BIOBANKS

THE ONLY BANKS WHERE YOUR DEPOSITS ARE PRICELESS

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The Economics of Reproducibility in Preclinical Research

- **Irreproducible:** US$28.2B (50%)
- **Reproducible:** US$28.2B (50%)

**Estimated US Annual Preclinical Research Spend: US$56.4B**

**Categories of Preclinical Irreproducibility:**
- **Biological Reagents and Reference Materials:** 36.1% of total (US$20.2B)
- **Study Design:** 27.6% of total (US$15.9B)
- **Data Analysis and Reporting:** 25.5% of total (US$14.4B)
- **Laboratory Protocols:** 10.8% of total (US$6.1B)
Bring on the biomarkers

George Poste

A drop in the ocean
Few of the numerous biomarkers so far discovered have made it to the clinic.

Estimated number of papers documenting thousands of claimed biomarkers
150,000

Estimated number of biomarkers routinely used in the clinic
100
“The lack of standardization in the collection and storage of medical specimens can hinder subsequent research”

Source: www.cristanwilliams.com
FUNDING AGENCIES should support only research programs that:

• have access to a sufficient number of stringently characterized specimens
• impose rigorous quality control in specimen acquisition, handling and storage
• and possess the full spectrum of cross-disciplinary capabilities needed to translate laboratory findings to the clinic.

encourage academic laboratories to become part of larger research networks that include clinical and industrial partners.
For **biomarker research** we need **HIGH quality** samples from standardized and harmonized **BIOBANKS**
What is a biobank?

According to Swedish Act Biobanks in Medical Care (SFS: 2002:297):
"Samples (e.g. blood, cells, or other tissue) collected within healthcare, stored for a longer period (2 months) after analysis, and whose origins are traceable to a specific individual"

Samples collected for research purposes within healthcare are automatically covered by the Swedish Biobank Act
Different sample collections (SC)

• **Care and treatment**
  - e.g. clinical microbiology, clinical pathology

• **Research**
  - cancer, heart and lung diseases, diabetes, population based studies…
Different samples in a biobank
What do we store samples for?

- Care and treatment
- Inherited diseases
- Education
- Quality control and improvement of methods
- Research
The biobank sample-
From needle to freezer

- Informed consent from donors for storage and use of samples
- Research approved by Ethical Review Board
- Contact and agree with the Biobank Department and Laboratory of Clinical Chemistry for drawing and processing samples
- Transport to the Biobank and Storage
The number of samples are increasing...

Samples in storage

N. Of samples

Research samples

N. Of samples

2012; 1 825 000

2013; 3 640 000

2014; 4 540 000

2015; 7 050 000

2016; 1 560 000

2017; 1 385 000

2012; 45 000

2008-2011;...
Withdrawals-2016 and 2017

Withdrawals from samples collections collected for research

- Withdrawals
- Withdrawals-DNA
- Extractions

Withdrawals from sample collections collected for care and treatment

- Microbiology
- Pathology

[Bar charts showing withdrawal numbers for research and care/treatment in 2016 and 2017]
How to access existing sample collections (SC) for research?

Form needed: L1 - Access to sample collection and personal data for research

Samples collected and stored within Health and Medical care (90% of all samples in Sweden)

Informed consent from donor and specific for the research project

Collaboration with principal researcher

Research approved by an Ethical Review Board

Enough sample left to ensure legitimate care and treatment for patients
Scenarios to access to Sample Collections

- Legal responsibility and the access to SC is transferred from HC's principal to Research's Principal.
- Secondary SC cannot be released to a 3rd party (only for analysis).
- HC's principal is responsible for documentation regarding release of sample of data.

- Samples must be coded/pseudo-anonymized.
- Donor must give consent.
- Samples must be returned to the biobank or be destroyed when no longer needed.

