



Karolinska
Institutet

KI Biobank – a Research Integrated Biobank at Karolinska Institutet

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<https://ki.se/forskning/ki-biobank>

2024 – Karolinska Institutet Biobank celebrates 20 years!



Overview

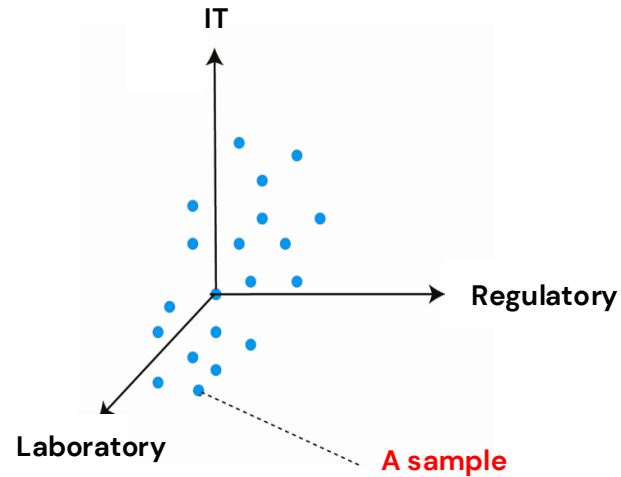
- Biobanking – how difficult can it be?
- What is biobanking?
- Biobanking at KI Biobank
 - Storage of human biological samples?
 - Research core facility at KI
- New Swedish Biobank Law
- Future

How difficult can it be?

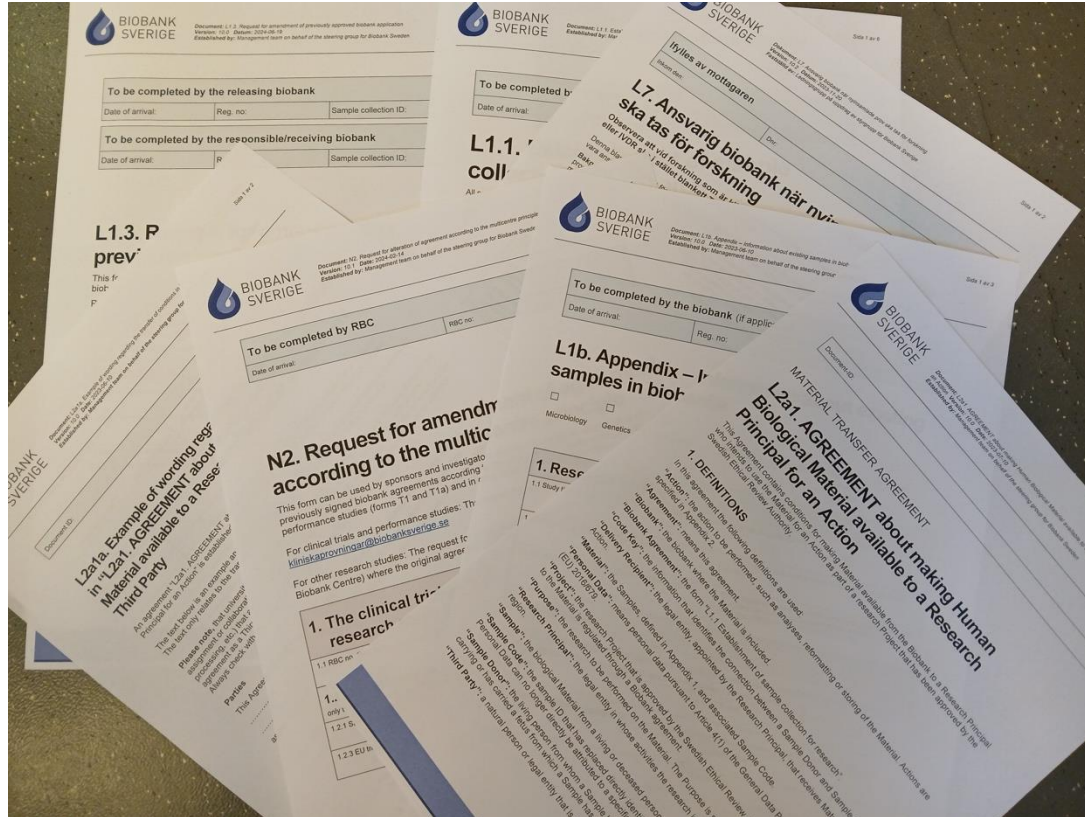
Bio-Bank vs Freezer hotel

What is biobanking?

