BBMRI-ERIC®

MAKING NEW TREATMENTS POSSIBLE

WHAT IS BIOBANKING AND WHY IT MATTERS TO CANCER PATIENTS?

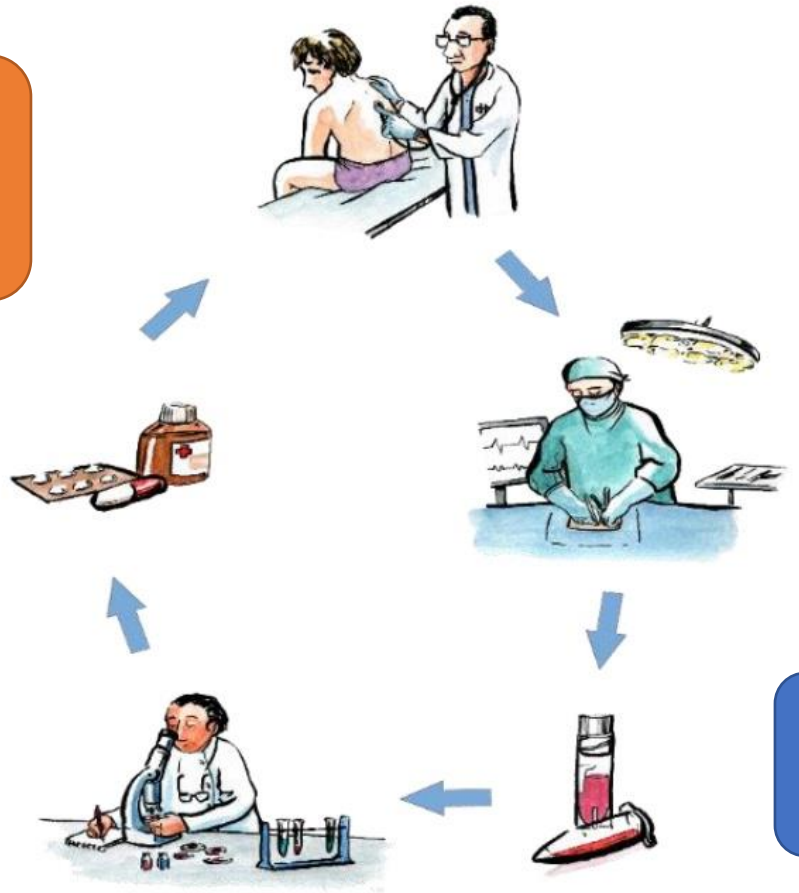
FRANCESCO FLORINDI
STRATEGY & PARTNERSHIP MANAGER

Annual Special Issue
TIME
10 IDEAS CHANGING THE WORLD RIGHT NOW
The global economy is being remade before our eyes. Here's what's on the horizon
WHY YOUR JOB IS YOUR MOST VALUABLE ASSET
REPURPOSING THE SUBURBS
SURVIVAL-STORE SHOPPING
BIOBANKS: SAVING YOUR PARTS
NEED LAND? RENT A COUNTRY
THE NEW CALVINISM
ECOLOGICAL INTELLIGENCE
AMORTALITY: FOREVER YOUNG
AFRICA: OPEN FOR BUSINESS
REINVENTING THE HIGHWAY

BBMRI-ERIC®

FROM COLLECTION TO SHARING

SOME OF BIOBANKING CRITICAL ISSUES



Drug/MD-IVD development
Personalised medicine

New treatments development

Informed consent

Sample & data collection

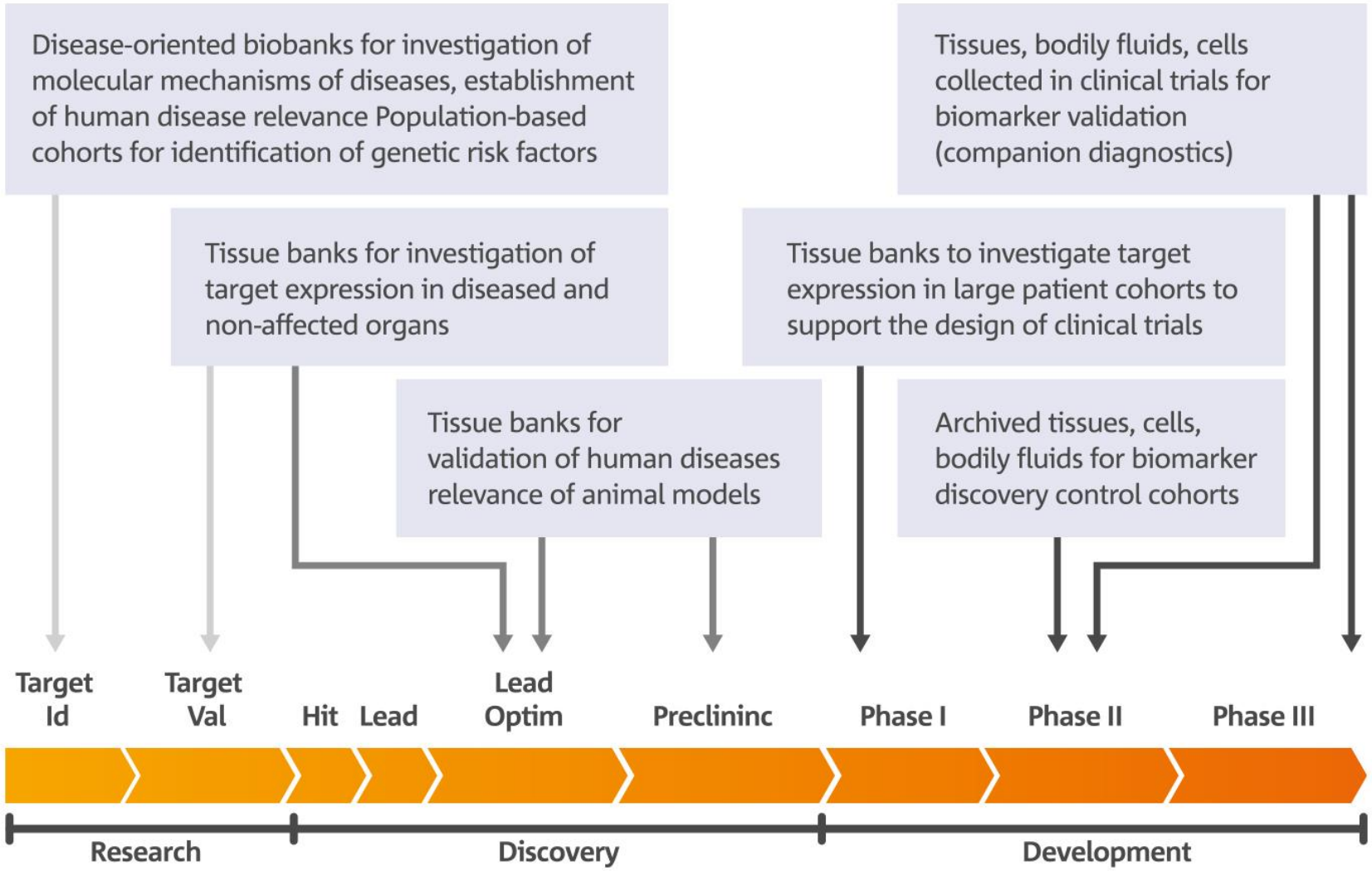
Sample processing:
1. Diagnosis
2. Biobank

