

Biobanks: European and National Perspectives

INNOCHRON - Training School on Bio-Banking on Neutropenias

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Biobanking as a Global Phenomenon

In the TIME magazine issue of March 2009, article featured biobanks as one of the “10 Ideas Changing the World Right Now.”¹

In the article, biobanks were introduced as an “organic bank account” to safeguard people’s most valuable assets. Rather than depositing money in a personal bank account, it is a repository for people to put in their biomaterials - blood, tissue samples and DNA - in order to earn medical interest some later day in the form of new knowledge and therapies for diseases”.



“What’s in a name? That which we call a rose by any other name would smell as sweet?”

- Historically, the phrase has been used to imply that the names we use to describe things do not always reflect what they actually are.
- Although the term “biobank” did not appear in the literature before 1996, the term “biobanque” may have been first used in 1992 by a pharmacist in the Picardie Regional laboratory to describe a collection of valuable biospecimens from a Sexually Transmitted Disease (STD) clinic **accompanied by full clinical and laboratory annotations**

‘What is a Biobank?’

- Biobanks contain ‘biological resources’ which refer to ‘living organisms, cells, genes, and the related information’ that are ‘the essential raw materials for the advancement of biotechnology, human health, and research and development in the life sciences’ (OECD 2001: 11).
- Biobanks can be defined as **facilities that hold biological material and associated data in an organized manner**
- The notion ‘biological material’ **can include** entire organs (such as the brain), tissue both normal and pathological, cells or so-called body waste products (such as hair, nail, urine or the placenta).

‘What is a Biobank? (cont.)

- ‘**Associated data**’ can consist of the name and date of birth of the patient/donor but also of the handling conditions of the derived sample or lifestyle data.
- The scope and scale of associated data **differentiates** from biobank to biobank; data may derive from existing medical files, or be generated in an extensive process, usually through comprehensive questionnaires, in other cases.
- An ‘**informational turn**’ was depicted in the biological sciences, especially as **new research practices reliant on information technologies**, such as the use of **databases**, which hold the promise of **searchability** and **easy access**, are **integrated** in biomedical knowledge production

‘What is a Biobank? (cont.)

- In the **post-genomic era**, material or biological samples and their associated data are collected, registered, manipulated, conserved, stored, and distributed for many purposes.
- This procedural practice has been lately referred to as ‘**biobanking**’. The term ‘**biobank**’ appeared for the first time in the article “Cancer risk and oxidative DNA damage in man” by Steffen Loft and Hendrik E. Poulsen (Loft and Poulsen 1996) but was not frequently used until 2000.
- Originally, ‘biobank’ was only used to refer to large population-based collections of human tissue and related data for research purposes.

‘What is a Biobank? (cont.)

- Today, ‘biobank’ is used as an **umbrella term** for ‘genetic database’, ‘tissue bank’, ‘human genetic research database’, ‘genomic database’, ‘population database’, ‘research repositories’, ‘DNA bank’, ‘DNA databank’, ‘plant and animal sample storage’, ‘forensic databank’, ‘gene bank’, ‘biological resource center’ etc.
- Consequently, all kind of biological repositories that store not only human but also animal, plant or microbial specimens for biomedical and public health research (e.g., the Nordic Canine Biobank, NCBB3; the Australian Plant DNA Bank; the Victoria Cancer Biobank), but also for biolaw (e.g., the UK National DNA database,) and business (e.g., Redcord, Colombia), are biobanks

What is a Biobank? (cont.)

- However, being a catchy term, ‘biobank’ is easily remembered, raises (mostly positive) associations, and sells the practice of collecting, registering, manipulating, conserving, storing, and distributing biological specimens to all audiences – **no matter for whatever purposes the collected specimens are collected and used later on.**
- In addition, the bank analogy also contains references to **commercialization** and might raise associations with banking practices, like trading and speculating but also refers to aspects of **ownership**.
- The use of the “bank” component, immediately suggests **security** and **competent management** of the collected samples and medical information and, **consent and legitimacy** as well.
- Consequently, the **bank metaphor** contains both saving account and entrepreneurial investment expectations, but also implies **distinct governance structure and well-established control mechanisms**.

Why biobanking?

