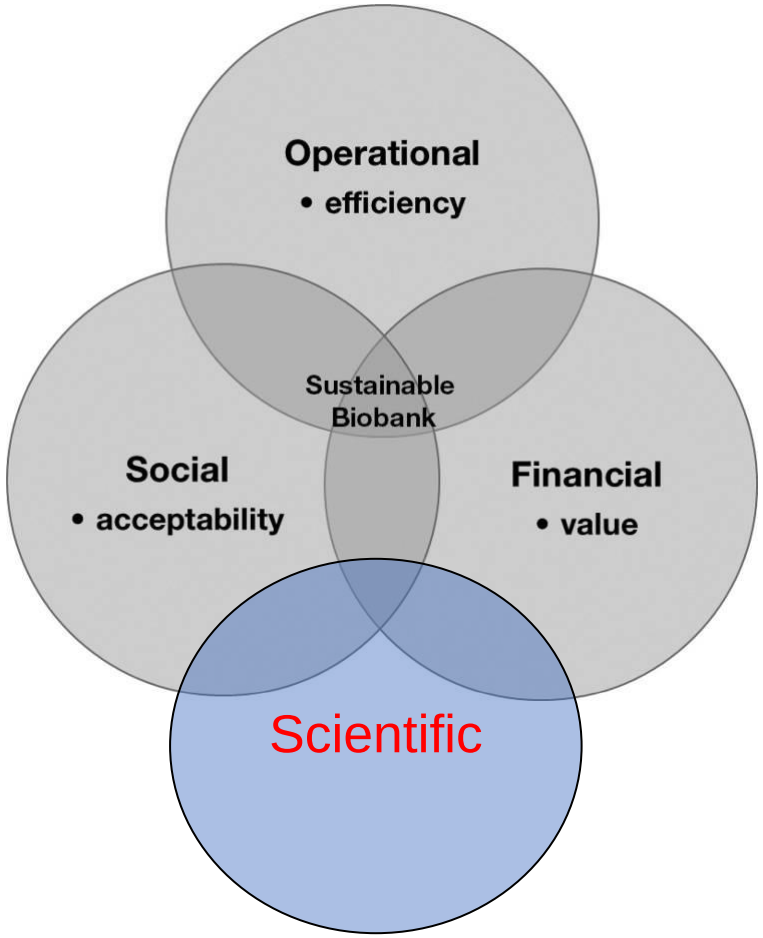
Definitions

Sustainability is the capacity of a research infrastructure to remain operative, effective, and competitive over its expected lifetime (OECD Global Science Forum 2017b).

The term biobank sustainability is often used as **fiscally self-sustaining**, but this restricted definition is not sufficient

Biobank sustainability should be considered within a framework of three (four?) dimensions –

Financial,	Operational	Social	Scientific



Watson PH et al , A framework for biobank sustainability. Biopreserv Biobank. 2014

Sustainability is challenged by

- Biobanks are different from research infrastructures
- Great diversity in the biobanking landscape and amongst biobanks
- Absence of universally understood or applicable value metrics for funders and other stakeholders
- Increasing requirements from the research community in terms of biospecimen diversity, numbers and annotation
- The need to implement standardized processes to attain higher quality standards, certification and accreditation
- Donors require transparency and accountability for their samples,
- The public has concerns around privacy, particularly in relation to their genetic information (GDPR)

Watson PH et al , A framework for biobank sustainability. Biopreserv Biobank. 2014

Financial dimension

Market strategy	Develop a strategic plan (e.g., business, marketing, academic etc.)
	Foster user fee adoption
	Revisit and revise the plan
Stakeholder needs	Identify different goals and motivations
	Define growing targets (e.g., biospecimen type, disease focus)
Brand recognition	Communicate value for investment with all stakeholders (e.g., PI, institution, funder, etc)
	Measure value and monitor impact of the biobank (**e.g., BRIF**)

Watson PH et al , A framework for biobank sustainability. Biopreserv Biobank. 2014

Operational Dimensions

Input efficiency	Patient or other enrollments
	Biospecimen accrual systems (e.g., LIMS, CHTN, BC BioLibrary,)
Internal efficiency	Optimize processing of biospecimens & annotation
	Balance resources to support • retrospective questions, legacy collections • prospective questions (disease outcome, other registry data)
Output efficiency	Assess responsiveness (measure response times and survey customer satisfaction)
	Offer more products (e.g., annotated biospecimen)