Reproducibility of research (quality)

Sample (& data) shared with researchers

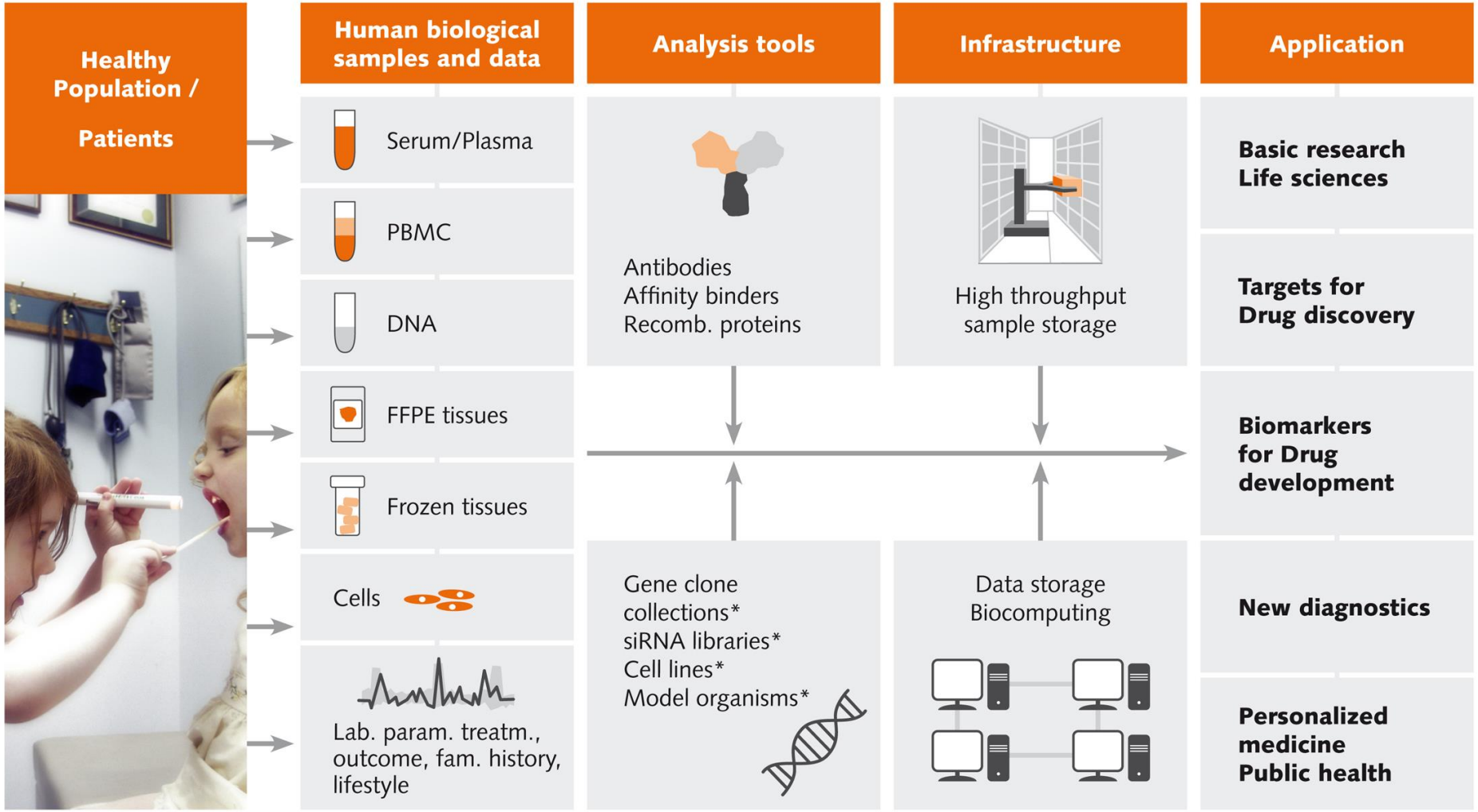
Governance
Data protection
Ethics

BIOBANKING IN DRUGS DEVELOPMENT



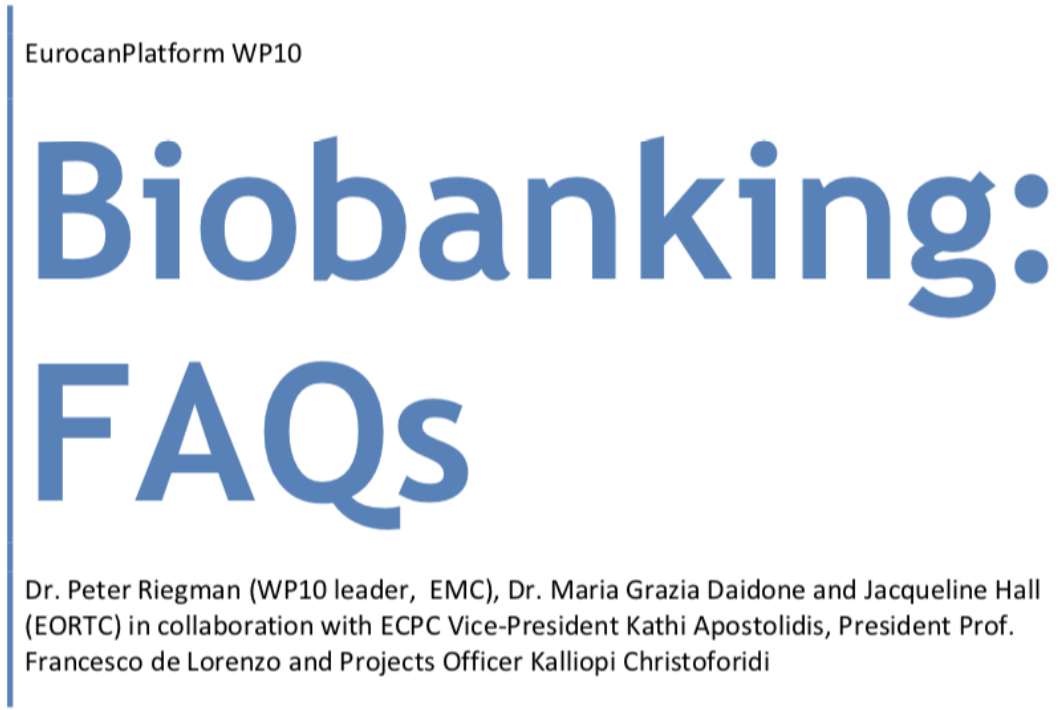
BIOBANKING, MEDICINES, MEDICAL DEVICES

BBMRI-ERIC®



TO KNOW MORE, LOOK INSIDE YOU

BBMRI-ERIC®



EurocanPlatform

http://www.ecpc.org/activities/projects/eurocanplatform

THE WORLD‘S BIGGEST

BIOBANK DIRECTORY

BBMRI-ERIC®

WHO

WE ARE

BBMRI-ERIC is a research infrastructure of biobanks and biomolecular resources that provides expertise and services in order to facilitate the use of European sample collections and data for the benefit of human health.

WHERE

WE ARE

MEMBERS OF BBMRI-ERIC

Austria
Belgium
Bulgaria
Czech Republic
Estonia
Finland
France
Germany
Greece
Italy
Latvia
Malta
Netherlands
Norway
Poland
Sweden
United Kingdom

OBSERVERS OF BBMRI-ERIC

Switzerland
Cyprus
Turkey
IARC

WHAT WE
OFFER

SUPPORT
WITH ETHICAL, LEGAL AND SOCIETAL ISSUES

IT TOOLS
AND EXPERTISE

QUALITY
MANAGEMENT SERVICES

COMMON

SERVICE ELSI

- Operational since the end of 2015
- All BBMRI-ERIC Members and Observers nominated participating experts (important for national sensitivities)
- Offers practical interpretation on new legislation (e.g. FAQs GDPR)
- Monitors relevant ethical and legal frameworks in development (joint statement on the Council of Europe recommendations).
- Test runs a federated custom-based helpdesk (providing 1:1 guidance)
