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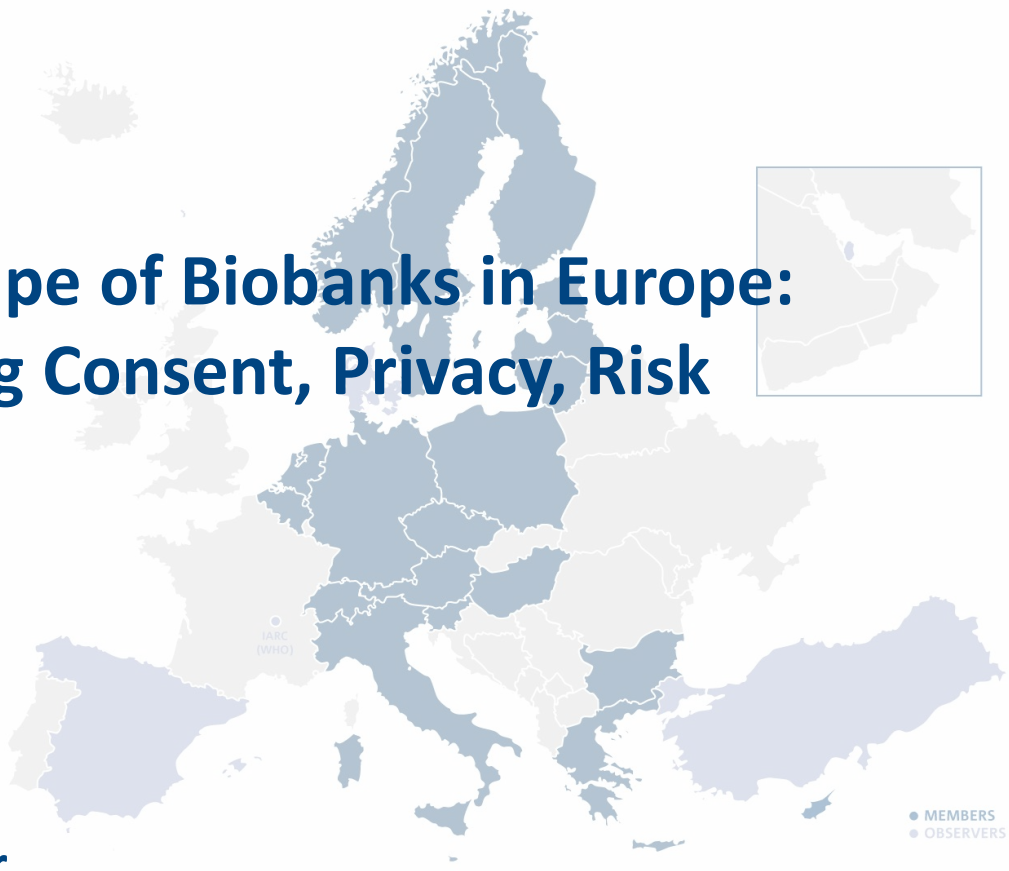
Navigating the Legal and Ethical Landscape of Biobanks in Europe: Simplifying Procedures While Addressing Consent, Privacy, Risk Governance, and Public Engagement

BIOBANK OPEN FORUM JAPAN

22 JANUARY 2025



Dr. Ilaria Colussi, Dr. Kaya Akyüz, & Ms. Irene Schluender

Department of ELSI Services & Research

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ELSI ISSUES RELATED TO BIOBANKING

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PREMISE: COMPONENTS OF BIOBANKS & ELSI

Biological **samples** (collection, processing, storage) and **quality** aspects

Data (attached or connected information) and **IT** aspects

Humans (participants, researchers...) and **ethical**, **legal** and **societal** aspects: consent, governance, trust, engagement, data protection, privacy...

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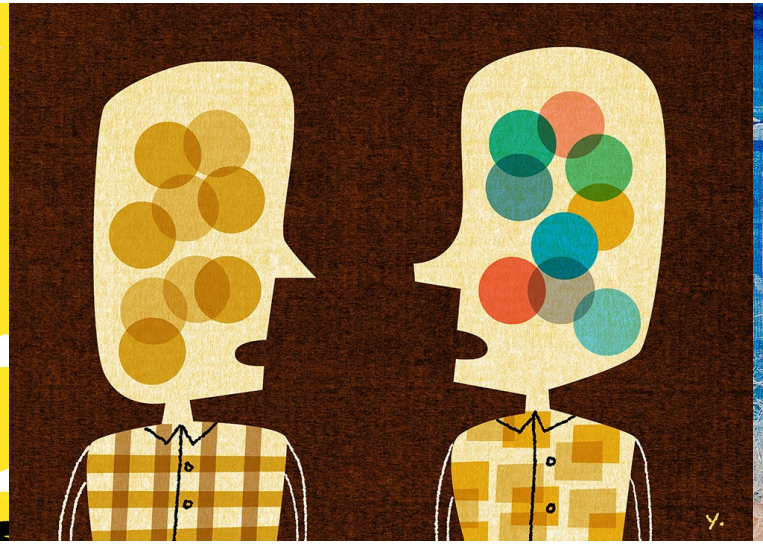

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REQUIREMENTS FOR A SUCCESSFUL BIOBANK

1

CLEAR GOVERNANCE:

- Procedures in place (about storage, access, data sharing, return of results)
- Roles of committees (data access committee, ethics committee, oversight committee…) and responsibilities of different actors involved
- Documents and policies in place

2

INFORMATION TECHNOLOGY:

- Adequate informatics infrastructure - hardware and software – for recording and storing data
- Adequate security measures in place to safeguard data
- Protocols as to how to share data
- Rules about access to ensure confidentiality and safety

3

LABORATORY FACILITIES & QUALITY OF SAMPLES:

- Standardization (e.g., ISO)
- Infrastructure (instruments, procedures, etc.)
- High quality: Sample preparation and for advanced analysis

ETHICAL, SOCIETAL & LEGAL PRINCIPLES IN PLACE:

- Clear informed consent procedures and forms (ethics committees)
- Data/samples access, transfer and sharing: data protection rules
- Transparency, accountability, equity, fairness principles adopted: clear distribution of roles and oversight