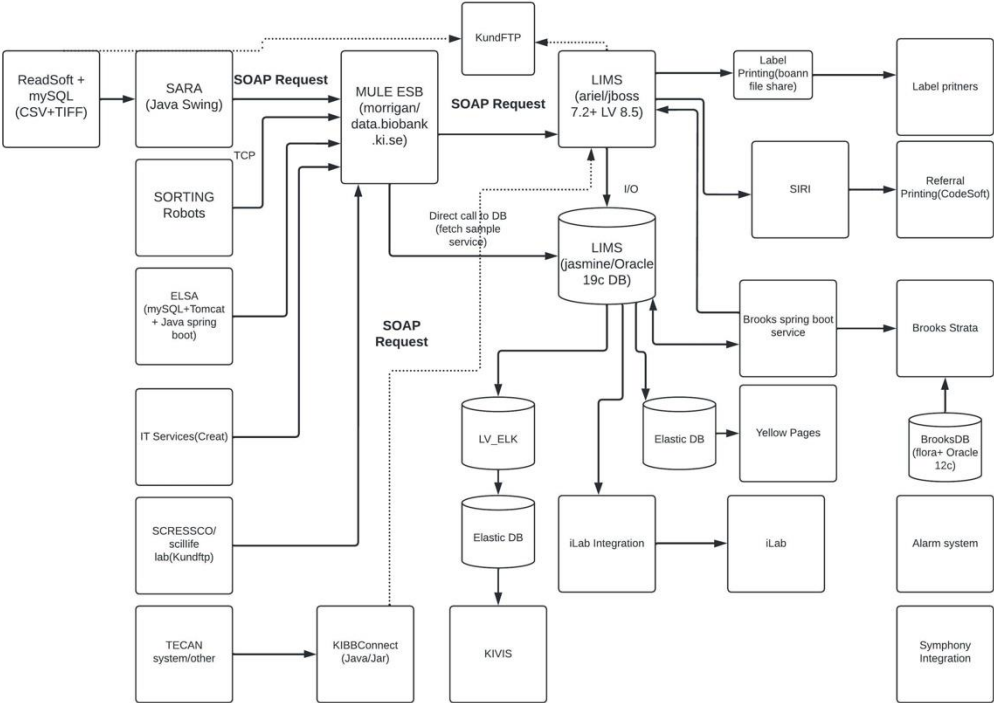
- Three important dimensions:
 - Regulatory
 - Laboratory
 - Data / IT
- In order to
 - Fulfil ethical and legal claims
 - Handle and prepare human samples
 - Guarantee traceability of samples
 - Secure storage of samples
 - Send samples for analysis



Biobanking – how difficult can it be?



Biobanking – how difficult can it be?



Biobanking – how difficult can it be?

Transport to
KI Biobank



Registration



Centrifuging
Decapping
Volume detection



Sorting



Aliquoting



DNA extraction

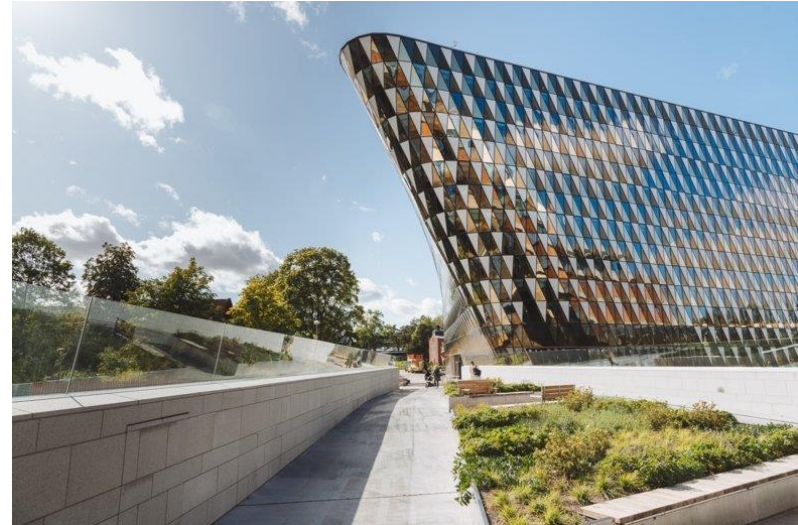


Biobanking at KI Biobank

Storage of biological samples only?

Karolinska Institutet Biobank

- Core facility at Karolinska Institutet
 - The biggest and one of the oldest core facilities
- **Research Integrated Biobank**
 - Aim: Research
 - Close collaboration with researchers
 - A comprehensive tailor-made solution for research needs.
 - This includes deeply integrated, and harmonized solutions regarding regulatory aspects, samples, and sample data



A short history of KI Biobank...

Progressive growth

- Capacity
- Competence
- Quality
- Study diversity
- Impact

• 2004 kick-off!