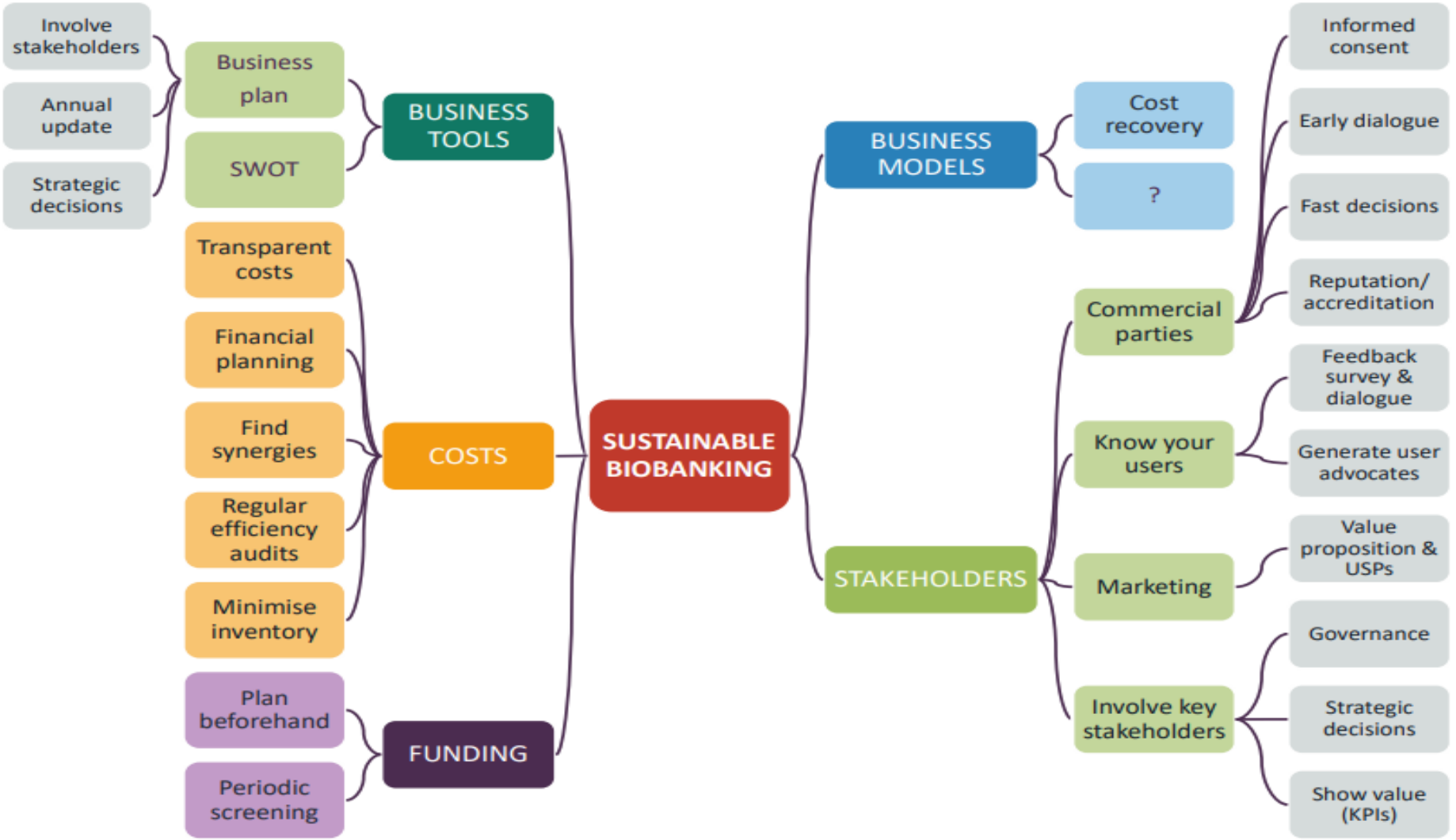
Watson PH et al , A framework for biobank sustainability. Biopreserv Biobank. 2014

Social dimension

Acceptability	Ensure appropriate ethics review board approval for biobank and research projects using the biobank
	Public/donor engagement, stakeholder forums, active roles in governance, be transparent
Standards	Assurance of commitment to good practices (e.g., Accreditation or Certification)