4

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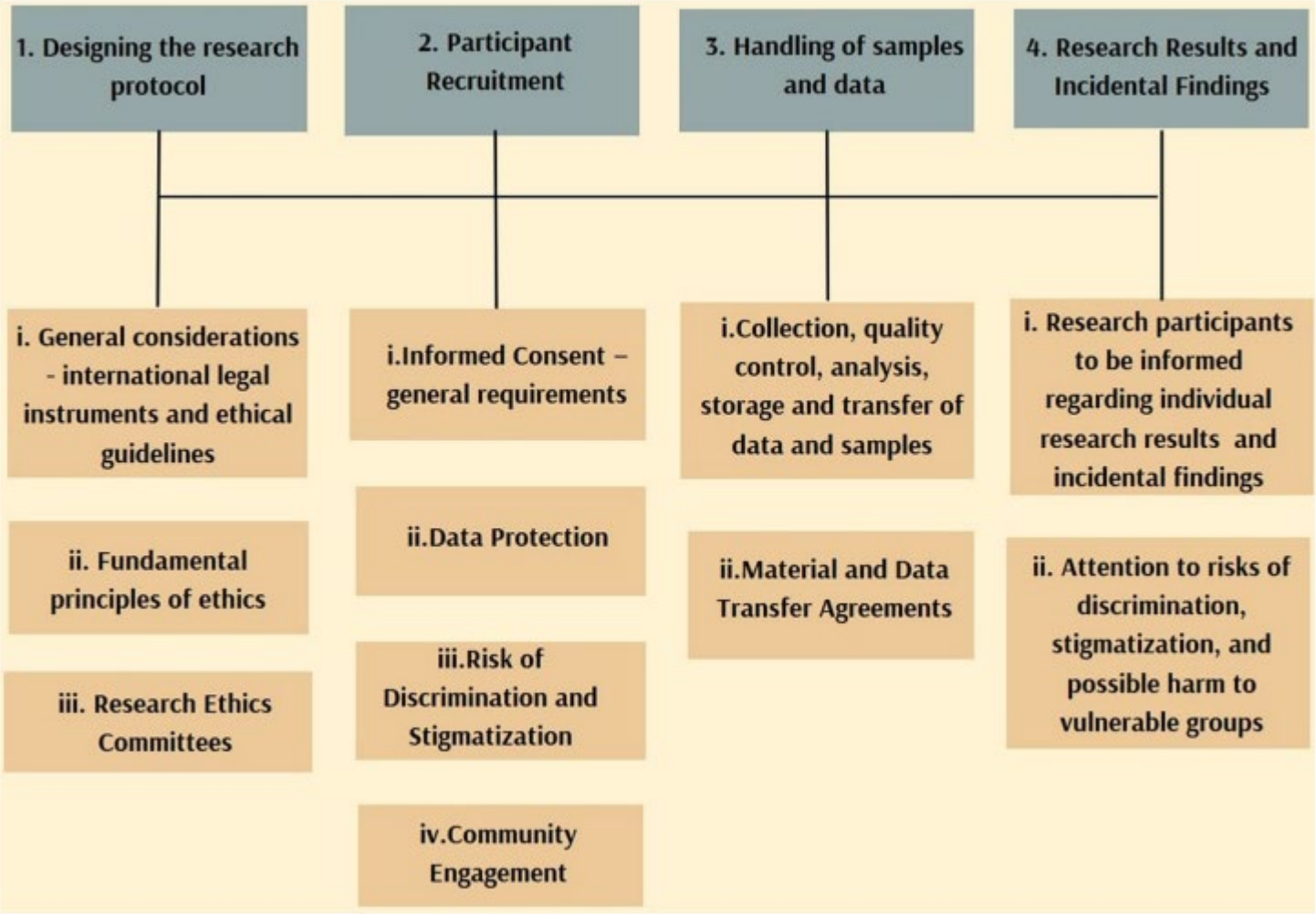
ELSI CHECKLIST FOR BIOBANKING



Tzortzatou-Nanopoulou et al. (2023). **Ethical, legal, and social implications in research biobanking: A checklist for navigating complexity.** *Developing World Bioethics*. 1-12.

Step 1: Take into account ethical and legal instruments

INTERNATIONAL LEVEL

1. ISO 20387:2018: quality standards for biobanks
2. OECD, Recommendation on Human Biobanks and Genetic Research Databases (HBGRD): guidelines for the establishment, management, governance, operation, access, use and discontinuation of biobanks
3. OECD Best Practice Guidelines for Biological Resource Centres, focusing on organizational aspects, data management, data access, supply, biosecurity risks
4. World Medical Association (WMA) Declaration of Helsinki and the Declaration of Taipei on Ethical Considerations Regarding Health Databases and Biobanks
5. International Ethical Guidelines for Health-related Research Involving Human of the Council for International Organizations of Medical Sciences (CIOMS)

COUNCIL OF EUROPE

CONSEIL DE L'EUROPE

INTERNATIONAL REGIONAL LEVEL (EUROPE)

1. Recommendation Rec (2006) 4 revised by Rec. (2016) 6 of the Committee of Ministers to Member States on Research on Biological Materials of Human Origin (Council of Europe) : principles of transparency and accountability to collect and manage biological materials; consent principle; confidentiality; independent ethical assessment of research projects; governance aspects
2. Oviedo Convention (Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (ETS No. 164): focus on consent

Step 1: Take into account ethical and legal instruments (2)

REGIONAL LEVEL (EU)

- There is **no single specific law on bio-banking** but the topic falls under other existing regulatory frameworks (e.g., the GDPR for data protection aspects). As regards Human Tissue and Cells directives (Directive 2004/23/EC) → Scientific research is NOT in scope
- COMMISSION IMPLEMENTING DECISION of 22 November 2013 on setting up the Biobanks and Biomolecular Resources Research Infrastructure Consortium (BBMRI-ERIC) as a European Research Infrastructure Consortium: Annex 1, art. 1 definition of biobank
- Biobanking law is **not harmonized** between the jurisdictions in EU
- Not all countries have specific rules relating to biobanks: LACK OF A UNIFIED LEGAL FRAMEWORK ABOUT GOVERNING BIOBANKS
- 3 groups of countries:
  - Countries with **specific law** (e.g., Belgium, Finland, Spain and Sweden)
  - Countries **with composite regulations, often accompanied by soft law** (e.g., Denmark)
  - Countries with **no specific regulation** (e.g., Bulgaria, the Netherlands, Germany, Italy and the UK). However, there exist certain national rules on the use of human materials (tissues and blood). E.g., in the Netherlands rules on use of human material are provided in the Medical Treatment Contract Act (WGBO) and Dutch Code for proper secondary use of human tissue. In the UK, there is fragmented patchwork of laws that applies to medical research on humans, providing for a distinction between human material (samples) and data

Step 1: Ethics principles

ETHICS PRINCIPLES: RESPECT FOR AUTONOMY, BENEFICENCE, NON-MALEFICENCE, AND JUSTICE

INFORMED CONSENT is crucial: Consent is an expression of the human dignity and self-determination

In biobanking, consent means the agreement to participate to research and give samples/information to the biobank.

Information should be given as regards how using biomaterials, purpose, where it will be kept and for how long, how it will be protected and who will be able to see or use it → full information

1. “opt in” system means that explicit consent (agreement) must be requested of participants to provide materials to biobanks
2. "opt out" system presumes that everyone generally agrees to give samples (presumed agreement) unless they explicitly state their refusal to participate. This system is only used in some countries for left over materials or secondary use of archived materials. E.g., Belgium, use of residual material with opt-out consent - consent is presumed, unless prior to any operation with the material, the donor announced his/her refusal

In Europe/EU:

- Different countries may use different models, although most countries in Europe favour the opt-in model.
- Even in those countries where an “opt-out” system exists, this system will never be applied in situations that involve significant risks that could affect a patient’s quality of life. If significant risks are present, each patient will still be informed of the risks, and asked if they wish to participate or not.