- Lab, LIMS, processes
- Ethics and legal compliance addressed
- 1st studies, including Swedish Twins

• 2006

- First withdrawals
- Quality System
- IT support to external collections

• 2010

- Technical re-development
- Big cohorts start

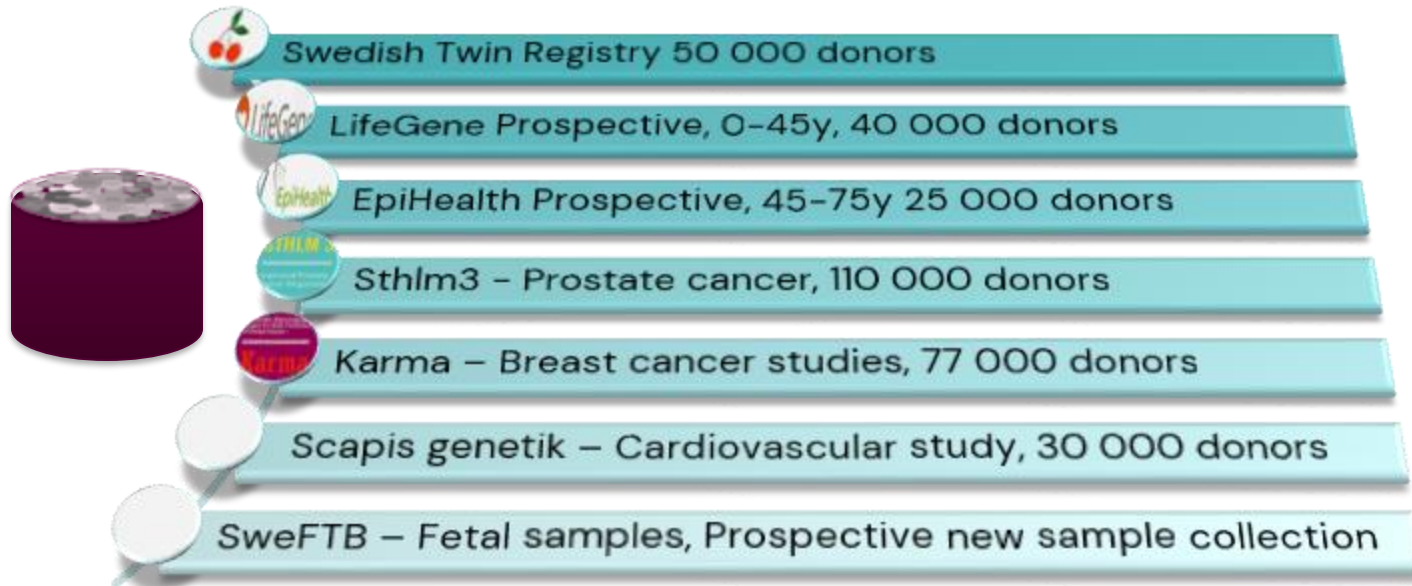
• 2024

- 750K donors
- 8.5M samples
- 200 papers/year

Some statistics


- Number of sample types: 80
- Number of tube types: 70
- Number of samples: 8.5 million
- Number of scientific publications: 150–200/year
- Sample withdrawals:
 - 2007–2020 mean: 60 000 samples/year
 - 2014–2023 mean: 70 000 samples/year
- IT
 - 48 servers
 - 25 applications
 - 2 integrations buses
 - 79 Robot scripts

KI Biobank big cohorts



KI Biobank – research integrated, highly automated core facility at KI

- Planning biobank studies
- Ethics & regulatory advice
- Referrals & registration – design and integration
- Sample preparations
- Long term storage of samples
- DNA extraction
- cell free DNA extraction from STRECK tubes
- Preparation of viable cells
- Blood sampling
- Sample and data withdrawals
- Lab info management (LIMS)



KI Biobank är en core facilitet som erbjuder service för provinsamling, provförvaring och provdistribution.

Kontaktperson: _____

Gubbar av ettåringar dömda av 25000000
Bilaga till bilaga 6 Biobank "tag" nr 001, Karlenska
teknik

E

Fyll i av provtagaren. Avläs maskinellt. Skriv tydligt.