- In order to **investigate the complex mechanisms underlying diseases**, large populations need to be studied, a requirement which led to considerations and claims about what populations are most suitable for this endeavor.

Biobanks and biomedical research

- Biobanking is not merely “the simple technical and logistical approaches to collecting, processing, and storing biospecimens
- In our imagination, biobanks are usually huge freezers with frozen blood or tissue samples, or pathology departments with collections of formalin-fixed, paraffin-embedded (FFPE) tissues. This was the fact over 100 years ago. These collections, generally of the FFPE type, were (and still are) necessary for patient diagnoses in clinical centers. Nevertheless, **biobanking evolved during the last 20 years**, and such collections may contribute significantly to biomedical research.

Biobanks and biomedical research

- Biobanking is now considered a cornerstone in the development of Translational Research (TR) and Precision Medicine (PM).
- The very idea of biobanks is being **reshaped**, as actual operations, conventions, regulatory frameworks, are linked to TR and PM
- The core idea for the **reproducibility of research results** is absolutely related **to the quality of the biological material** and the technical processes, and they have to be adequately controlled.
- This principle led to the development of best practices, the evolution of biospecimen methods research and the general recognition that **biobanking needed to come of age and become a science in its own right**.
- **Biobanks are considered to be promising infrastructures for biomedicine and related to biomedical knowledge production as well.**

Biobanks and biomedical research

- What biobanks are ‘doing’ goes far beyond contributing to basic research in biology. They are **connected to a variety of scientific, economic and political objectives**.
- In recent years they have become an **important policy matter**, with large genomics initiatives being introduced in different countries in order to be at the fore front of research and development.
- These include the “100,000 Genomes Project” in the UK and the “All of Us” Program in the USA (which has been accompanied by a renewed call to arms regarding the war on cancer – Cancer Moonshot), as well as the German Personalized Medicine Initiative.

European Policy

- In the context of the European Research Policy, the development of a European Research Infrastructure (BBMRI-ERIC) gathering stakeholders from different countries, regulations, developments, and projects that condition and constrain biobanking have had (and continue to have) an effect **on what biobanks are** and what kind of knowledge or scientific practices they could produce.
- Biobanks are not merely constrained to technological themes.
- They also highlight matters of informed consent, ethics or the relationships between publics and biobanks.

Scaling up biobanks: the BBMRI-ERIC

- The European Strategy Forum on Research Infrastructures (ESFRI) was set up in 2002 following an EU Council call to support and encourage multilateral projects in the EU and internationally, aiming to develop and improve different research infrastructures.
- The BBMRI-ERIC, as one of the projects within the pan-European research infrastructures' strategy in the **2006 roadmap** began its preparatory phase in 2009 and ran until 2011. During this phase, in 2010, the **JRC Scientific and Technical Report published "Biobanks in Europe: Prospects for Harmonization and Networking."**
- This report served as a call for attention for what **was yet to come in biobanking**, as well as a formal **recognition of the overwhelming harmonization challenges** to be faced not only at the pan-European level but also at the national and regional levels.

Scaling up biobanks: the BBMRI-ERIC (cont.)

- However, harmonization processes and procedures allowed the transformation of researchers' fridges or hospital anatomical pathology deposits into the technoscientific infrastructures we call biobanks, which later would be proposed to become virtually networked by the European Commission in 2013 as the **Biobanking and “BioMolecular Resources Research Infrastructure—European Research Infrastructure Consortium” (BBMRI-ERIC)**.
- This pan-European initiative placed biobanks **in a process of transition from individual research tools to complex international research infrastructures**.
- **This process is not an ordered and homogenous** change, but rather a complex transition, since a linear development cannot be assumed.
- These infrastructural transitions and their complications take part in biobanks' social worlds and practices.

Scaling up biobanks: the BBMRI-ERIC (cont.)