Step 2: Participant Recruitment

Models of Informed Consent

- "**specific**" informed consent means that a specific medical research project is already identified and can be outlined in detail to the patient. The patient can then either consent or decline to participate in that specific project
- "**broad**" consent means the general area of research may be outlined to the patient (e.g., cancer research, genetic research or medical research), but with no specific project defined. This means the sample can be used within the scope of the permission provided without having to recontact the patient to obtain a specific consent for each project in the future. Any future project would still be performed in compliance with local rules and ethics approval by an appropriate committee

In biobanking, specific consent is problematic (difficult to re-consent for each project)

Sweden: reconsent at any time there is a new project

Iceland: informed consent only for tissues and samples donated to biobank, but for samples and data collected for other reasons there is presumed consent and opt out

Belgium: IC must be obtained by a medical specialist, IC is required also for secondary use, but if it is impossible to seek consent, or where such a request would be exceptionally inappropriate, the positive opinion of an ethics committee would be sufficient

Step 2: Participant Recruitment (2)

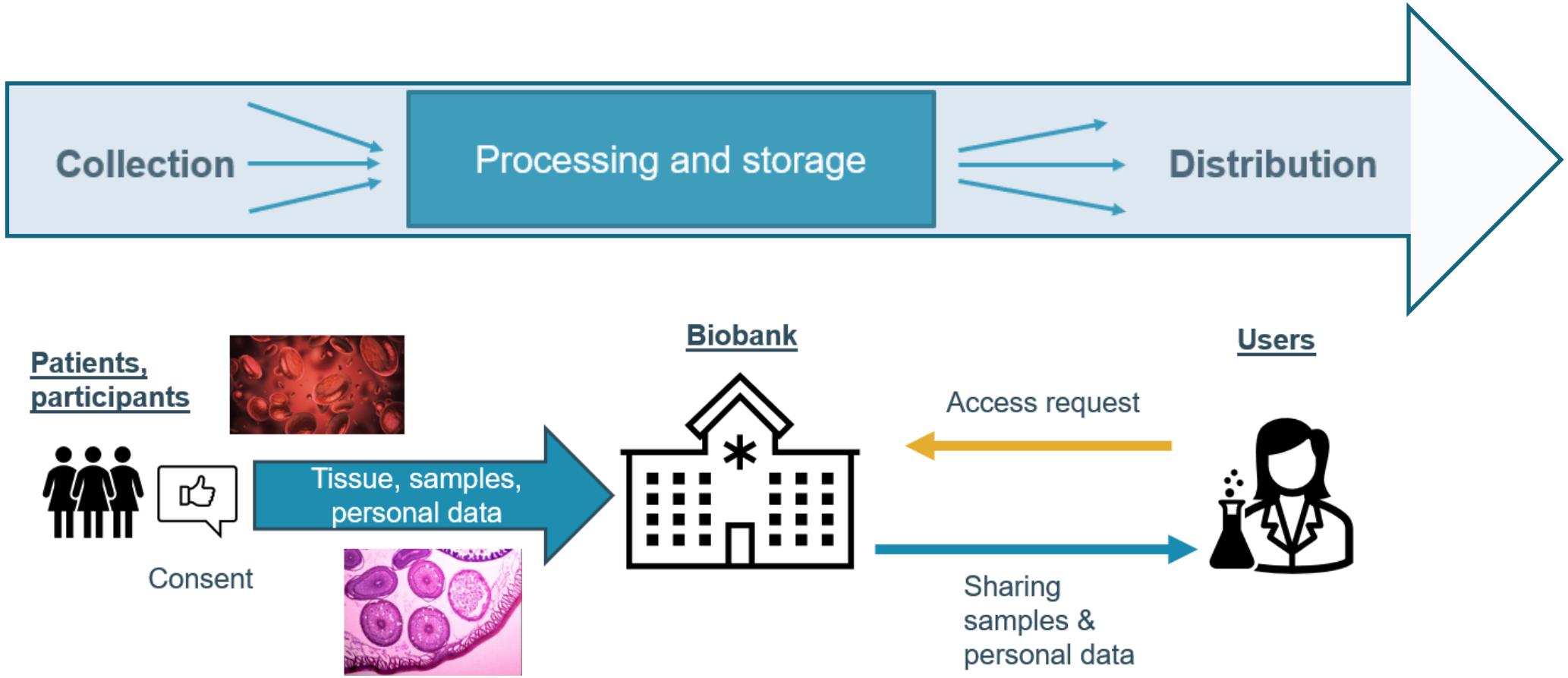
Blanket: consent to scientific research in general without reference to a specific project/area of research

Open: the biobank requests consent once from the data subject for all future research uses of genetic material and data. Consent to an unlimited usage of data with the purpose of making them publicly accessible through an online database (informational altruism, based on the moral duty to participate to research)

Multilayered consent: it gives research participants the option of giving broad consent only to certain types of research or research use, e.g. specific diseases/indications such as cancer or neurological diseases; only publicly-funded research; or only specified institutions or researchers. So, it is a consent to multiple options, such as all the activities pursued by the biobank; no reference to a specific project. E.g., Spain ley 14/2007 allows to consent to a specific research project and related research. What is 'related'? Ethics committee should integrate the individual specific consent. With tiered consent, research participants can also choose whether their samples and data are identifiable or anonymised.

Dynamic consent: possibility to adapt preferences in the course of time. More options but also more participation/engagement. It allows participants to track online the use of their data and biosamples and to opt out of certain areas of research. Dynamic informed consent is facilitated by interactive digital platforms that allow research participants to regularly check the research activities of a biobank and modify their consent for any upcoming research projects.

Step 3: Data Protection issues



Step 3: Data Protection issues (2)

Legal basis for collecting and processing health data (special category of data), who is processor and controller, research participants' rights…

Anonymous or **pseudonymized** manner

SHARING / TRANSFER

- Material Transfer Agreement (MTA) or Data Transfer Agreements (DTA): provider vs user, samples vs data → the agreements describe the how and by whom, legal basis, subjects, purposes for transfer/sharing
- Samples and data will be released for use in research only after projects have been reviewed and approved by appropriate bodies (such as Research Ethics Committee)

BEST PRACTICES: to take into account the balance of different rights at stake (researchers' right to conduct research, participants' rights, etc.) and proportional measures

Step 3: Data Protection issues (3)

In EU the cornerstone for data protection is represented by the **EU General Data Protection Regulation (GDPR):** all EU entities and entities dealing with data about EU citizens must adhere to it.