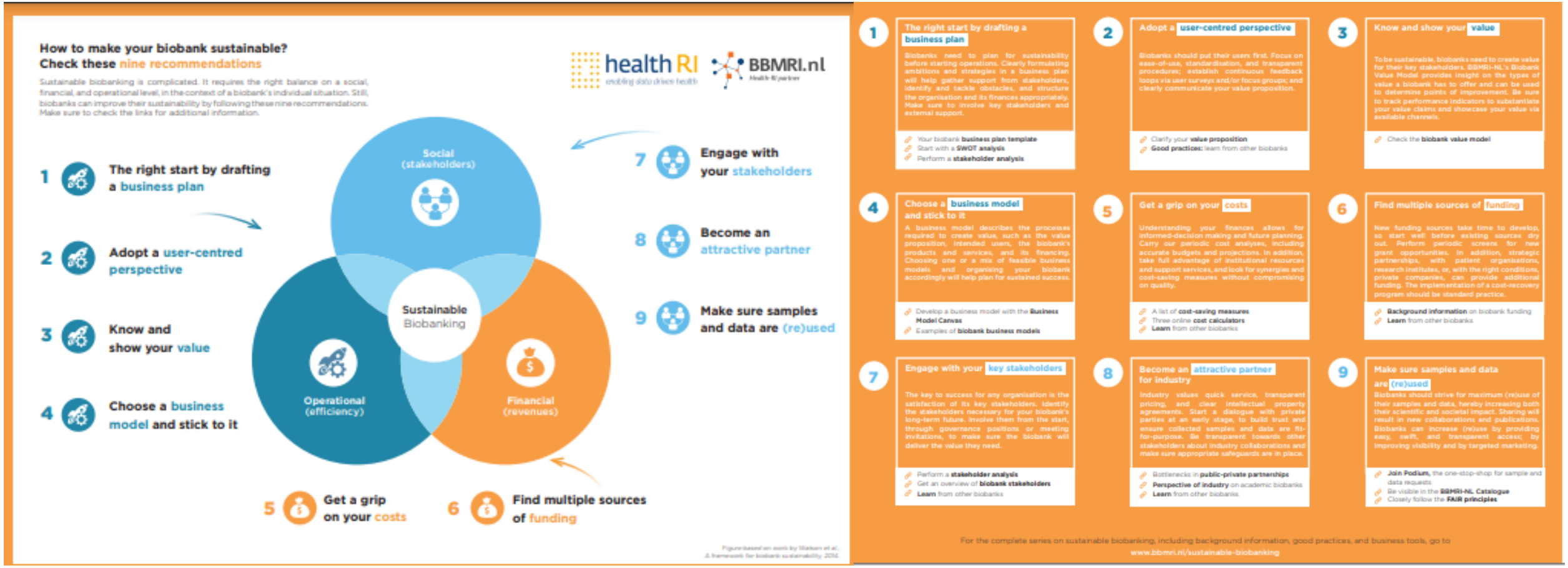
Watson PH et al , A framework for biobank sustainability. Biopreserv Biobank. 2014

Good practices for sustainable biobanking based on a case study of 22 biobanks conducted by BBMRI.nl



https://www.bbmri.nl/services/knowledge/sustainable-biobanking

Final Infographic Sustainable Biobanking - BBMRI.nl (30102019)



https://www.bbmri.nl/services/knowledge/sustainable-biobanking

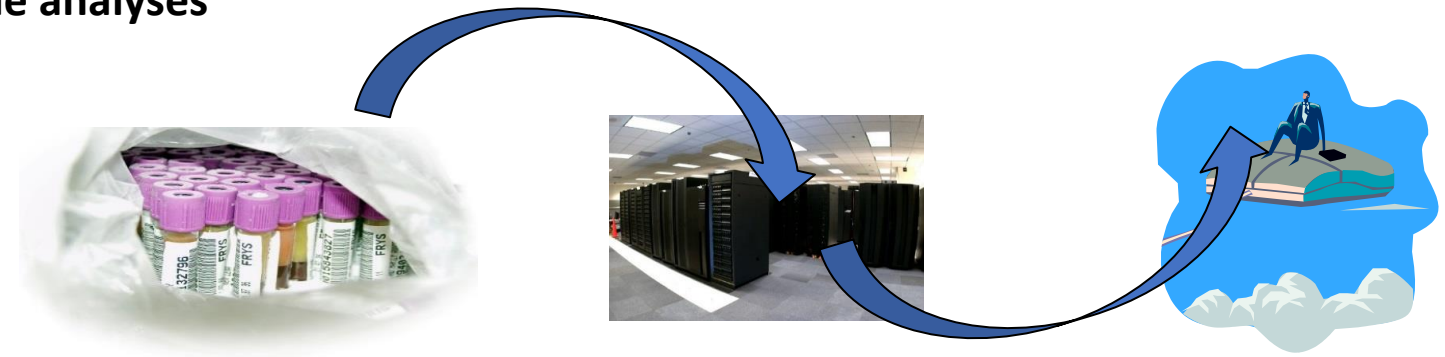
The Scientific dimension

- A critical dimension and success criteria?