- Biobanks became national projects involving articulations between the state, the public, the scientific community, and economic agents. The spread and rise of national biobanks run chronologically and in parallel with the last phase of the Human Genome Project (HGP).
- HGP, is a large-scale biology project that has been considered as a transformative agent of biology and medicine throughout a “**big science**” approach. In April 2003, at the completion of the HGP and the start of the referred to as the **post-genomic era**, a benchmark for “**thinking bigger**,” which is inseparable from biosciences research and thus from biobank projects, had germinated.
- “**Thinking bigger**” can be understood as the result **of a shift in biological research** to examining **the larger picture** in order to research “what life is: the mechanisms, pathways, and systems”, and **discerning complex connections that, on a smaller scale, could not be detectable**.
- A part of “thinking bigger” in biomedical research **draws upon biobanks**, whose procedures called for harmonization to allow the general use of samples, their associated data, and the services required to ease the post-HGP biomedical research

Scaling up biobanks: the BBMRI-ERIC (cont.)

- The BBMRI-ERIC does not consist of the establishment of a new physical European biobank, but the creation of an **active network among existing biobanks and bioresources**.
- **Network membership requires an economic contribution by the member state**, and then, each member state **designates a national node** that will coordinate the existing biobanks in that country to scale-up their bioresources to the pan-European level.
- This network brings forth tools such as the **BBMRI-ERIC directory**, which enables **searches** of the bioresources of European biobanks by applying several search filters and variables. Expansion occurs through **scaling-up**.

Scaling up biobanks: the BBMRI-ERIC (cont.)

- Overall, the BBMRI-ERIC intends to integrate already existing research infrastructures and research communities from the field of life sciences in Europe, taking advantage **of information systems and boosting biobanks' capabilities for biomedical and drug research.**
- **Bioinformatics'** combination of molecular biology investigation and computer science **has promoted an emergent way of understanding diseases** that depends upon infrastructures that build and maintain **large-scale networks of databases**, establishing and integrating research infrastructures for the “**virtualization of biological work and biological objects**”.
- From the scientific community perspective, thicker networked infrastructures are crucial in order to use the biomedical capabilities that biobanks can provide for PM as well as for research on **biomarkers** and their resulting potential treatments

Biobanking and Biomolecular Resources Research Infrastructure

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European Research Infrastructure Consortium

European Commission Decision 2013

Life Science Research Infrastructure build upon:

18 Member States

Austria
Belgium
Bulgaria
Czech Republic
Estonia
Finland
Germany
Greece
Hungary (joined 2021)
Italy
Latvia
Malta
Netherlands
Norway
Poland
Slovenia (joined 2022)
Sweden
United Kingdom



6 Observers

Cyprus
IARC/WHO
Lithuania
Spain (joined 2021)
Switzerland
Turkey

Comprising

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

 MEMBERS OF BBMRI-ERIC
 OBSERVERS OF BBMRI-ERIC

... and growing interest in & outside Europe

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.

BBMRI enabling precision medicine through:

Knowledge Base

Helpdesk Network

Ethics Check

Training

Code of Conduct for Health Research

Member States & Strategic Partners

EU & Global Affairs

Patients & Public

Scientific Societies

Industry Collaborations

ELSI Services & Research

Public Affairs & Stakeholder Engagement

Biobanking Development

Biobanks & Universities

National Nodes

Expert Centres

Sustainability

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

ELSI Services & Research



We support the research community by facilitating knowledge exchange, compliance with regulatory requirements, promoting best practices and ensuring guidance on ethical, legal and societal (ELSI) issues. www.bbmri-eric.eu/elsi

Key topics: Quality of Life, AI, GDPR Compliance & Code of Conduct, Incidental Findings



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.

- > [EU Projects](#)
- > [Publications and Results](#)

Open-access resource platform that provides practical know-how for responsible research



SERVICE

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

- > [ELSI Helpdesk](#)
- > [ELSI Knowledge Base](#)
- > [Ethics Check](#)