Some relevant notions for biobanking:

a) Principles (art. 5) about how data should be collected, stored, or processed

1. Lawfulness, fairness and transparency
2. Purpose limitation: Data should be processed only for the purposes for which it was collected (but admitted further use for scientific research purposes)
3. Data minimization: Biobanks should process only as much data as is necessary to achieve the intended objective.
4. Accuracy: Biobanks must ensure that data accuracy is maintained at all times.
5. Storage limitation: Personal data should be stored only for the duration for which it is necessary (but admitted longer storage for scientific research purposes)
6. Integrity and confidentiality: These values should be upheld concerning personal data.
7. Accountability: The controller of a biobank must be able to demonstrate that the biobank complies with the EU GDPR through appropriate records and measures.

b) Controller/Processor/Joint Controller: Whether or not biobanks assume the roles of data controllers and/or data processors for GDPR compliance purposes will largely depend on their actual functions, manner of operating and whether the specific tasks can be considered data processing of personal data

Step 3: Data Protection issues (4)

c) Rights of data subjects: right of access, right to erasure, to rectify, to restrict processing, to data portability, to object

d) Legal basis (art. 6 and 9): reason to process data should be clearly indicated (consent, a contract, legitimate interest, etc.)

e) Space to MS derogations (art. 9, par. 4) with regard to the processing of genetic data, biometric data or data concerning health: limits to EU common space for biobanking→ **GDPR as a *de facto* directive for biobanking: FRAGMENTATION!**

f) Technical and organizational measures: when processing data for scientific research purposes, appropriate safeguards for the rights and freedoms of the data subject should be adopted:

- Technical: ex. Anonymization, pseudonymization, encryption…note that adopting anonymization reduces data quality and prevents from recontacting participants
- Organisational: limited access, RECs…

g) Further use: see art. 5.1.b (further processing for scientific research purposes shall, in accordance with Art. 89.1, not be considered to be incompatible with the initial purposes) and art. 5.1.e (personal data may be stored for longer periods insofar as the personal data will be processed solely for scientific research purposes)

h) Data transfers: the GDPR enables data transfers with third countries under 3 main avenues, which apply in hierarchical order: 1) the existence of an adequacy decision 2) the provision of appropriate safeguards and 3) derogations for exceptional situations explicitly prescribed under GDPR (art 49 GDPR). One form of appropriate safeguards is the Data Transfer Agreement (DTA)

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Step 4: Ethical & societal aspects ➔ Research to knowledge & training

ELSI SERVICES & RESEARCH

RESEARCH

We conduct research relating to ethical, legal and societal issues (ELSI). This is fundamental to staying up to date with and contributing knowledge to our services and training.

SERVICE

We support the biobanking and life science RI communities by facilitating compliance with regulatory requirements and best practice standards.

TRAINING

We provide training and workshops on ELSI issues such as Data Protection Impact Assessment (DPIA), ethical compliance and social engagement, among others.

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bigpicture
EUCAN connect
HEALTHYCLOUD Health Research & Innovation Cloud
DIAMOND MAKING DIAGNOSIS PERSONAL
B1MG
BY-COVID
euCanSHare
ISIDORe
CINECA
biobank.cy
EHDS HealthData@EU Pilot
EOSC Future
canSERV
epnd European Platform for Neurodegenerative Diseases
eosc | cancer
EUCAN IMAGE
EOSC-Life
EUROPEAN JOINT PROGRAMME RARE DISEASES
IC2PerMed
INTERVENE
PROPHET a PeRsOnalized Prevention roadmap for the future HEalThcare

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Step 4: Ethical & societal aspects ➔ Key topics

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INCIDENTAL FINDINGS

DATA SHARING

VULNERABILITY

SEX & GENDER IN BIOMEDICAL RESEARCH

MTA / DTA

GDPR

DATA PROTECTION

EHDS: European Health Data Space

PEDIATRIC BIOBANKING

CITIZEN ENGAGEMENT

RISK GOVERNANCE

MINORS' ENGAGEMENT

ETHICS OF AI

INFORMED CONSENT

GENOMIC IDENTIFIABILITY

DATA PROTECTION IMPACT ASSESSMENT

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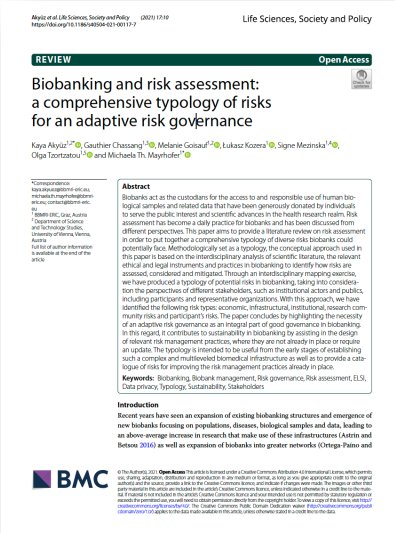
Entanglement of risks: Need for a holistic approach



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Life Sciences, Society and Policy

REVIEW — Open Access

Biobanking and risk assessment: a comprehensive typology of risks for an adaptive risk governance

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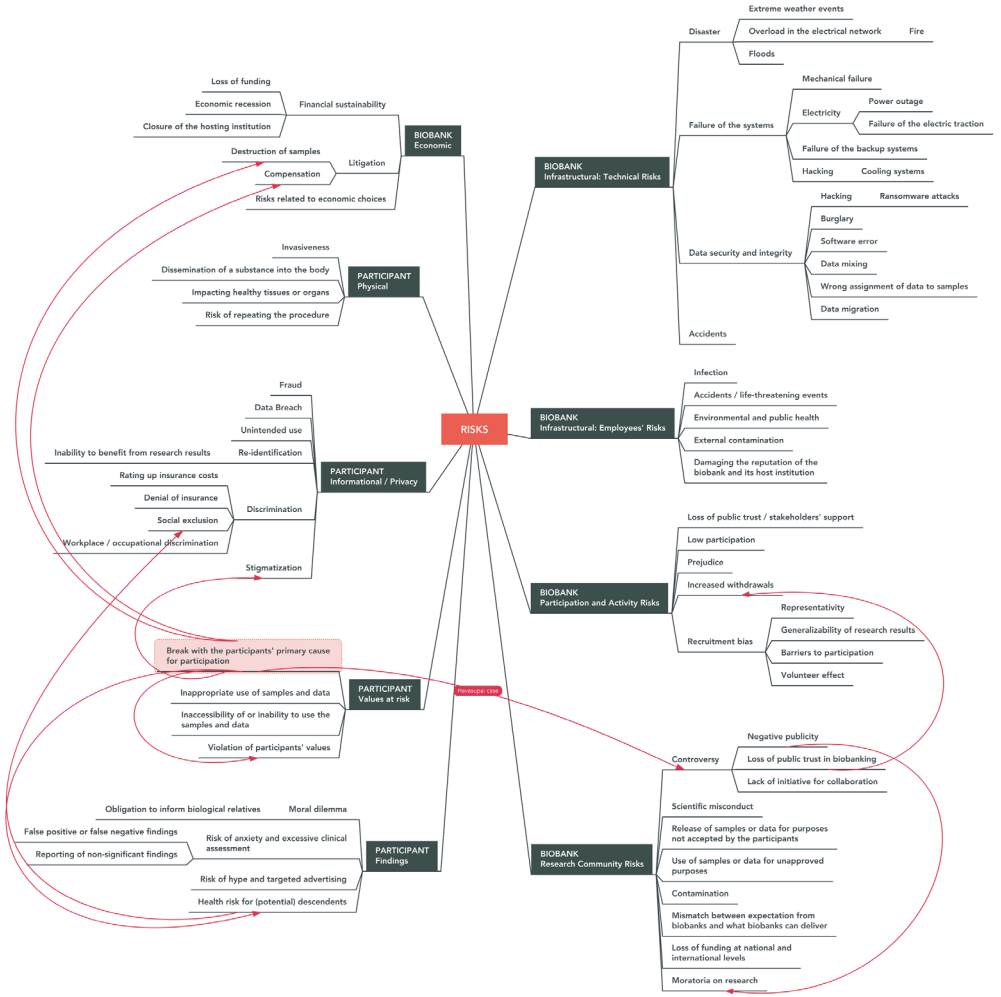
Abstract