- Develops ELSI guidelines for researchers (e.g. how-to-engage with patient organisations)

Michaela Th. Mayrhofer
Chief Policy Officer

Jasote Grewal
ELSI Helpdesk Coordinator

COMMON

SERVICE IT

- Operational since the beginning of 2016
- All BBMRI-ERIC Members contribute
  - Main partners develop and operate services
  - Smaller partners focus on piloting and testing services

Delivered core IT services:

- Directory, Negotiator, BIBBOX, HelpDesk, CCDC, AAI

Development of Upcoming IT services:

- Locator, data harmonisation services

Michael Hummel
(DE)

Peter Holub
BBMRI-ERIC

QUALITY

QUALITY MANAGEMENT SERVICE

- International biobanking standards (ISO 9001, ISO 20387, CEN Technical Specifications, etc.)
- Quality management tasks in EU projects
- Quality management in national and international research projects

- International biobanking standards
- General quality management systems
- Integrated management systems
- Interface management systems

Andrea Wutte
Quality Manager
BBMRI-ERIC

- BBMRI-ERIC Self-Assessment Survey for biobanks
- BBMRI-ERIC Audit

BBMRI-ERIC QUALITY MANAGEMENT SERVICES FOR BASIC AND APPLIED RESEARCH

KNOWLEDGE HUB

TRAINING & SUPPORT

AUDITING

SETTING BIOBANKING STANDARDS FOR PERSONALIZED MEDICINE

THE SPIDIA4P PROJECT

- **Achieved:**
  - 9 CEN Technical Specifications (CEN/TS) for pre-analytical workflows in Europe.
  - 1 ISO Standard
- **Next**
  - 14 other CEN/TS – ISO standards by the end of the project.