  - UK Biobank
  - FinnGen
  - KI Biobank
  - deCODE
  - FinRisk
  - Copenhagen Hospital Biobank and the Blood Donor Study
  - HUNT Biobank
  - The Norwegian Mother, Father and Child Cohort Study (MoBa)
  - ……

A different business model

- **A shift from samples to data (digitalization)**
- Reduced costs for access to larger sample sizes (omics-driven analyses) as a trade off for significant return of results to the biobank
- Increased costs for data storage
- Increased focus on data security (GDPR)
- Limitted data export, researchers will be granted virtual access to biobank clouds
- Biobanks will play a significant role in precision medicine
- Access to annotated biobank samples and national registry data may be be centralized to publicly governed Health data platforms and Health analyses platforms
- **Public-Private Partnerships for large-scale analyses**
  - Science driven
  - Precompetitive
  - Transparent
  - Mutual beneficial



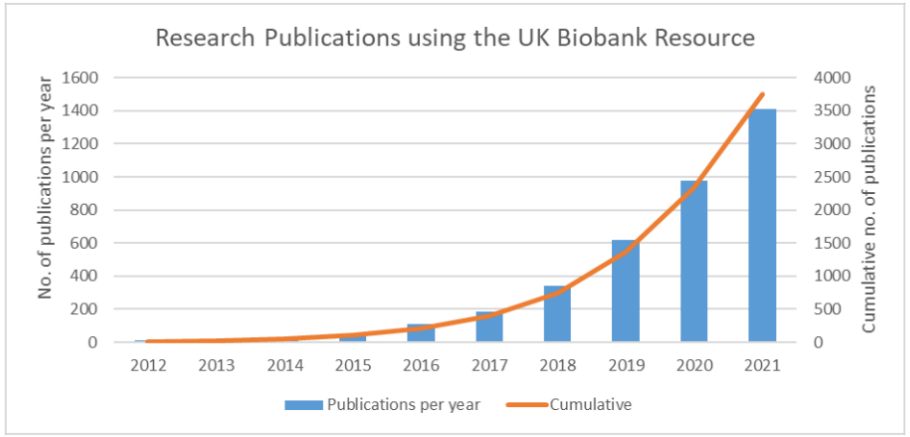
Cost recovery model

- explained simply as regaining the value of an expense,
- an important concept for accountants and founders – both parties being interested in **cost recovery solutions**.
- Is it a realistic and applicable model?

User fee

UK Biobank - biobank uk

- Cord funding by Sept 2021: **~£ 132 mill** (€ 153mill)
- Additional funding:
  - genetic analysis, biomarkers, imaging, WGS etc:
  - **~£140 mill** (€ 153mill)
- Total by sept 2021: **~272 mill (3356 mill sv. kr.)**