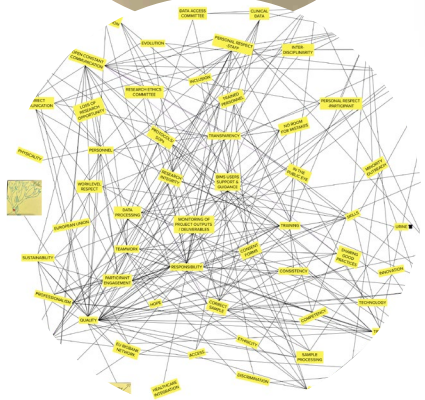
Biobanks act as the custodians for the access to and responsible use of human biological samples and related data that have been generously donated by individuals to serve the public interest and scientific advances in the health research realm. Risk assessment has become a daily practice for biobanks and has been discussed from different perspectives. This paper aims to provide a literature review on risk assessment in order to put together a comprehensive typology of diverse risks biobanks could potentially face. Methodologically set as a typology, the conceptual approach used in this paper is based on the interdisciplinary analysis of scientific literature, the relevant ethical and legal instruments and practices in biobanking to identify how risks are assessed, considered and mitigated. Through an interdisciplinary mapping exercise, we have produced a typology of potential risks in biobanking, taking into consideration the perspectives of different stakeholders, such as institutional actors and publics, including participants and representative organizations. With this approach, we have identified the following risk types: economic, infrastructural, institutional, research community risks and participant's risks. The paper concludes by highlighting the necessity of an adaptive risk governance as an integral part of good governance in biobanking. In this regard, it contributes to sustainability in biobanking by assisting in the design of relevant risk management practices, where they are not already in place or require an update. The typology is intended to be useful from the early stages of establishing such a complex and multileveled biomedical infrastructure as well as to provide a catalogue of risks for improving the risk management practices already in place.

Keywords: Biobanking, Biobank management, Risk governance, Risk assessment, ELSI, Data privacy, Typology, Sustainability, Stakeholders

Introduction

Recent years have seen an expansion of existing biobanking structures and emergence of new biobanks focusing on populations, diseases, biological samples and data, leading to an above-average increase in research that make use of these infrastructures (Astrin and Betsou 2016) as well as expansion of biobanks into greater networks (Ortega-Paino and





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Risk mapping for better governance in biobanking: the case of biobank.cy

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Introduction: Risk governance is central for the successful and ethical operation of biobanks and the continued social license for being custodians of samples and data. Risks in biobanking are often framed as risks for participants, whereas the biobank's risks are often considered as technical ones. Risk governance relies on identifying, assessing, mitigating and communicating all risks based on technical and standardized procedures. However, within such processes, biobank staff are often involved tangentially. In this study, the aim has been to conduct a risk mapping exercise bringing biobank staff as key actors into the process, making better sense of emerging structure of biobanks.

Methods: Based on the qualitative research method of situational analysis as well as the card-based discussion and stakeholder engagement processes, risk mapping was conducted at the biobank setting as an interactive engagement exercise. The analyzed material comprises mainly of moderated group discussions.

Results: The findings from the risk mapping activity are framed through an organismic metaphor: the biobank as a *growing, living organism in a changing environment*, where trust and sustainability are cross-cutting elements in making sense of the risks. Focusing on the situatedness of the dynamics within biobanking activity highlights the importance of prioritizing relations at the core of risk governance and promoting ethicality in the biobanking process by expanding the repertoire of considered risks.

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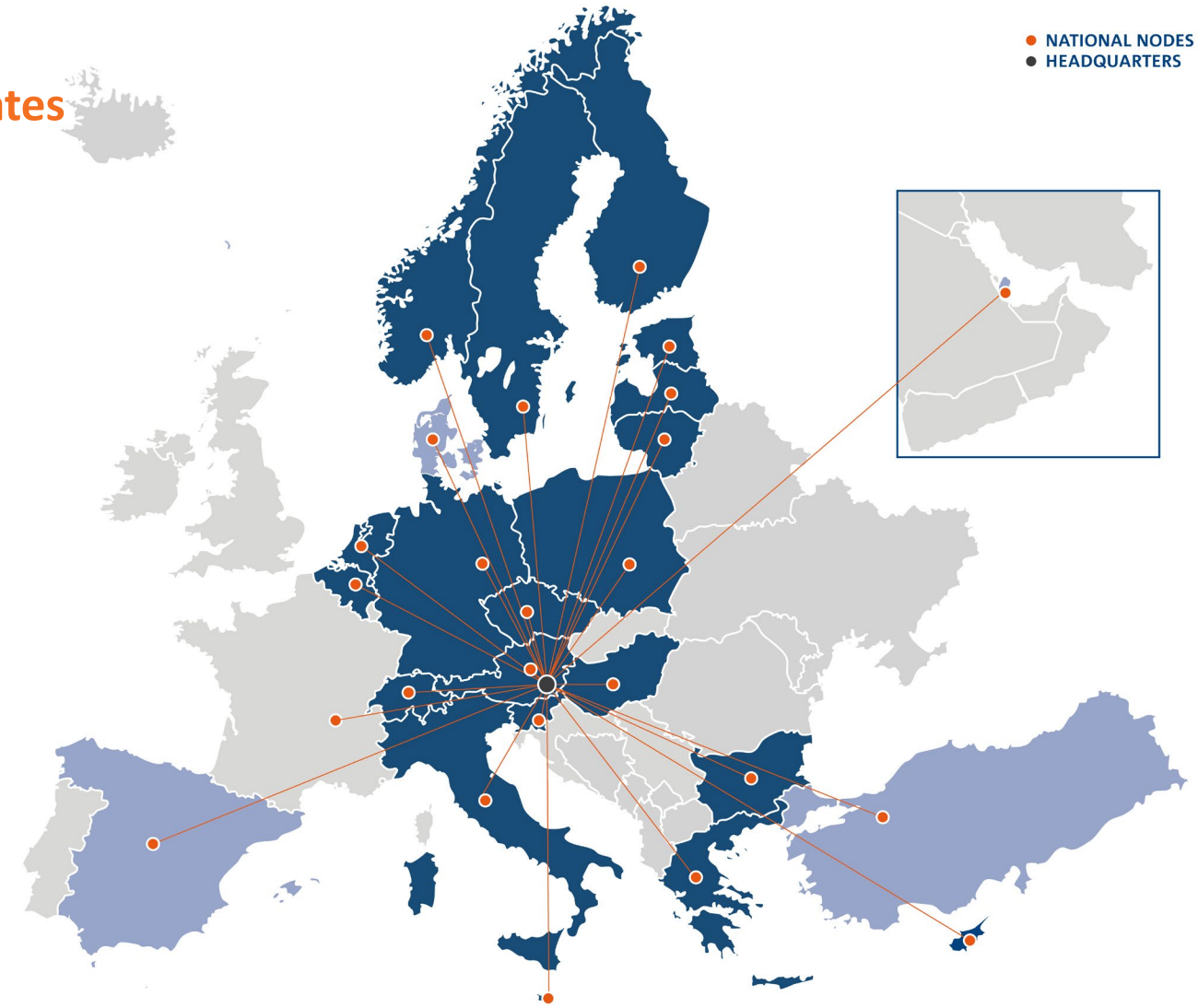
Switzerland