SPIDIA4P event on standards
at the European Parliament in Brussels

TACKLING ISSUES ON IN VITRO DIAGNOSTICS FOR PERSONALISED MEDICINE, SPIDIA4P

Tuesday 5th March 2019
Room P5B001, 9:00 – 12:00

Hosted by Lieve Wierinck (ALDE Belgium) and Gesine Meissner (ALDE Germany), Members of the European Parliament.

VISIT: www.bbmri-eric.eu
REGISTER: https://buff.ly/2BATEzQ
CONTACT: francesco.florindi@bbmri-eric.eu

The SPIDIA4P project receives funding from the European Union's Horizon 2020 research and innovation programme under grant agreement no. 733112.

GDPR

CODE OF CONDUCT FOR HEALTH RESEARCH

To contribute to the proper application of the regulation, taking into account the specific features of processing personal data in the area of health;

To clarify and specify certain rules of the GDPR for controllers who process personal data for purposes of scientific research in the area of health

To help demonstrate compliance by controllers and processors with the regulation

To help foster transparency and trust in the use of personal data in the area of health research.

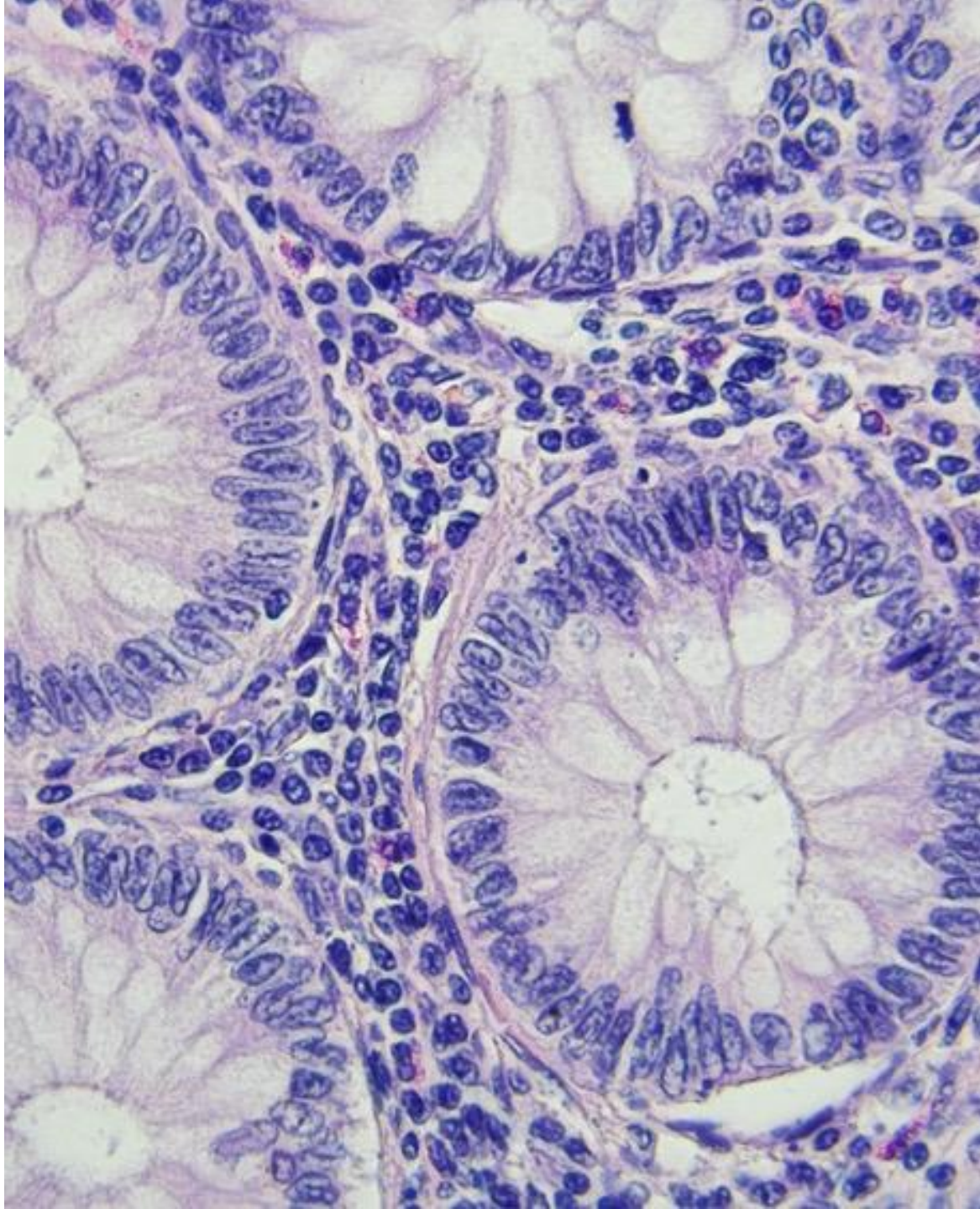
WHAT WE OFFER

EUROPEAN COLLECTION OF 10,000

COLORECTAL CANCER COHORT

DATASETS SOON AVAILABLE VIA

ADOPT BBMRI-ERIC PROJECT



This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 676550.

THE PROBLEM

ONLY ABOUT 10% OF SAMPLES COLLECTED/STORED IS USED FOR RESEARCH.

ETHICAL

PATIENTS/CITIZENS GIVE SAMPLES WITH THE EXPECTATION THAT THEY ARE USED TO ADVANCE RESEARCH

SUSTAINABILITY

WHO IS GOING TO PAY FOR THE STORAGE OF SOMETHING THAT IS NOT BEING USED?

NO NEW TREATMENTS

THE FULL POTENTIAL OF BIOBANKS IS NOT EXPLOITED

GOAL OF THE NEW BBMRI-ERIC STRATEGY

MOVE FROM RESEARCH-ORIENTED ORGANISATION TO SERVICE ORIENTED ORGANISATION

NEVER SWIM ALONE

MEDICAL ERICS COMMIT TO WORK TOGETHER

Key recommendations from joint position paper on Horizon Europe

- Avoid undesired duplication and fragmentation;
- Safeguard quality and enhance reproducibility;
- Support public engagement by promoting responsible research policies;
- Enable rigorous innovation management.