A A A A N M D D N N N N

Deltagarens personnummer

GEM-ID (nio siffror)

A A A A M M D D T T M M

Provtagingsdatum

Provtagingstid (24-timmarsklocka)

Samtycke

Kommentar

Provtagares signatur

E m

Ref	99999998
blood1	99999998
blood2	99999997
serum	99999996
serum	99999995
serum	99999995
serum	99999994
RID	99999999

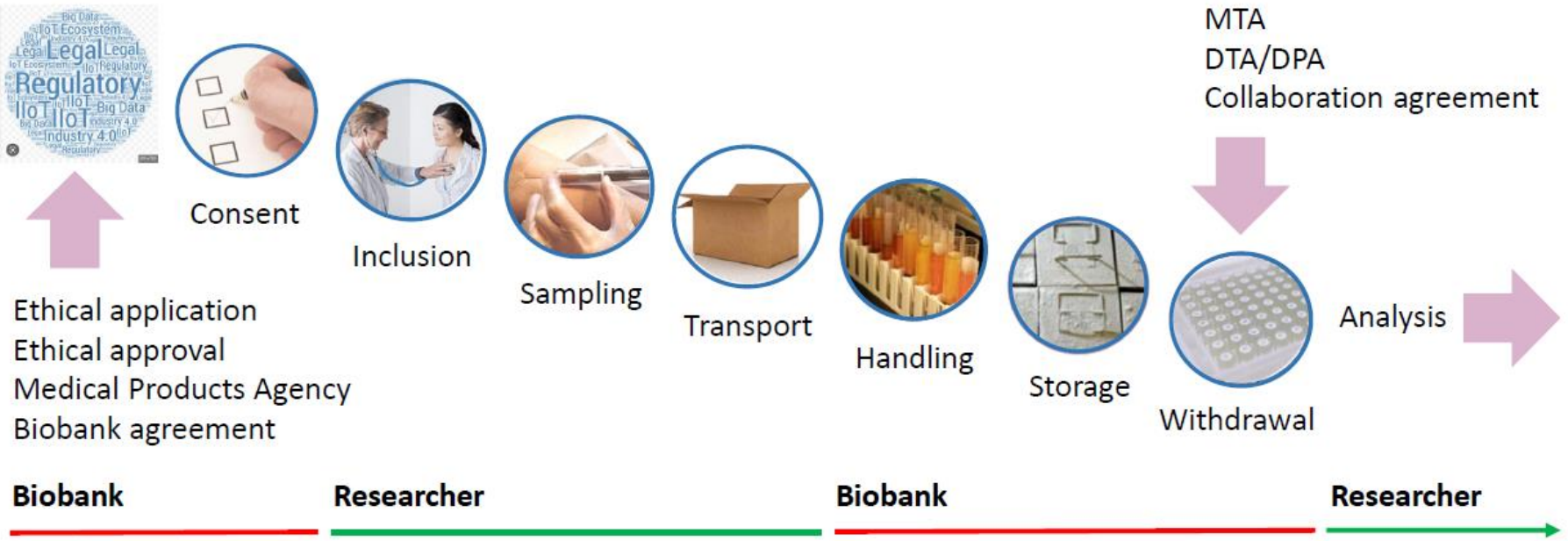
Tag rätt etikett till rätt rör/prov

EDTA	EDTA	SP1	Serum	PAX
4 ml	4 ml	8,5 ml	Plus 8 ml	2,5 ml

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Biobanking process overview



Example – ProBio prostate cancer trial

- Cancer study, part of personalized medicine initiative at KI
- Want to study both germline DNA and free circulating tumor DNA
- Regulatory aspects
 - Ethical approval
 - Informed consent
 - Biobank agreement
- Referral design and referral integration
- Pre-analytical handling
- Withdrawal of samples

Referral/Data



KI Biobank
Remiss för provtagning

Instruktion till provtagaren:

1. Kontrollera identiteten.
2. Fyll i remissen med deltagarens personnummer samt annan information och märk upp rören med medföljande streckkodsetiketter. (Använd tomma etiketter och märk med personnummer ifall de andra etiketterna går sönder.)
3. Provtagning som vid vanlig venpunktion. Vänd rören försiktigt 8-10 gånger.

Provtagning: EDTA (1 st 4 mL-plaströr, lila propp).
STRECK Cell-Free DNA (3 st 10 ml STRECK Cell-Free DNA-rör, spräcklig propp).
Provtagning som vid vanlig venpunktion. Vänd rören försiktigt 8-10 gånger efter provtagning.

Deltagarens uppgifter. Avläses maskinellt. Skriv tydligt.

Guldmetall av tillverkningsmyndigheten
dnr:2018/1451-51,2012-0383
Mottagande biobank: KI Biobank (reg.nr.222),
Karolinska Institutet.