… and growing interest

5 Observers

Denmark
IARC/WHO
Qatar
Spain
Turkey

Comprising

- > 700 biobanks
- 24 National Nodes
- 3 Expert Centres
- 1 Headquarter
- & affiliated partners

MEMBERS OF BBMRI-ERIC
OBSERVERS OF BBMRI-ERIC

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BBMRI enabling personalised medicine through:

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- Helpdesk Network
- Ethics Check
- Training
- Code of Conduct for Health Research

Public Affairs & Stakeholder Engagement

- Member States & Strategic Partners
- EU & Global Affairs
- Patients & Public
- Scientific Societies
- Industry Collaborations

Biobanking Development

- Biobanks & Universities
- National Nodes
- Expert Centres
- Sustainability

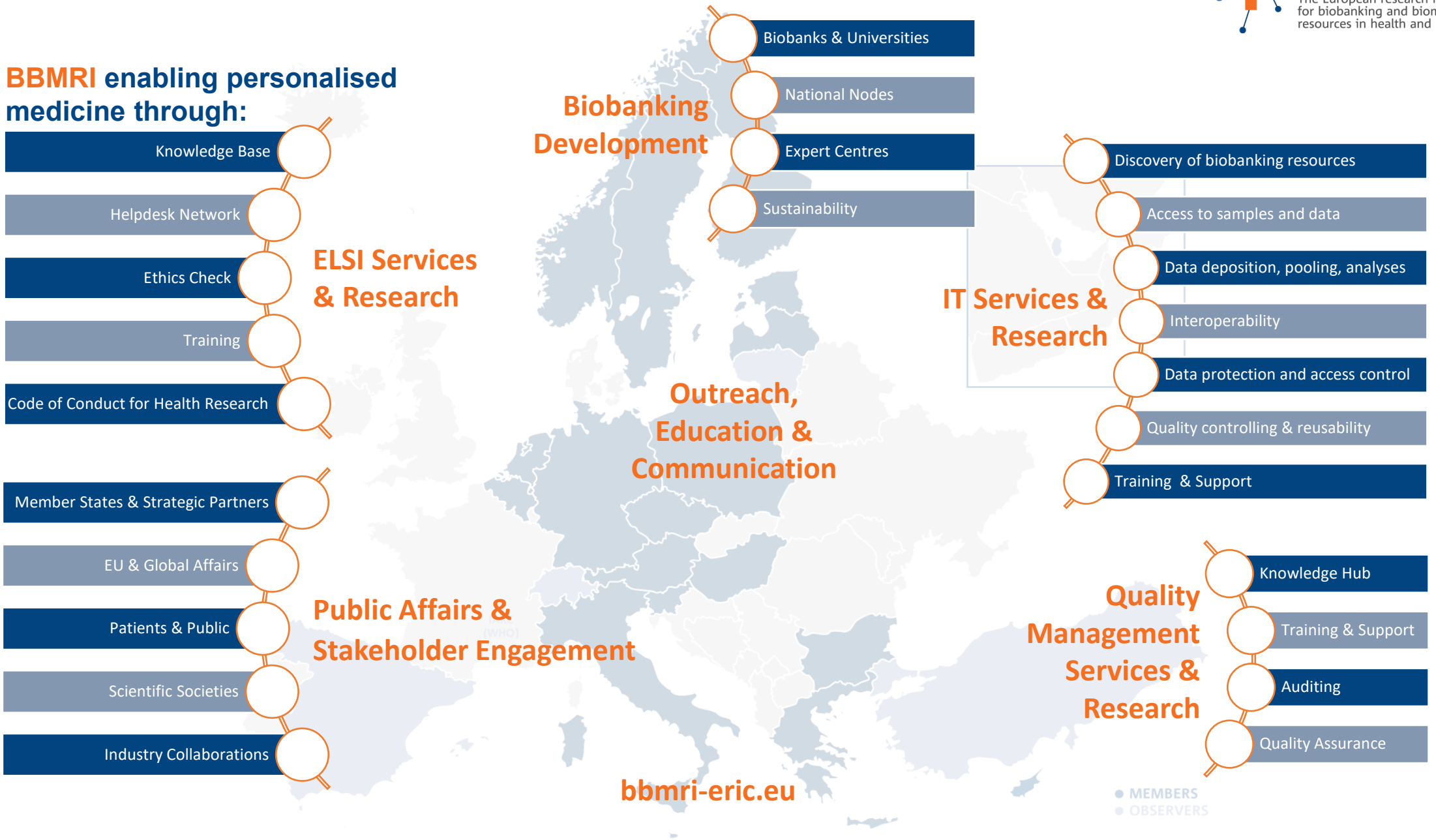
Outreach, Education & Communication

IT Services & Research

- Discovery of biobanking resources
- Access to samples and data
- Data deposition, pooling, analyses
- Interoperability
- Data protection and access control
- Quality controlling & reusability
- Training & Support

Quality Management Services & Research

- Knowledge Hub
- Training & Support
- Auditing
- Quality Assurance



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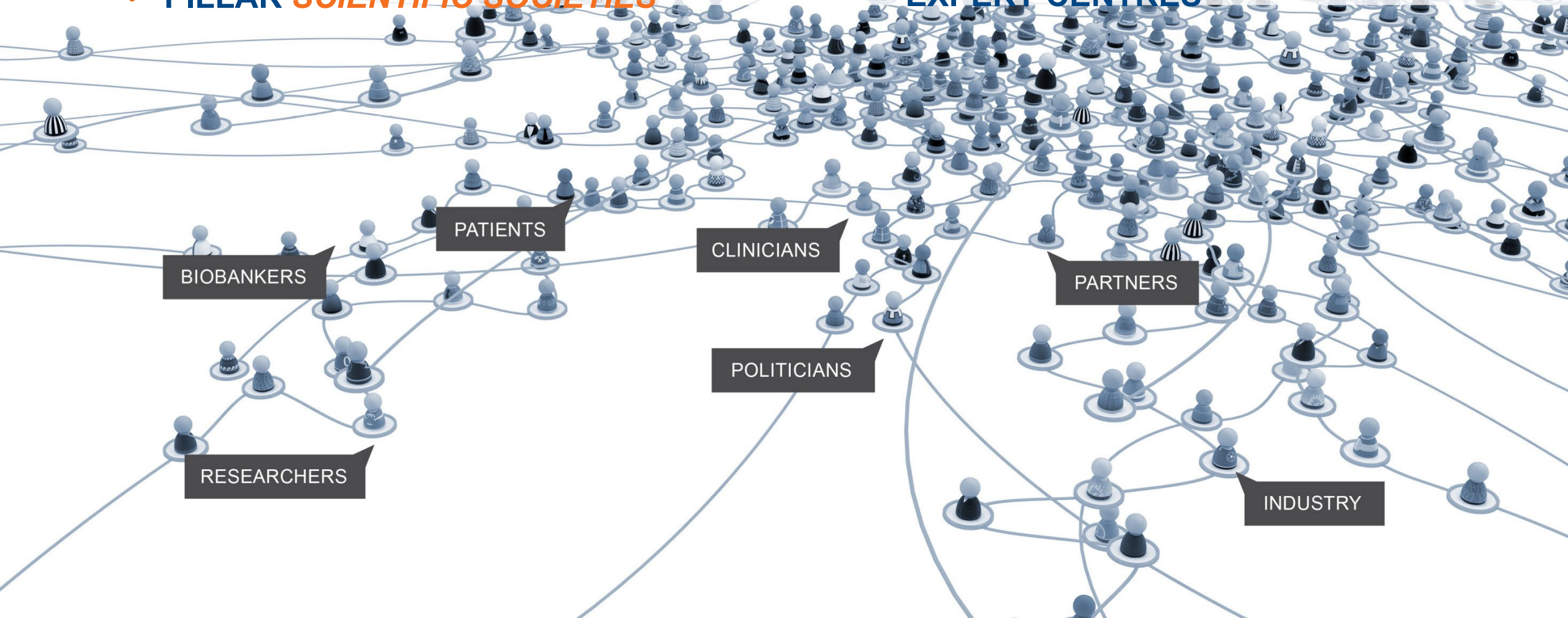
STAKEHOLDER FORUM & COMMUNITY ENGAGEMENT