BBMRI-ERIC
Biobanking and BioMolecular resources Research Infrastructure

eatris
European infrastructure for translational medicine

ECRIN
EUROPEAN CLINICAL RESEARCH INFRASTRUCTURE NETWORK

Medical Research Infrastructures: Solid foundations for Horizon Europe

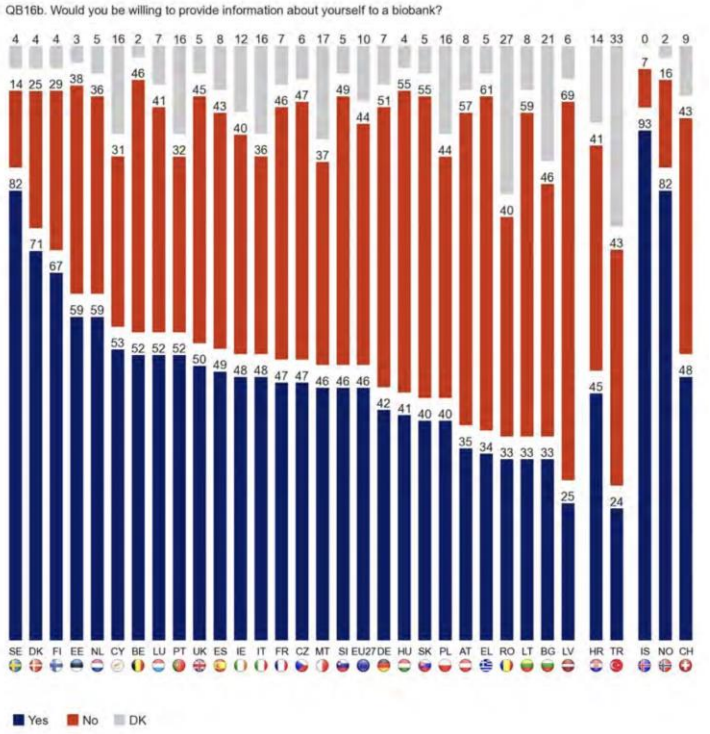
LET'S MEASURE THE LEVEL OF TRUST IN BIOBANKS IN THIS ROOM…

PLEASE OPEN YOU SLI.DO APP

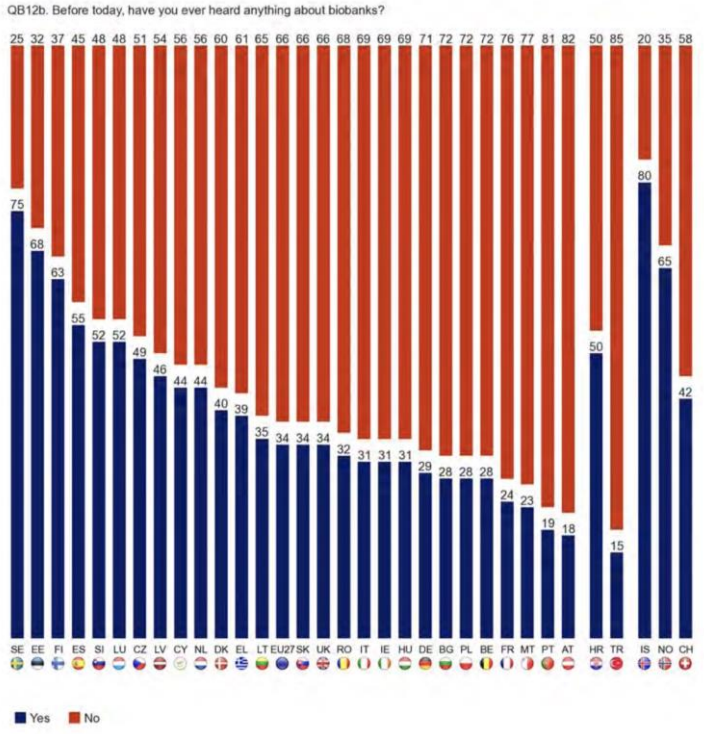
- Have you heard about biobanking before this presentation?
- Would you provide your sample to a biobank?
- Should biobanks be allowed to share samples across borders?

DO EUROPEANS TRUST BIOBANKS?

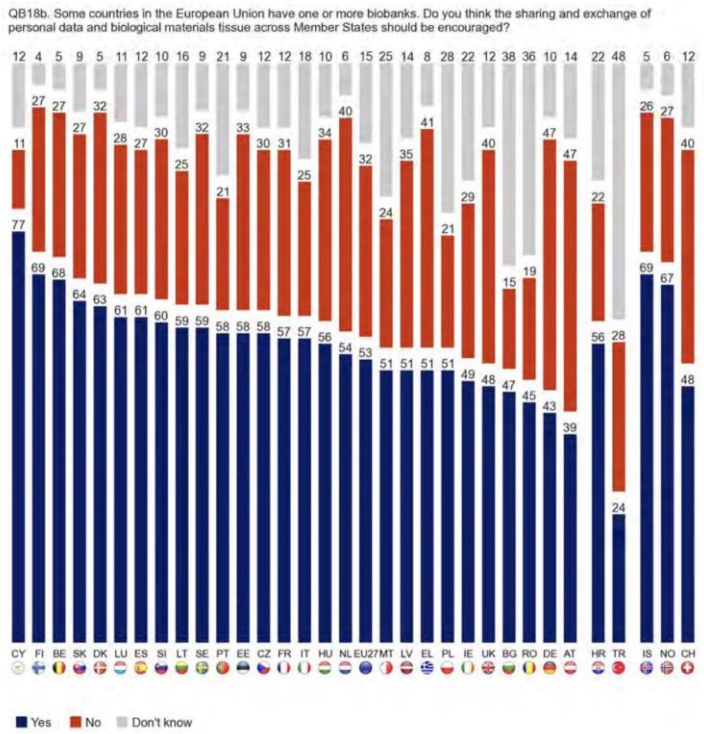
Have you heard about biobanking?