Experts answer your specific questions



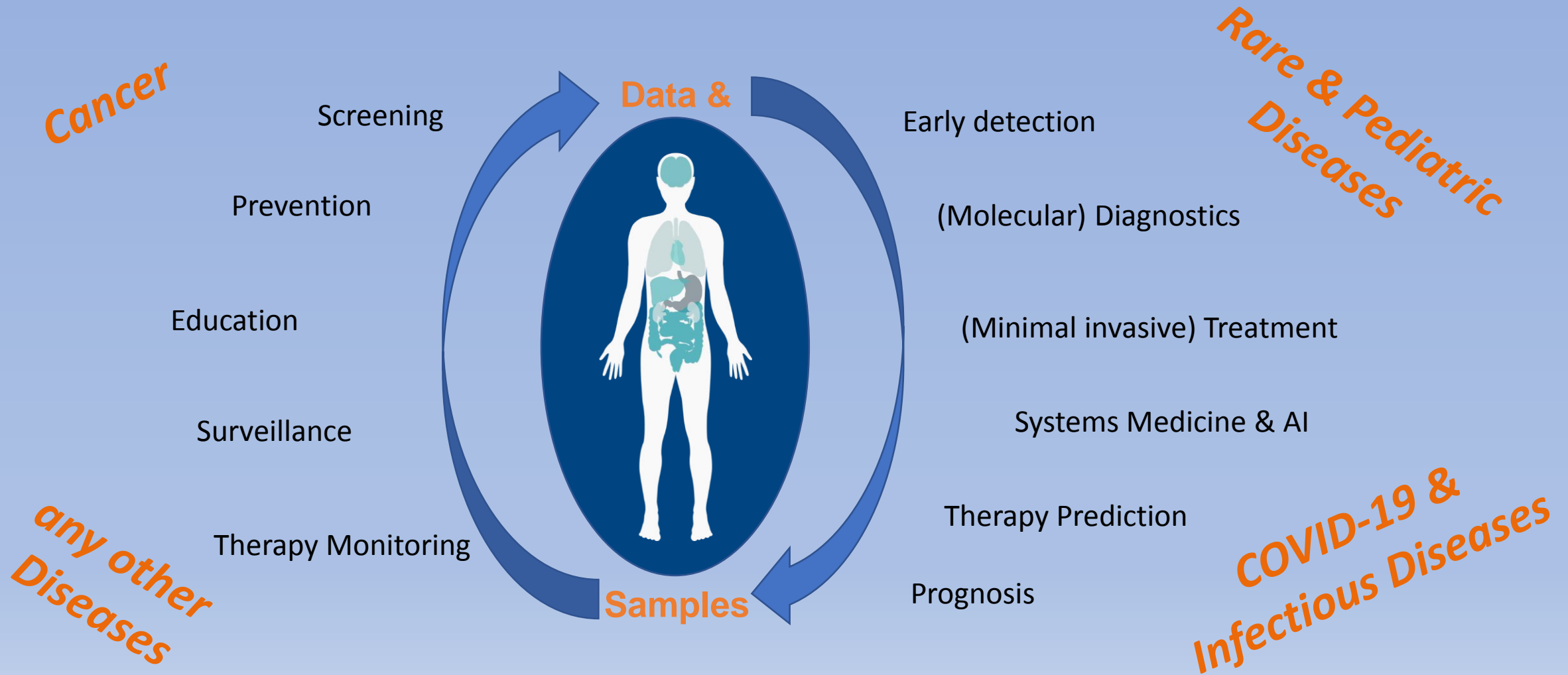
TRAINING

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

- > [ELSI Webinars](#)
- > [ELSI Training Courses](#)

Code of Conduct for GDPR

Advancing & Implementing *Precision Medicine*





#BBMRI_QM
@BBMRIERIC

BBMRI-ERIC QUALITY MANAGEMENT SERVICES FOR BASIC AND APPLIED RESEARCH

CME-accredited BBMRI Academy



KNOWLEDGE HUB

Find everything you need to know about quality management in biobanking and biomedical research in one place: The BBMRI.QM Knowledge Hub consists of a pool of experts that can help you with any of the following:

- BBMRI-ERIC liaisons with international standardization organizations
- International standards relevant for biobanking and biomedical research
- Quality management tasks in EU projects
- Biobanking in times of COVID-19
Recordings available!



TRAINING & SUPPORT

Whether you are looking for training opportunities or practical support with your quality management – quality experts can provide you with a solution tailored to your needs.

Within the BBMRI.QM network, we offer in-house and online training, university courses, summer schools, short courses, workshops, and consulting services covering different quality management systems:

BBMRI.QM Training & Education Programmes:

- Training series about molecular in vitro diagnostic examinations – specifications for pre-examination processes **NEW**
- Training series about the biobanking standard ISO 20387:2018 **Recordings available!**



AUDITING

If you run a non-certified biobank and/or you want to know if the samples stored fulfill certain quality requirements, get the support of BBMRI.QM. We offer peer-review-style audits on request. Take the next QM improvement step together with us!