A A A A M M D D N N N N
 Deltagarens personnummer: _____

Studie_ID (8 tecken): _____ Länsbeteckning(1-2 bokstäver): _____

A A A A M M D D T T M M
 Provtagningsdatum: _____ Provtagningstid: _____

Kommentar: _____ Provtagares signatur: _____

Ref

blood 99999998
 cellFreeDNA1 99999997
 cellFreeDNA2 99999996
 cellFreeDNA3 99999995
 RemissID
 99999999

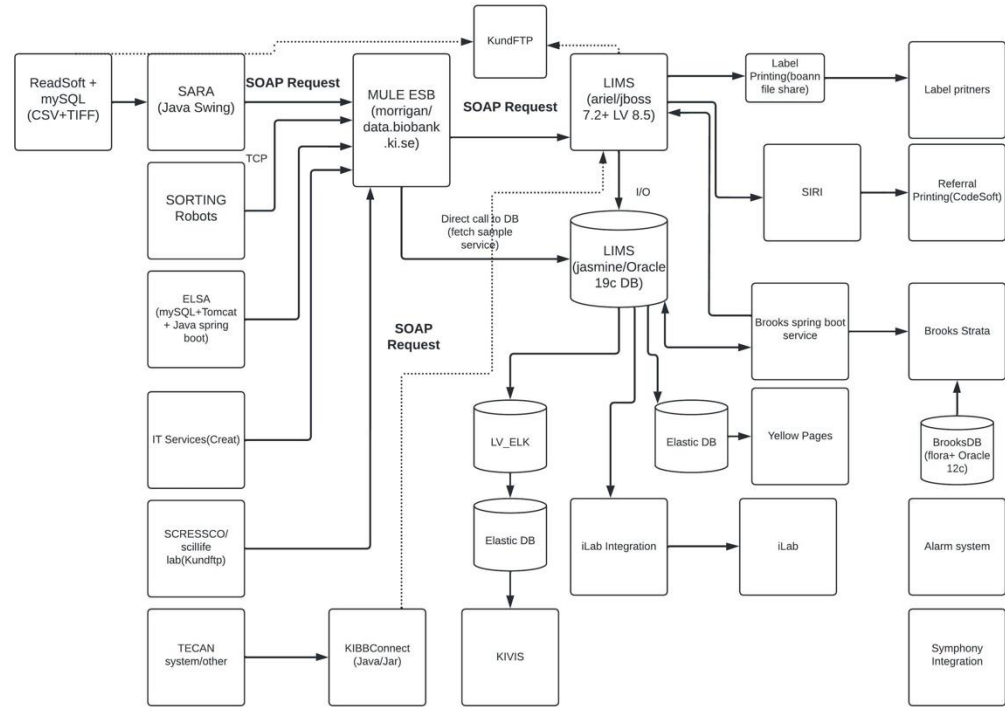
Tag rätt etikett till rätt rör.



- ID
- Time point
- Sample type(s)
- Tube type(s)
- Site
- Pseudonymised data

Referral data and automation integration

- Depends on a very advanced IT infrastructure
- Guarantees traceability and data integrity
- Connects whole process:
 - from sample collection to processed aliquots in freezers
 - And getting samples out!
- Looks complicated
 - But is a critical success factor