Would you provide your sample to a biobank?



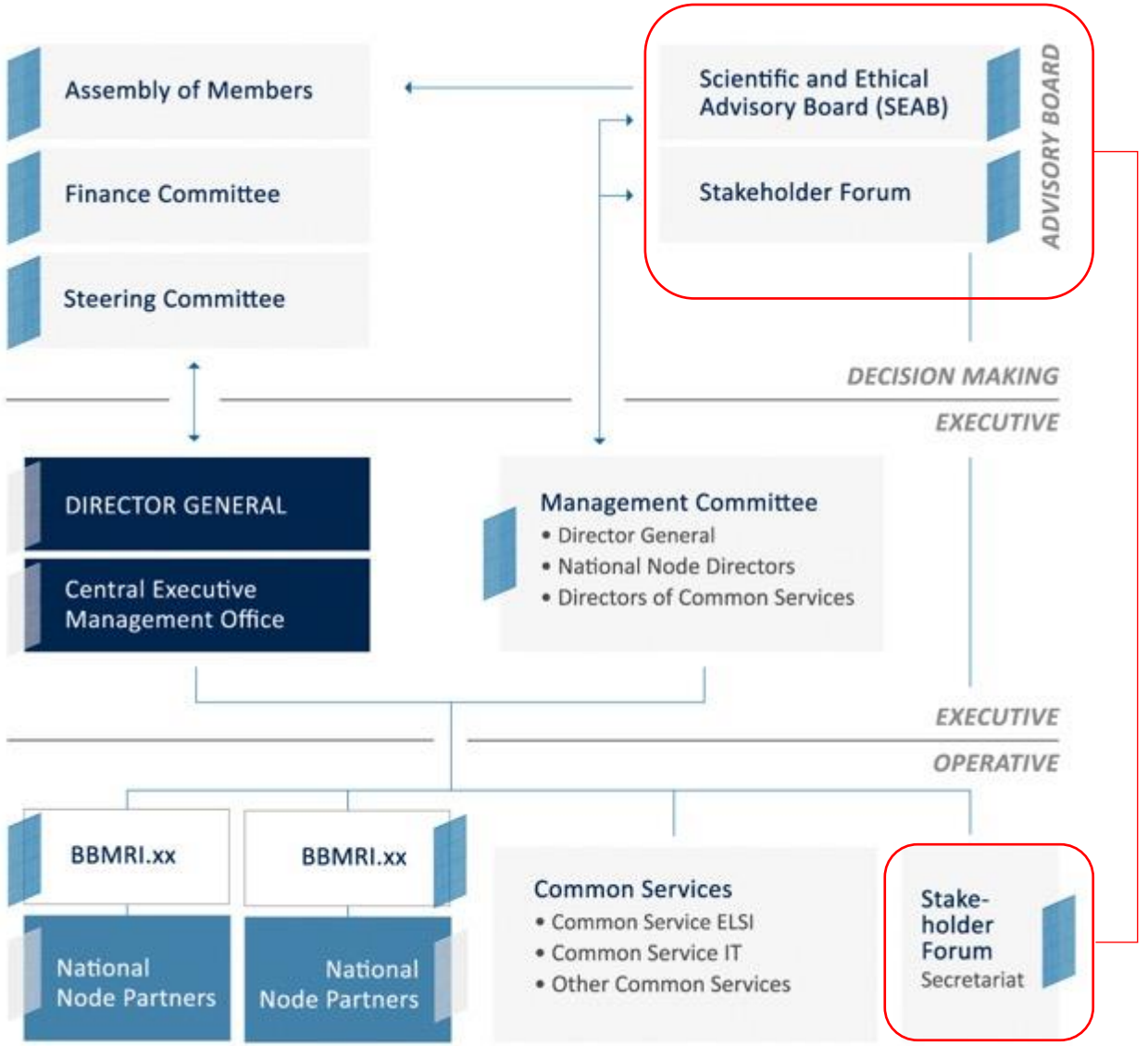
Should biobanks be allowed to share samples across borders?



WORKING WITH BBMRI-ERIC

THE STAKEHOLDER FORUM

BBMRI-ERIC®



STAKEHOLDER FORUM

PATIENTS AND CITIZENS' PILLAR

- Specific rules of procedure
- Exchange of information
- Role in BBMRI-ERIC decision making (paper on FP9…)
- Contribution to BBMRI-ERIC projects (H2020, Code of Conduct)