L1a o L1b: appendix-information about existing clinical samples.
L2a- Agreement on the transfer of human biological materials (MTA).
L2b Agreement-Destruction or return of samples after analysis.
Biobanks in Sweden

- In Sweden, more than 150 million samples are handled in 450 biobanks
- Annual growth of about 3-4 million samples
- 90% of the samples are handled by the 200 healthcare biobanks
- About 55 biobanks at universities, colleges, some authorities
- About 200 biobanks with private principal, laboratory (4%), private clinics, companies, CRO (about 96%)
Biobank Organization in Region Skåne

Supervising agency - The Health and Social Care Inspectorate (IVO)

Healthcare Principal (Region Skåne)

Region Skåne Biobank
Biobank custodian, Biobank coordinator

Biobank department
Biobank department custodian

Sample collection
Responsible researcher

Sample collection
Responsible researcher

Sample collection
Responsible researcher

Sample collection
Responsible researcher

Southern Healthcare Region

Regional Biobank Center (RBC)
RBC manager

Region Skåne
Region Kronoberg
Region Halland
County council Blekinge

Courtesy of Marie Sverud
What do they do?

**RBC**
- Healthcare Regional Services and Expertise Centre
- Handles regulatory issues regarding collection, storage and use of biobank samples
- Support to and advice healthcare providers, researchers, pharmaceutical companies and the general public regarding biobank-related issues.
- Provides information material, education
- Supervision of biobanks in the health care region

**SBR (Swedish biobanks register) is the necessary work tool**

**BD47**
- One of 37 biobank divisions within Region Skåne's biobank
- Physical storage of biobanks samples; care and treatment as well as research
- Registration, storage and release of samples
- Support, counselling and planning for collection of samples
- Extraction of DNA from different types of material
- Participates in national groups regarding biobank issues
- **LIMS is necessary and is an ongoing process**
For the benefit of the patient, the care and the research

- Knowledge of causes of diseases: Why some individuals get sick when others do not?
- Precision diagnostic and personalized medicine
- Development of new drugs
BIS: Biobank Sverige (Biobank Sweden)
Strong collaboration of different Stakeholders for a strong Biobank Infrastructure

- Technology
- Method of Analysis
- Bioinformatics
- Study legacy

- Patients
- Samples
- Data
- Clinical Records and Resources

- Product development and ideas
- Technology
- Clinical samples

University
Health Care/Regions
Industry
AU1: Regulatory biobank service

Biobank Sweden Committee
Strategic Plan

National biobank-strategist
Prioritized investigations together with the working group

AU2: Operative biobank service

Biobank Sweden Committee
Strategic Plan

National IT-strategist
Strategic development of common IT issues together with the working group

Heads Regional Biobank Centrum (RBC)

21 Biobank Coordinator (BBS)
The entrance to the county council / regions in all biobank issues

Heads for biobank facilities

7 Biobank Service Coordinators
Research support and national coordination

Temporary working groups
National coordination, IT/SBR2introduction of SIB, education website, templates, quality etc.
19 countries - 16 members/3 observants
International organization IARC/WHO

Services:
• **ELSI:** Ethical, legal and societal guidance and platform
• **IT:** Directory (harmonized) for Biobank collections and population cohorts. Directory for Biomolecular Resources and Technologies
• **Quality Management:** Harmonized standards for Sample Quality

Built on existing sample collections, resources, technologies and expertise
Placed in the European scientific, ethical, legal and societal frameworks.
Why Networks of Biobanks?

- Huge **number of samples** required to achieve statistical significance in biomarker discoveries.
- Even more relevant in **Rare Diseases**
- Biopharmaceutical companies operate in a **global world**: Diversity of Ethnicity has to be investigated.

**Cooperation even with differences in ethical and legal structures.**
Why do we need then biobanks and bioank networks?

- Biobanks for **Quality**
- Biobank Networks for **Quantity**

**High Quality Research** that will revert to the patient in **Precision Diagnostics** and **Personalized Medicine**

**Better Health and Quality of Life**
CONTACT ME FOR ANY BIOBANK-RELATED ISSUE AND/OR IF YOU FANCY TO VISIT THE BIOBANK

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