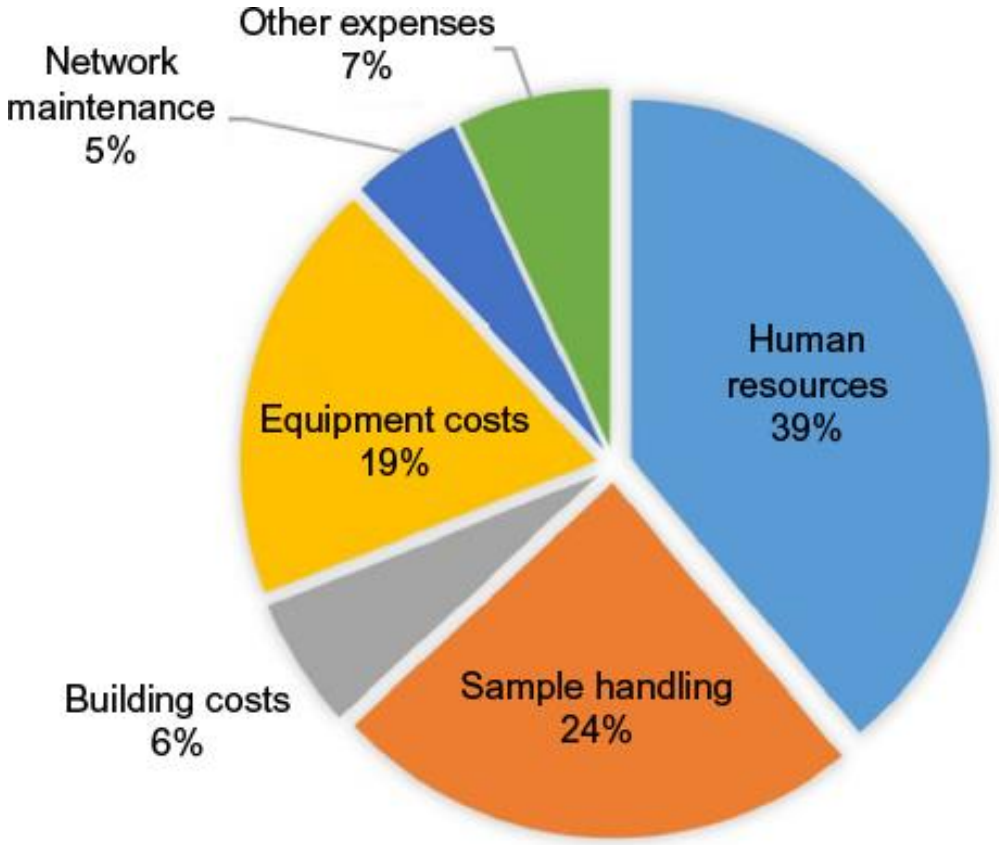


Note the figure above includes 2021 publication data through to 26 October 2021.

During the Covid-19 pandemic alone, 777 research groups accessed data for Covid-19 research. This generated 260 published papers, which were cited over 3,200 times and attracted over 42,000 mentions on social media, blogs and mainstream news. The resource has also supported 275 patent filings from academic and commercial research users for novel methods, imaging and therapeutics globally. UK Biobank's impact continues to grow exponentially, and these figures provide quantitative evidence of the research it enables, much of which would not otherwise be possible.

- Total income 2020: **£ 27,5 mill**
- Access fee, 2020: **£ 2,2 mill** (8%)

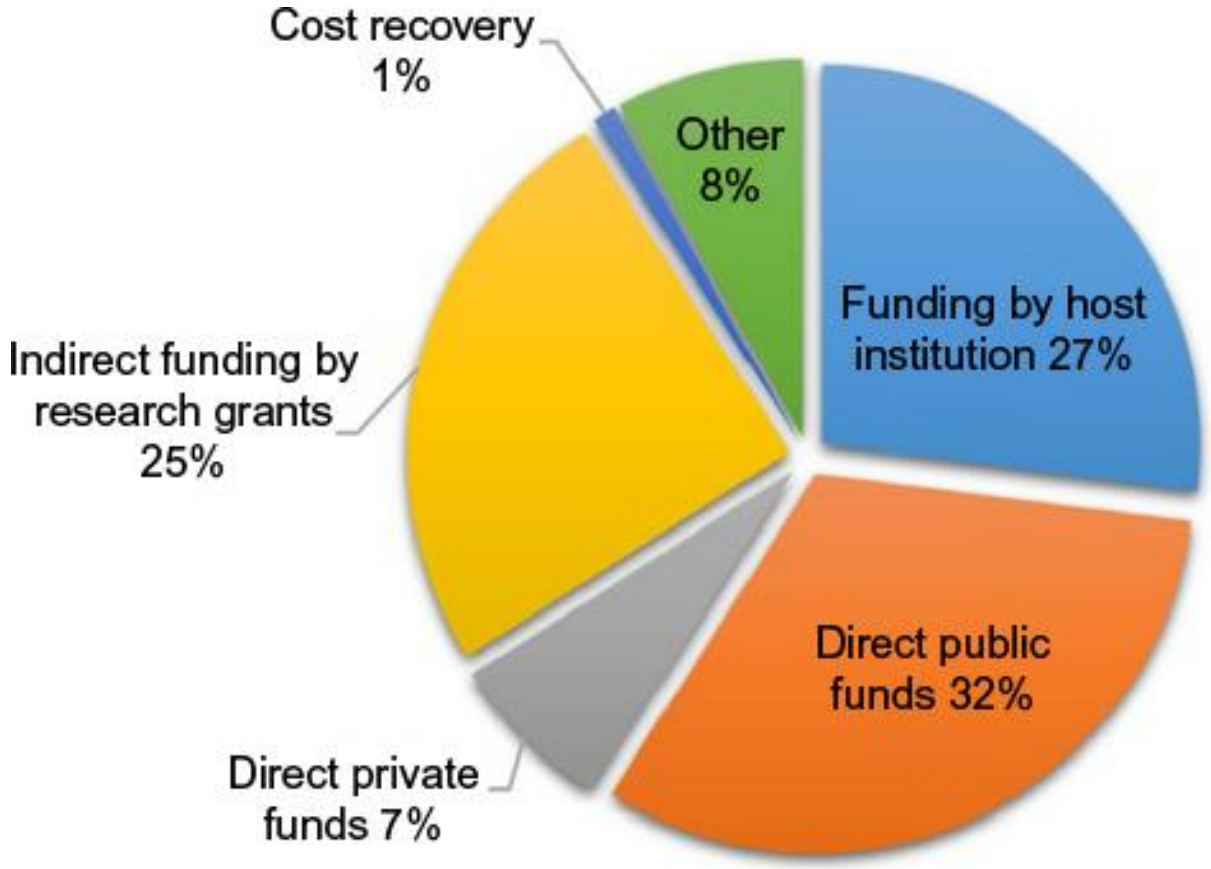
Biobank expenses



Doucet M et al Biobank sustainability: current status and future prospects; Journal of Biorepository Science for Applied Medicine 2017