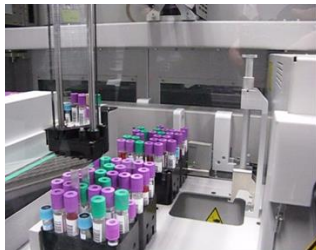


Automated sample handling

Transport to
KI Biobank



Registration



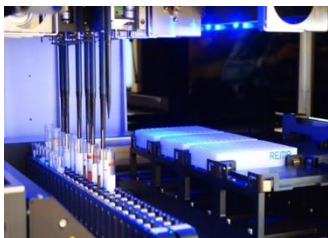
Centrifuging
Decapping
Volume detection



Sorting



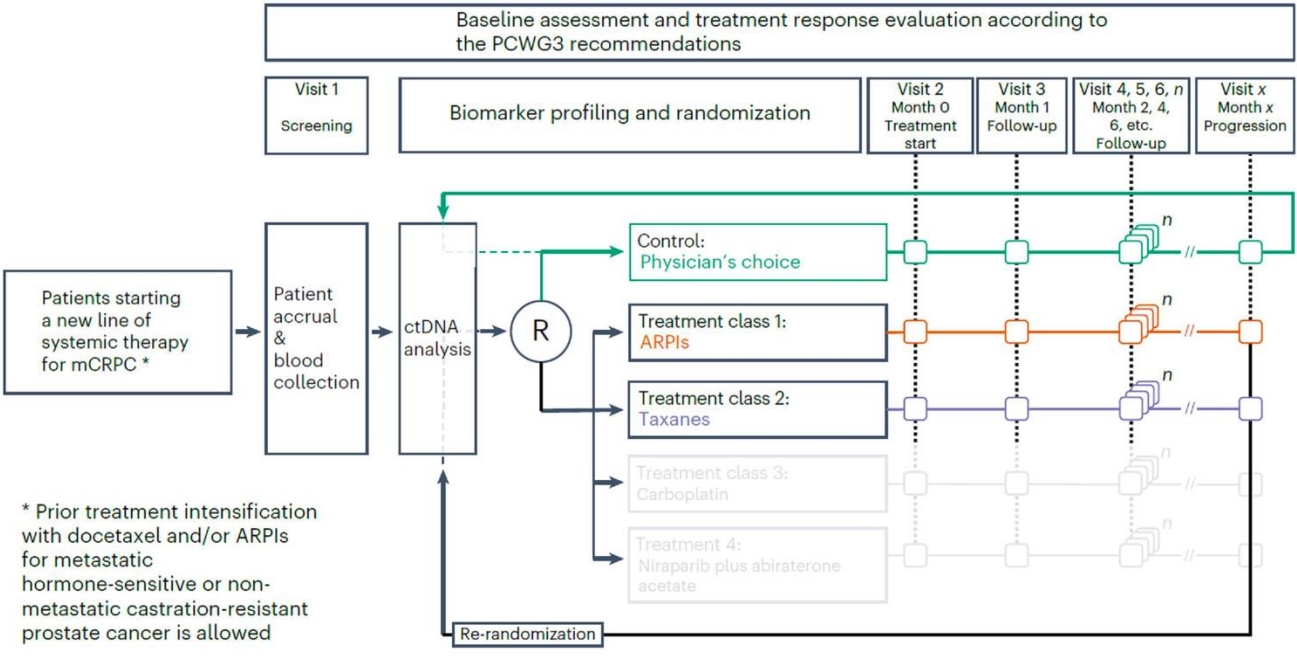
Aliquoting



DNA extraction



Personalized medicine at KI



DeLaere et al 2024, Nature Medicine; "Androgen receptor pathway inhibitors and taxanes in metastatic prostate cancer: an outcome-adaptive randomized platform trial"

Storage

- Static storage
 - Room temperature filter paper
 - +4°C saliva
 - -20°C DNA
 - -80°C plasma, serum
 - -196°C liquid nitrogen viable cells
- Automated storage: Autofreezer (-80°C)



Fast sample withdrawals from KI Biobank

The screenshot displays the KIBB Manager web interface. At the top right, there are links for [Kivis2](#), [Invoicing](#), and [Logout](#). The main header includes the **Karolinska Institutet** logo and the text **KIBB Manager**. Below the header, there is a search bar labeled "Search without input file" with a search icon. A "Search criteria" section contains several input fields: "Study Name *", "Barcode", "Sample type", "Received date" (with a calendar icon), "Status", "Tube type", "Concentration: min value and/or max value", "Volume: min value and/or max value", and "Deviation". At the bottom of this section are "Reset" and "Submit" buttons. The right side of the interface features a large background image of a laboratory setting. A person wearing blue gloves is holding a clear multi-well plate and a pipette. A purple text box is overlaid on the image with the text "KIVIS-2.0 Tool for Data Withdrawal".

Sample withdrawals



>>

Search Participants Min Max [Reset filter](#) [Filter](#) [Export](#)

Filter criteria Aliquots per participant

Study Name	Barcode	Sample type	Received date	Parent Barcode	Mother Barcode	Storage Location	Donor	CDK	Rid	Customer Rid	Status	Tube type	Concentration	Volume	DNA Extraction Date	Collection Date	Cell Count	Sample Site	Deviation	Deviation Comment	Deviation Reason	Sample Notes
LifeGene		DNA	2011-04-27 10:10:10			/HD_39002488/I46					Received REMP300		72.8	123					No			
LifeGene		DNA	2011-04-27 10:09:08			/HD_39002135/G3:					Received REMP300		77.9	129					No			
LifeGene		DNA	2011-04-27 10:10:56			/HD_39001890/L1:					Received REMP300		85.7	150					No			
LifeGene		DNA	2011-04-27 10:10:45			/HD_39001872/K3:					Received REMP300		86.2	129					No			
LifeGene		DNA	2011-04-27 10:09:15			/HD_39001980/N4:					Received REMP300		113.4	79					No			
LifeGene		DNA	2011-04-27 10:09:04			/HD_39000492/N3:					Received REMP300		73.4	110					No			
LifeGene		DNA	2011-04-27 10:11:03			/HD_39000442/E5:					Received REMP300		90.4	129					No			
LifeGene		DNA	2011-04-27 10:10:23			/HD_39002361/D1					Received REMP300		76.2	108					No			
LifeGene		DNA	2011-04-27 10:10:28			/HD_39001492/A5:					Received REMP300		92	79					No			
LifeGene		DNA	2011-04-27 10:01:08			/HD_39001890/K6:					Received REMP300		93	129					No			
LifeGene		DNA	2011-04-28 09:45:36			/HD_39001284/J5:					Received REMP300		136.2	73					No			