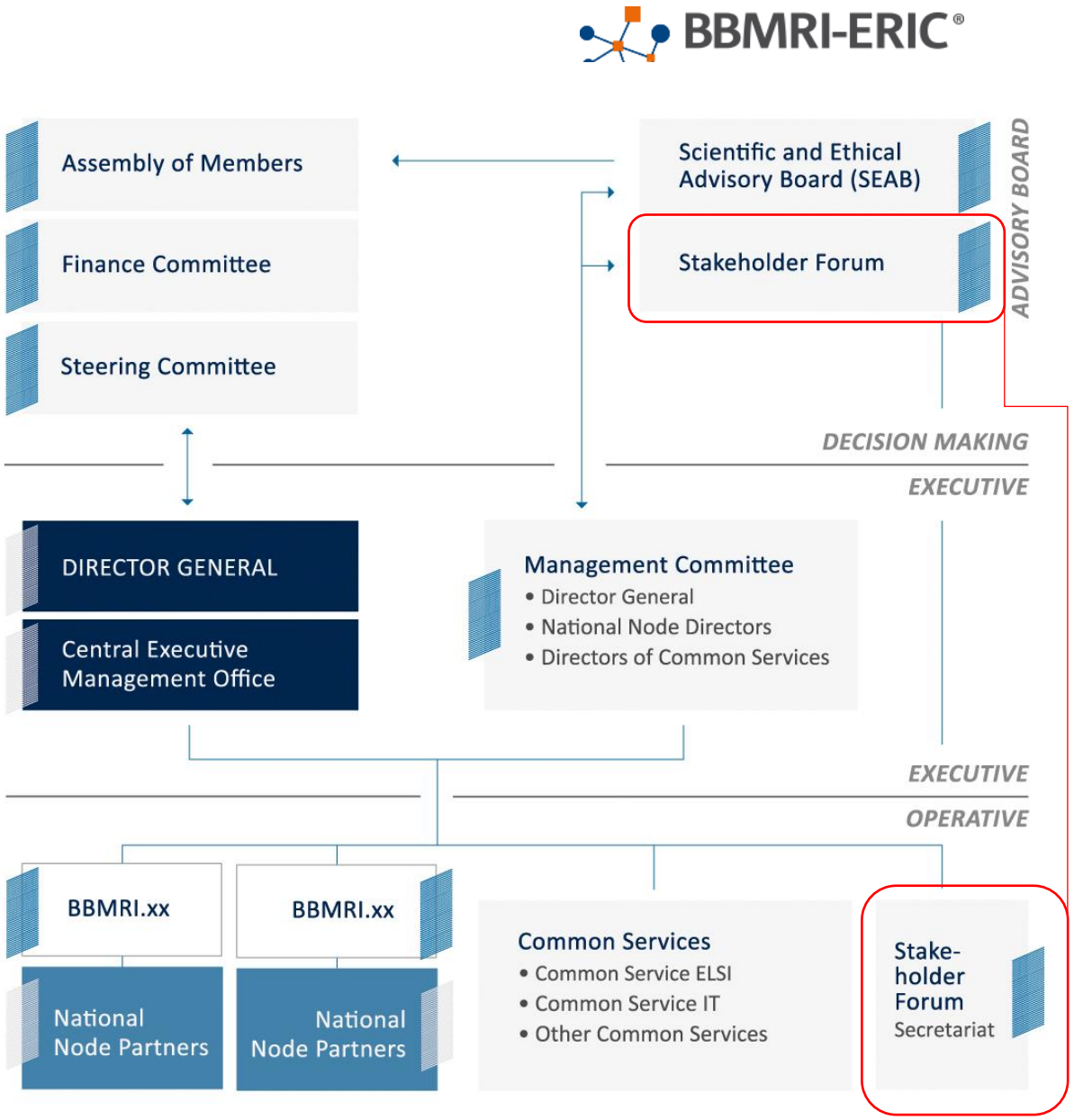
THE FUTURE OF BBMRI'S STAKEHOLDER FORUM

3 pillars

Patients/citizens ✔

Industry

Healthcare professionals



THE POWER OF OUR COMMUNITY: CO-PRODUCING INFO MATERIAL

THE EXAMPLE OF GERMAN BBMRI NODE

"I support the research. This is my contribution to the future of medicine. "

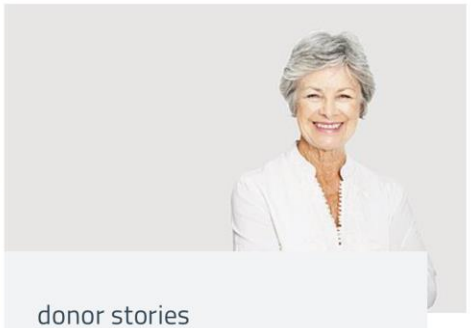
SHOW MORE

#DANKE

Why participate?

Biobanks - Medicine of the

From the bio-sample for



donor stories

How can I donate biomaterial?

What is my sample used?

Is my data secure?

Do I have a personal benefit from my donation?

What are my rights as a donor have?

How long will my sample is stored in the Biobank?