Funding vs Cost Recovery

Data based on literature review and questionnaire data from 43 biobank centers in France and the Netherlands *



*** Doucet M et al Biobank sustainability: current status and future prospects; Journal of Biorepository Science for Applied Medicine 2017**

Future perspectives affecting biobank sustainability

Improving operations through quality standards is essential

- Certification by different ISO-standards/CEN norms
- New biobank standard, ISO 20387:2018, implemented by BBMRI-ERIC
- Accreditation
- Best Biobank Practices
- More advanced technologies

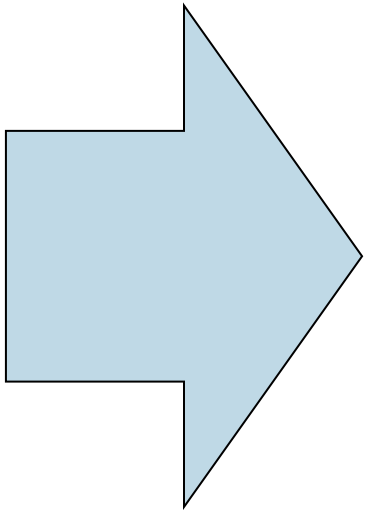
- Find the best alternative for your biobank favoring maintained and improved quality

Environmental consideration

- We need to redefine global bioethics, to be attentive to the ethical issues associated with environmental sustainability of data and digital infrastructures in global health systems
- We must foster a heightened responsibility to assess, evaluate, and disseminate the social and environmental impacts and risks posed by technology

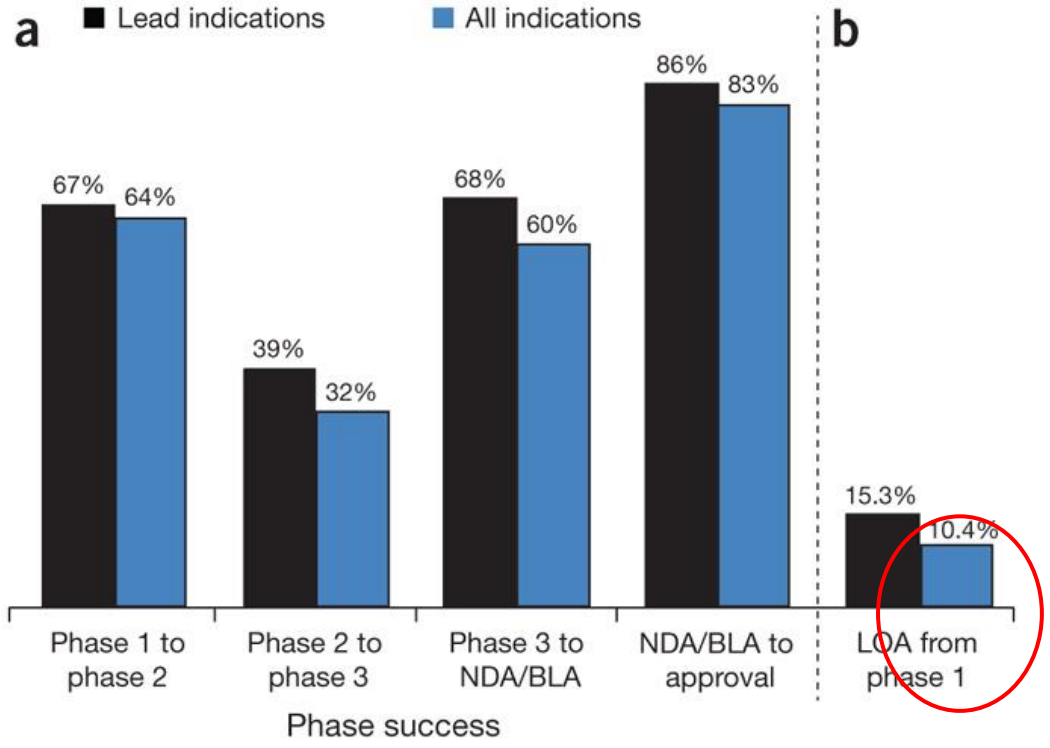
Samuel G, Lucivero F, Lucassen AM. Sustainable biobanks: a case study for a green global bioethics. Glob Bioeth. 2022 Feb 24;33(1):50-64.