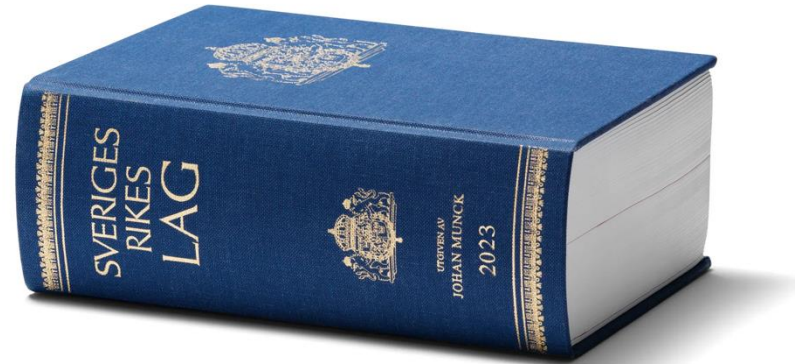
New Swedish Biobank Act

Changes in the legal landscape

Decision

Swedish parliament approves on January 25th 2023 the Swedish Government proposal that the biobank legislation from 2003 is replaced by a new legislation.

The new Biobank Act (2023:38) is valid from July 2023.



Sample handling according to the new Biobank Act

- Samples shall be **coded** and **stored** in a safe way
- Sample shall be **traceable**
- Samples must not be released for **profit purposes**
- The biobank custodian (head of KI Biobank) decides about **access to the samples**

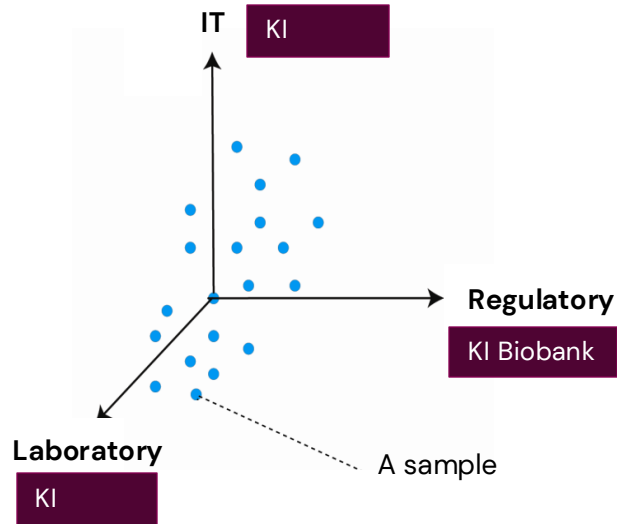


Approved purposes according to the new Biobank Act

- Treatment and diagnosis
- Research, Clinical trials
- Quality assurance
- Development
- Education



The three dimensions of biobanking kept together



Research projects originate from KI

If samples are collected for research, the research principal can be the host biobank directly (even if samples are collected in healthcare).

Samples taken in healthcare, KI or elsewhere

Sample collection legally at KI biobank

Sample collection can be legally handed over more than once

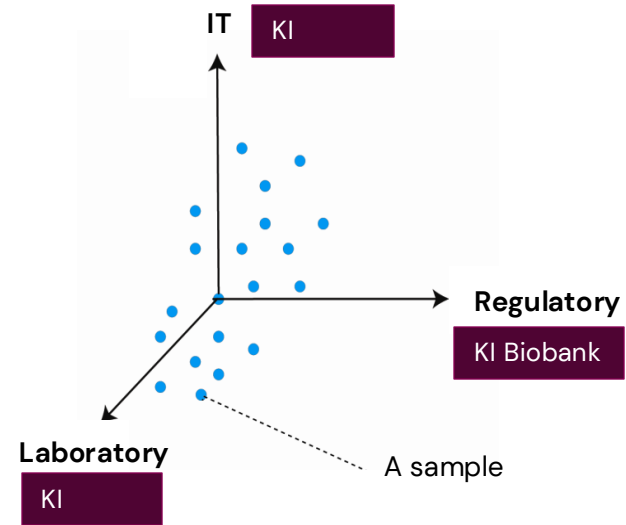
Samples can be long term stored abroad

The process involves only KI biobank and the responsible PI

How about data? KI PUA

The new Biobank Act makes it easier for KI researchers!

- The three dimensions can be kept together
 - Preanalytical handling/storage
 - IT/data
 - Regulatory aspects
- Centralized storage with multicenter studies
 - Easier regulatory process



Neo incident

Neo incident, Christmas 2023

- Freezer hotel at KI campus South
- Not part of KI Biobank
- 16 of 19 cryo tanks increased in temperature
- Due to a closed valve to the main liquid nitrogen tank (service)
- Large amount of research samples was lost
- Both internal and external investigations have been performed, and show at
 - Need for clarity regarding responsibility and roles
 - The importance of a clear structure
 - Good quality work

Future

Who are we and why do we exist?

- Why do we exist?