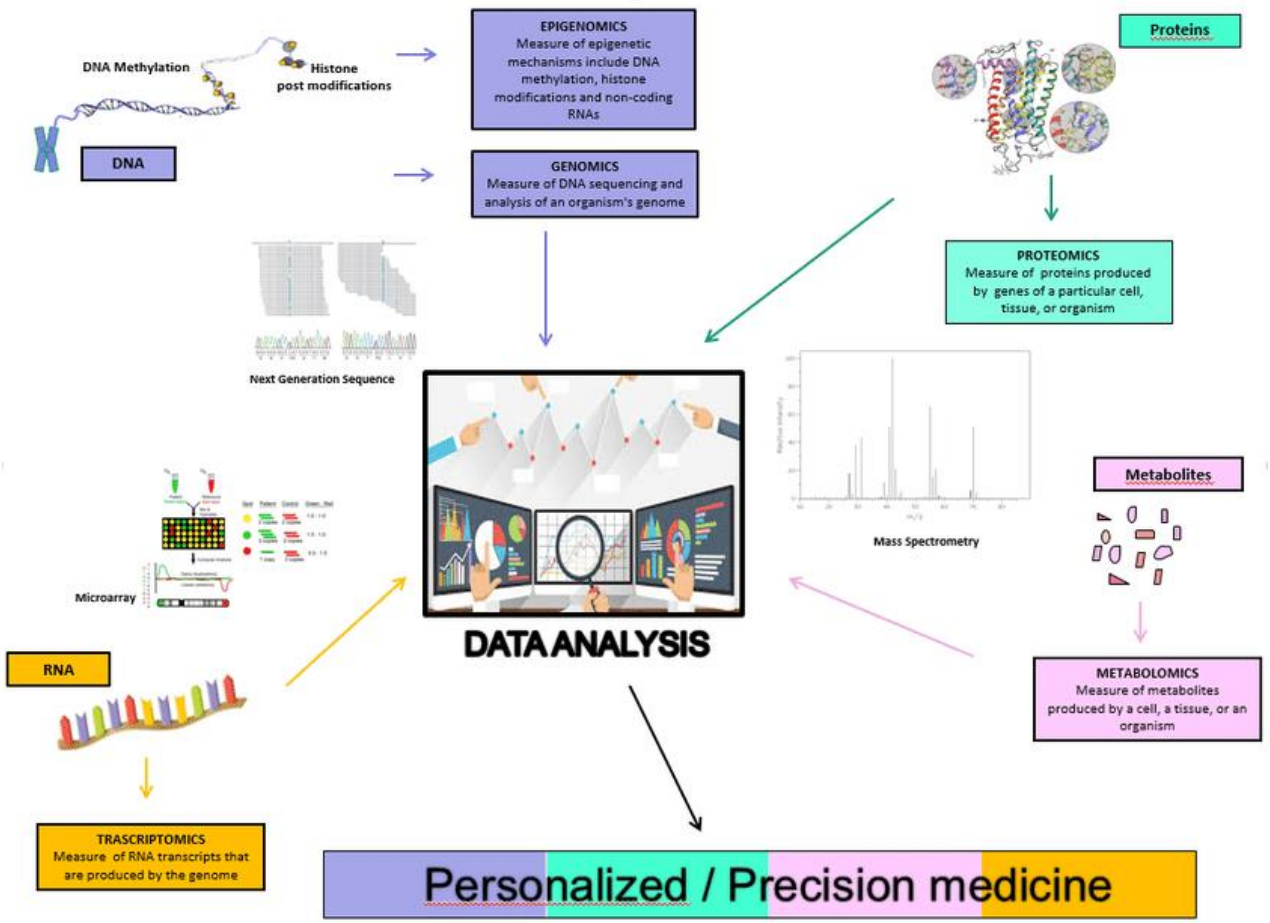
I get feedback on the research results?

THE POWER OF OUR COMMUNITY: PATIENTS IN THE BIOBANK'S GOVERNANCE

HOW BBMRI.NL INTEGRATES PATIENTS AND CITIZENS' PERSPECTIVE

- Public communication/patient information
- A national generic personal identifier for research
- Incidental findings (I think this might be the most concrete/appropriate example)
  - submitted an opinion article to BMJ on the reporting of incidental findings, in order to start a discussion to make the current EU policies a bit less conservative.

THE POWER OF OUR COMMUNITY: PILOT STUDY FOR BREAST CANCER MULTIOMICS PLATFORM



BBMRI-ERIC®

BBMRI.pl
Biobanking and BioMolecular resources Research Infrastructure Poland

Clinics (Warsaw, Gdansk, Wroclaw, Bialystok)
Biobank (PORT Wroclaw)
Data creation (PORT/Ardigen Krakow)
Data analysis (PORT/Ardigen)
Multiomics database creation (Ardigen)

BBMRI.pl – project financed by Ministry of Science and Higher Education *DIR/WK/2017/01-27.01.2017*

FinnGen study

Launched in 2017, FinnGen is a unique research project that combines genomic information with healthcare data from national registries in search of the next breakthroughs in disease prevention, diagnosis and treatment.

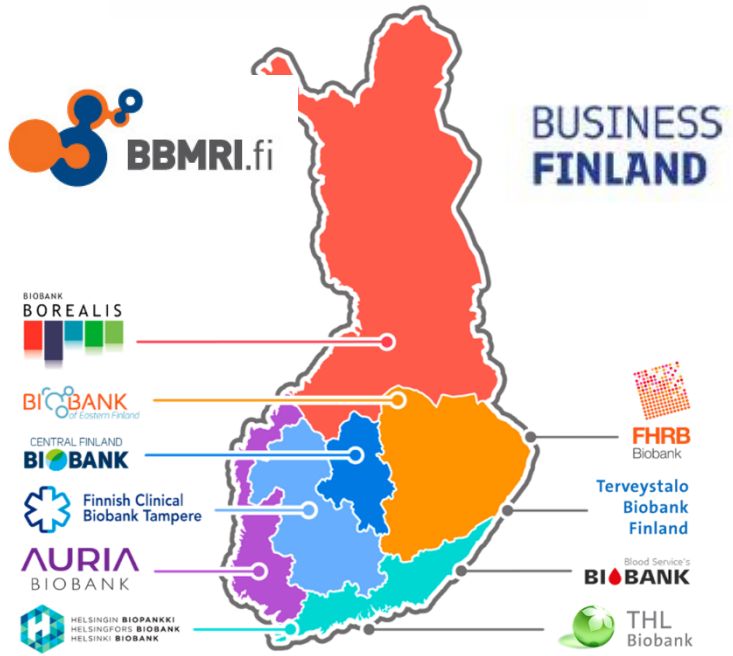
The aim is to get 500,000 Finns to participate in the study through donation of a sample to a biobank.

~10 % of the population =

500,000 Finns

FinnGen brings together academic partners, the nation-wide network of Finnish biobanks & nine pharmaceutical companies.

abbvie · AstraZeneca · Biogen · Celgene · Genentech · gsk · MSD · Pfizer · SANOFI



UNIVERSITY OF HELSINKI · HUS · THL

BBMRI-ERIC®

MAKING NEW TREAT MENTS POSSIBLE

THANK YOU!

FRANCESCO.FLORINDI@BBMRI-ERIC.EU
@FRANCESCOFLO

contact@bbmri-eric.eu
www.bbmri-eric.eu
@BBMRIERIC
BBMRI-ERIC