Biobank driven drug discoveries



Development of therapeutics in 2018

- Only **1 of 10** drug candidates reach the market
- Most failures occur in Phase II clinical trials
  - **50%** due to lack of efficacy
  - **25%** due to toxicity
- Pre-clinical models may be poor predictors of clinical benefit
- Compounds supported by human genetics evidence **are 2,5x more likely to succeed**
- The total costs of one successful drug is ~ $2,8 billion



Cohen JC. Sequence variations in PCSK9, low LDL, and protection against coronary heart disease. NeJM 2007

Sabatine MS et al. Efficacy and safety of evolocumab (PCSK9-inhibitor) in reducing lipids and cardiovascular events. NeJM 2015

Flannick J et al. Loss-of-function mutations in SLC30A8 protect against type 2 diabetes. Nat Genet. 2014

Ethical, legal and social aspects

Openness and Dissemination

- Active use of the webpage with updates on on-going research projects, project resumé, recent and previous publications and new findings.
- Ccientific meetings on health related issues open to the public
- Annual reports addressing the donor community
- Visitors both from the scientific and public environment

Access criterias should

- Be kept simple
- Focus on uniformed and harmonized criteria across studies and nations
- Ensure the rights and integrity of the study participant
- Comply with existing laws and regulations
- Strongly restrict access attempts by official authorities for non-research purposes
- Ensure fair access, also for industrial based research

Return of results

- International recommendations:
  - **Genetic information/risk must be "actionable" to trigger a feedback.**

- The National Committee for Medical and Health Research Ethics (Norway).
  - Provided good opportunities for prevention, or even treatment, the situation most commonly is referred to as **actionable.**
  - The researchers must then **plan for feedback.**

- Do you want feedback of results if the genetic information obtained may result in potential treatment or preventive measures
  - **93 % yes**
- Are you willing to participate in follow-up studies based on genetic findings with no clear clinical impact
  - **88 % yes**

21 women had their breasts and ovaries removed – should never been operated

Publisert: 2017-02-17 13:30
Anne Grete Storvik
anne.grete.storvik@dagensmedisin.no

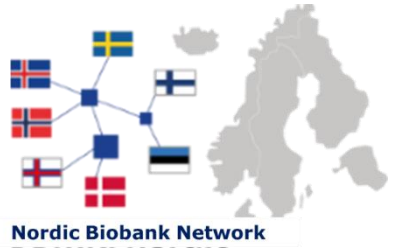
BRCA-mutations and return of results in HUNT

- Follow-up of approx. 50 000 women > 20 yrs
- Approval by REC dependent on the strategy for return of results
- Retesting and clinical follow-up of cases through Dept. of Medical Genetics

Networking

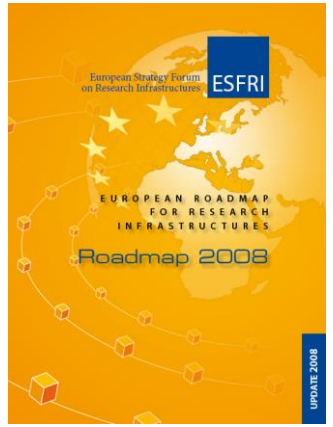
Nordic Biobank Network

- Established in February 2010 – supported by NordForsk,



ESFRI

European roadmap for research infrastructures for Biological and Medical Sciences



ERIC- European Research Infrastructure Consortium (legal entity)