- PILLAR *PATIENTS & PUBLIC*
- PILLAR *INDUSTRY*
- PILLAR *SCIENTIFIC SOCIETIES*

- RESEARCHERS & UNIVERSITIES
- CLINICIANS & HOSPITALS
- EXPERT CENTRES



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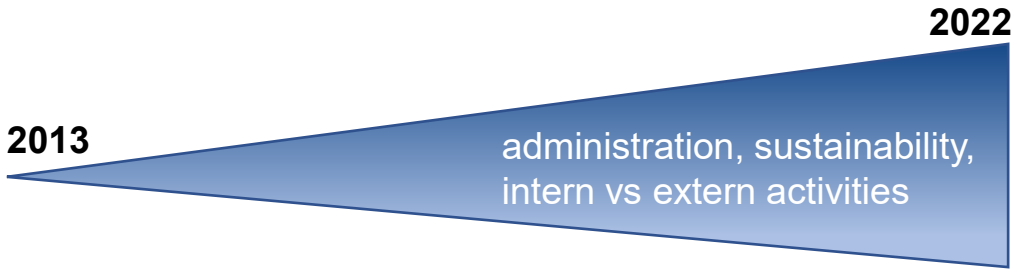
BBMRI-ERIC
HISTORY AND MISSION

2006: ESFRI Roadmap

2008-2011: BBMRI-Preparatory Phase (FP7 Project)

2011-2013: Interim Phase (establishing legal entity & MS commitment)

2013-ongoing: Implementation & Operation Phase



2 Employees

> 40 Employees

BBMRI-ERIC's Mission

Establish, operate, and develop a pan-European distributed research infrastructure of biobanks and biomolecular resources

to facilitate the ACCESS to RESOURCES as well as FACILITIES and to support high-quality biomolecular and medical research.

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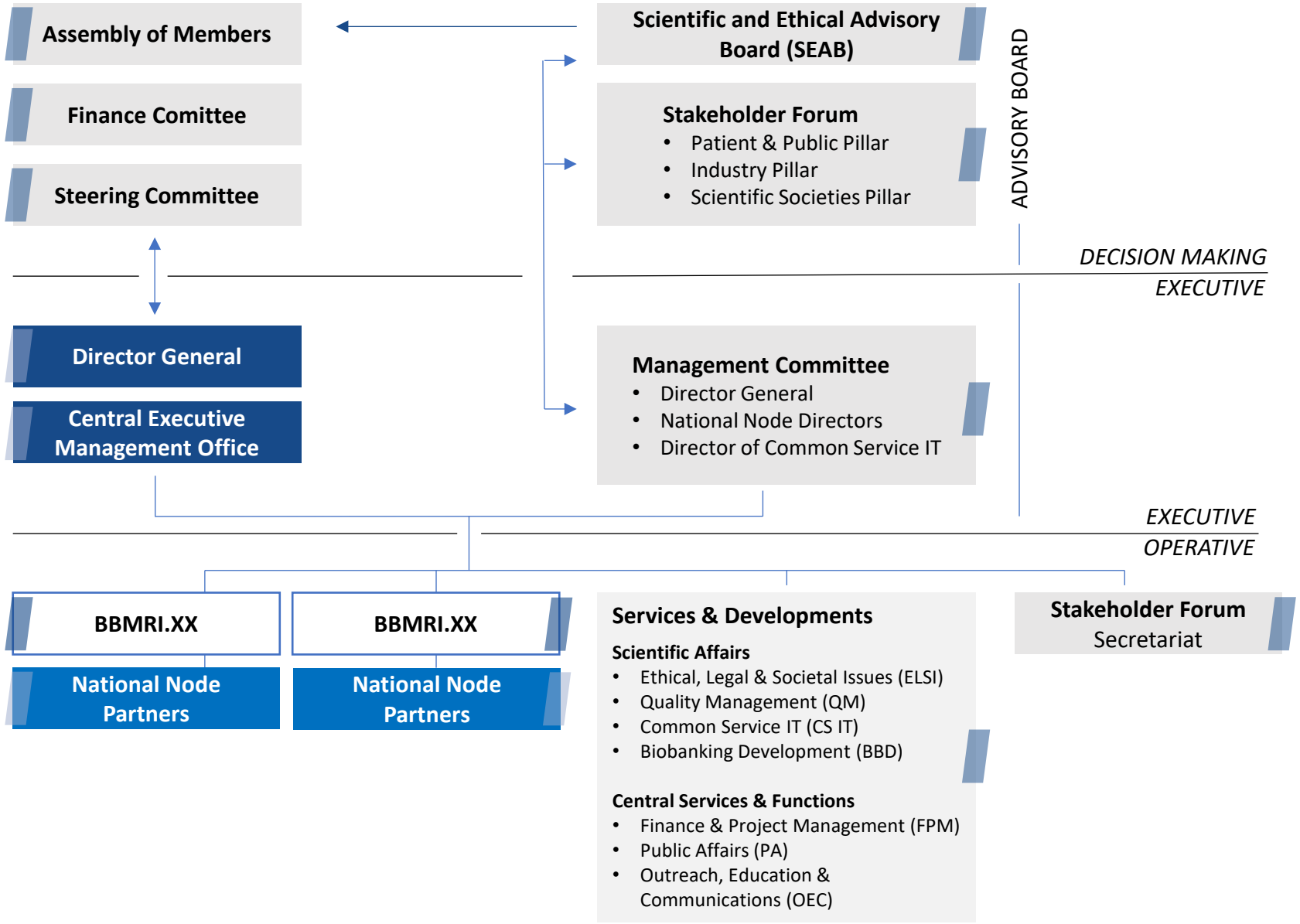
GOVERNANCE



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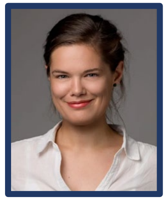
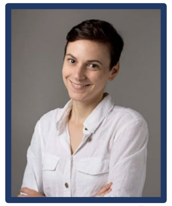
ELSI EXPERTS HQ & NNs