We are a research integrated biobank that acts as a core facility at KI. The purpose of the biobank is to support medical research.

- What do we do?

We help researchers with all aspects of biobanking of human samples: start-up, storage, and usage. This includes preanalytical handling, data, legal aspects, deep traecability, long-term storage, and effective withdrawal of human samples.

- How do we succeed?

We provide a seamless experience to the researchers at KI and beyond, with high focus on solving research demands.

Seamless integration in research at KI

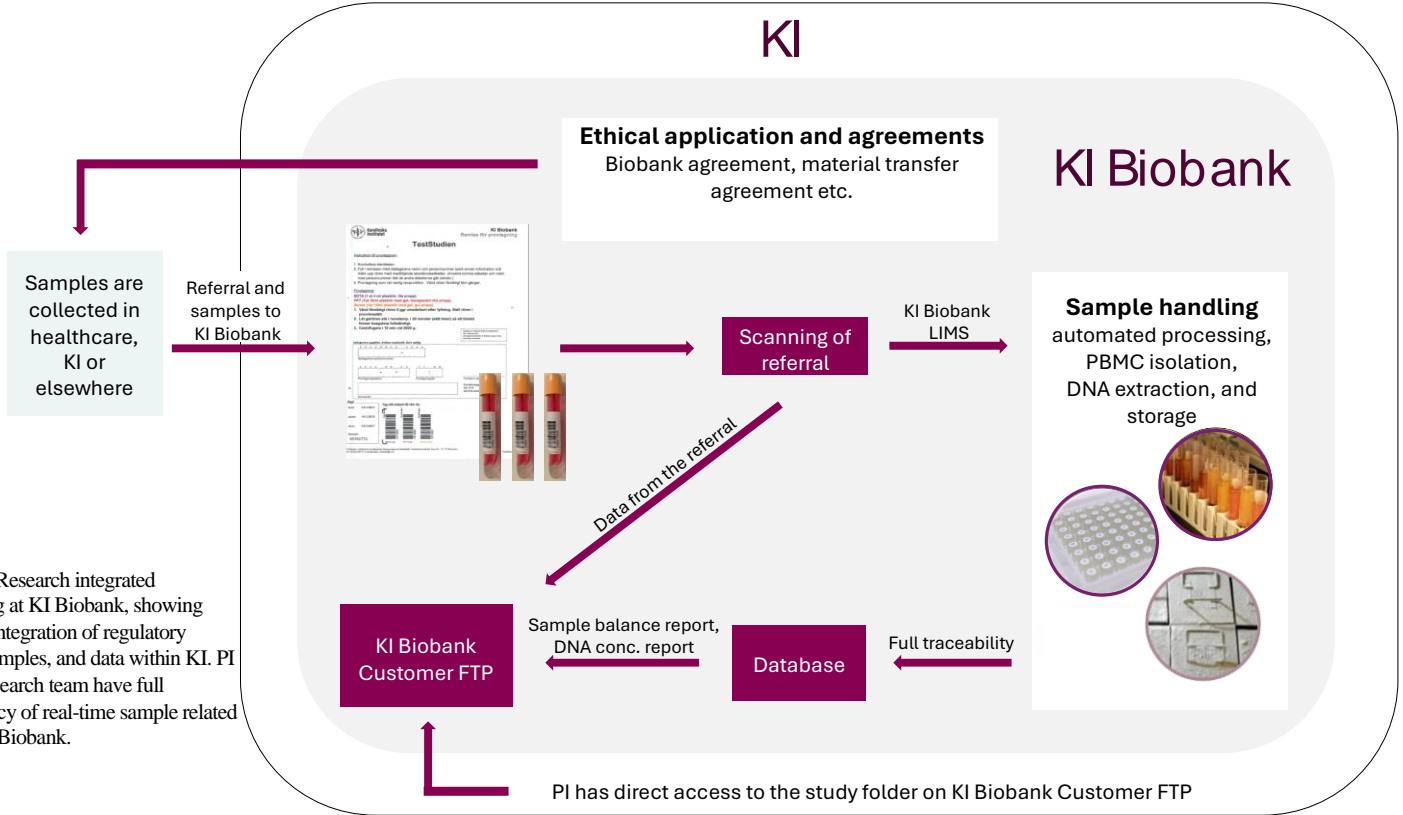


Figure 1. Research integrated biobanking at KI Biobank, showing seamless integration of regulatory aspects, samples, and data within KI. PI and the research team have full transparency of real-time sample related data at KI Biobank.

Acknowledgments

- Mark Divers
- Gunnel Tybring
- All current and former KI Biobank colleagues
- All our researchers
- Department of Medical Epidemiology and Biostatistics
- Current and former KI leadership
- Biobank Sweden



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THANK YOU!