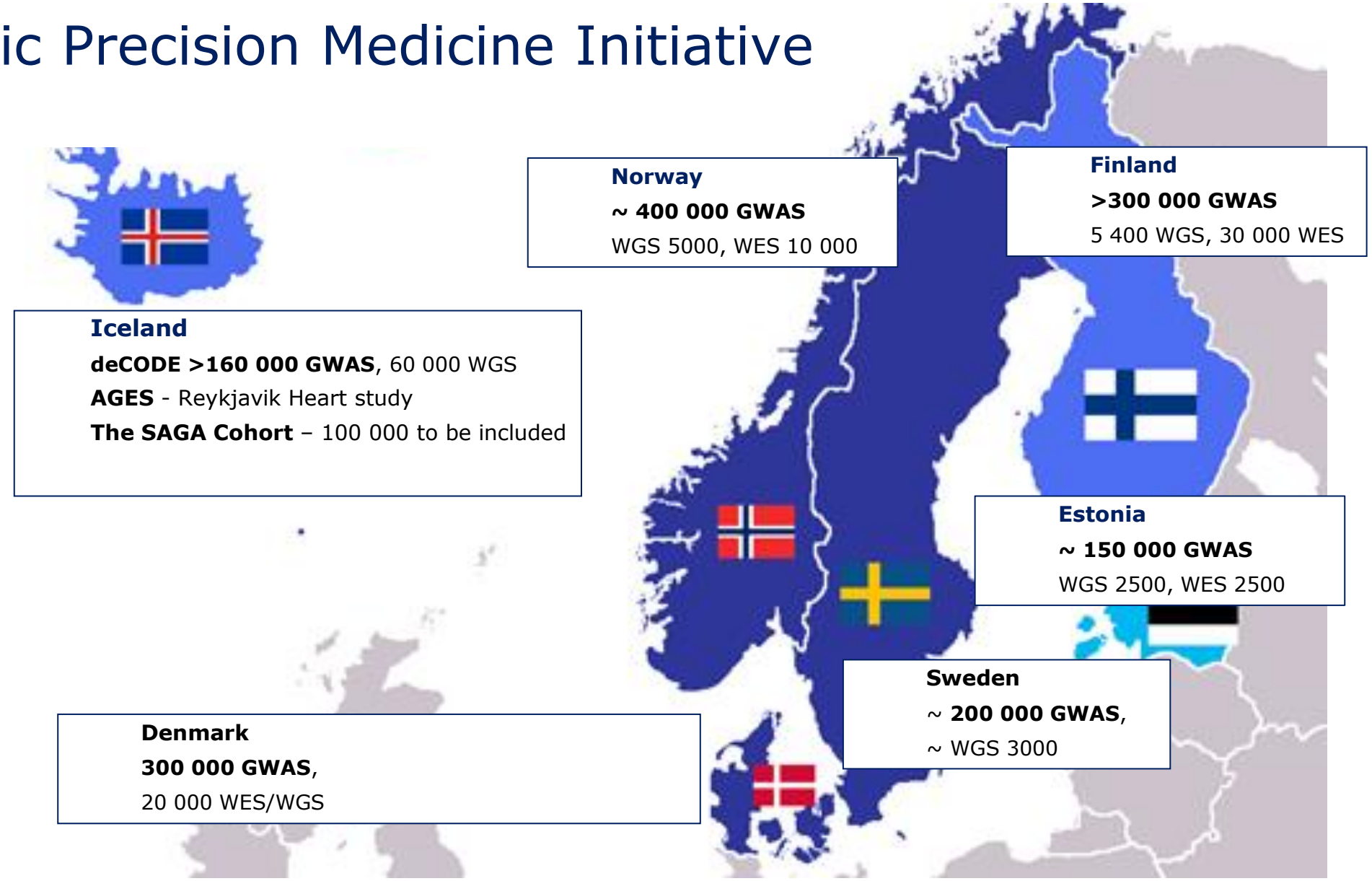
13 ERICs in total **BBMRI-ERIC**, EATRIS-ERIC, ECRIN-ERI: , CLARIN-ERIC, ELIXIR-ERIC ……

BBMRI-ERIC

- **B**iobanks and **B**io**M**olecular **R**esearch **I**nfrastructure
- Established Dec-2013
- 18 full member states + 6 observers

BBMRI-ERIC®
Biobanking and
BioMolecular resources
Research Infrastructure

Nordic Precision Medicine Initiative



Iceland

deCODE >160 000 GWAS, 60 000 WGS

AGES - Reykjavik Heart study

The SAGA Cohort – 100 000 to be included

Norway

~ 400 000 GWAS

WGS 5000, WES 10 000

Finland

>300 000 GWAS

5 400 WGS, 30 000 WES

Estonia

~ 150 000 GWAS

WGS 2500, WES 2500

Sweden

~ **200 000 GWAS**,

~ WGS 3000

Denmark

300 000 GWAS,

20 000 WES/WGS

The Nordic Society of Human Genetics and Precision Medicine,

inaugrated in June 7.-8.2018

Summary

- We need a better understanding of the many dimensions that influence sustainability
- Sustainability of biobanks cannot be determined just from the financial and operational measures
- Support for biobanks, initiating excellent scientific activity, should also be assessed in terms of a broad specter of values.
- A framework for sustainability is far more operational than a simple cost recovery model
- We must provide funders and stakeholders with examples of best practice in different areas of biobank activities, and communicate better the diversity and complexity of both biobank practices
- We need new business models as guidance for future discussions in improving biobank sustainability

Thank you for your attention