IT'S THE PEOPLE! 40+ ELSI EXPERTS

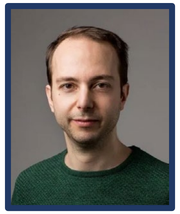

Michaela Th Mayrhofer


Melanie Goisauf


Mónica Cano Abadía


Irene Schlünder

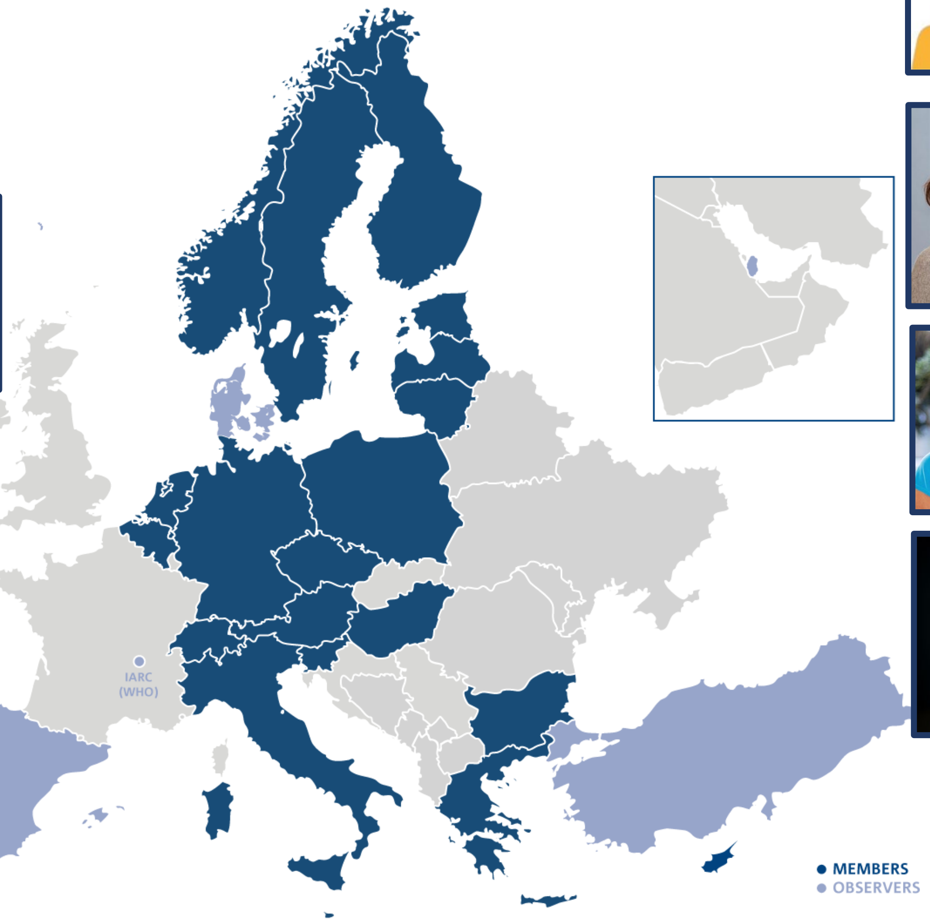

Ilaria Colussi

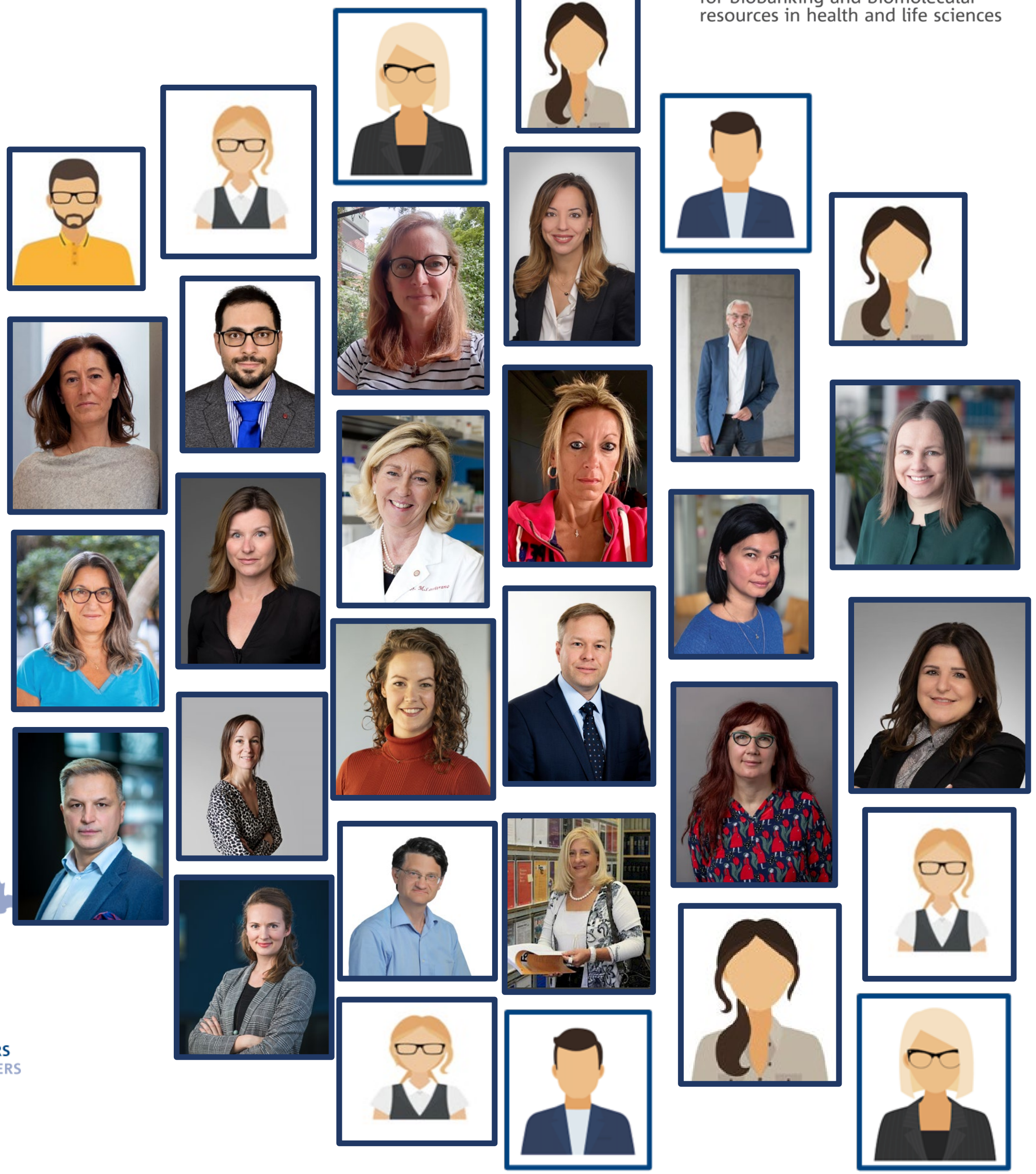

Kaya Akyüz


Jasjote Grewal


Erdina Ene


Verena Borecky



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Thank you!

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