Step 1: Assess your processes with the BBMRI-ERIC Self-Assessment Survey (BBMRI-ERIC SAS).

- What is the BBMRI-ERIC SAS?
- Short explanation about access principles to the BBMRI-ERIC SAS
- Request the BBMRI-ERIC SAS

Step 2: Request a BBMRI-ERIC audit

- BBMRI-ERIC Audit

Step 3: A positive audit will lead to a quality mark in the Directory

- Q-mark in the BBMRI-ERIC Directory



QUALITY ASSURANCE

Task Force to define and provide biomarkers (intrinsic/extrinsic) that allow for standardized assessment of sample quality with a focus on liquid biopsies) through biospecimen research.

RESEARCH
Biospecimen
Biomarker
Sample quality

QUALITY ASSESSMENT
Q-mark for
biobanks and
collections

CONTRIBUTE
international
standard
developments

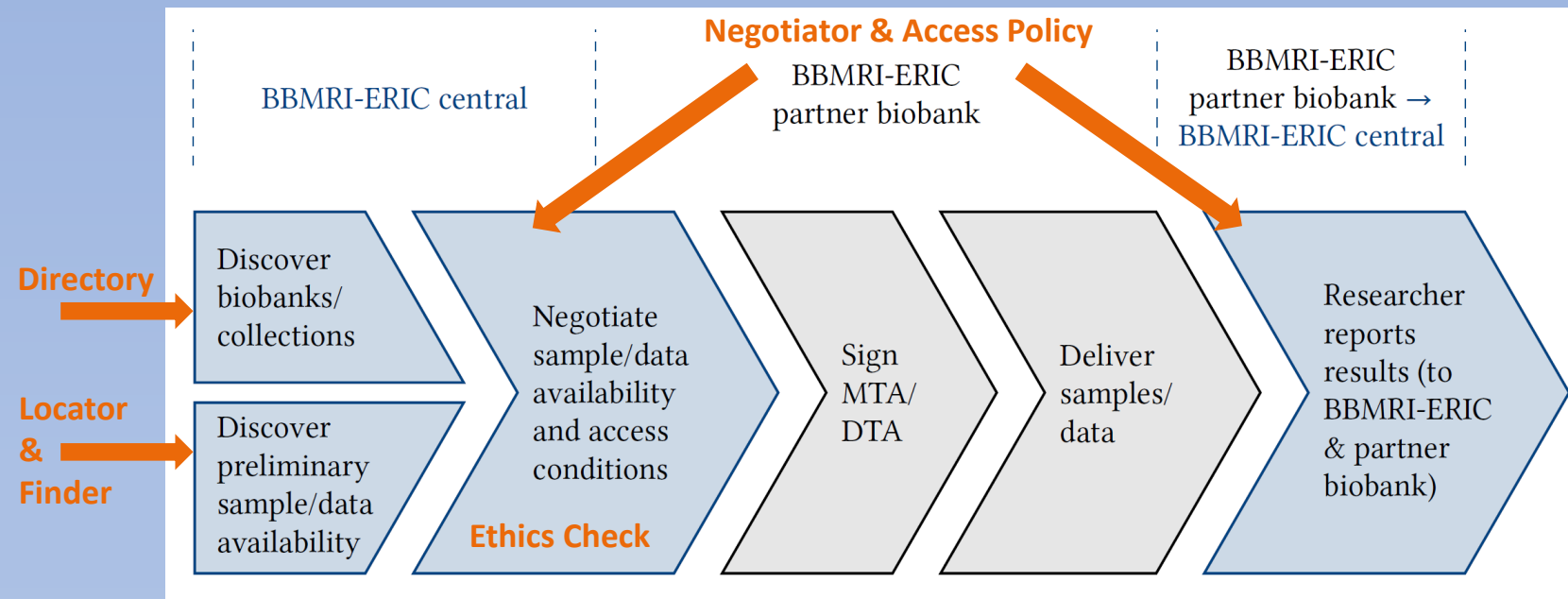
PROJECT
partner
providing QM
Services

OUTREACH
900
participants
56 countries

IT Services & research

BBMRI-ERIC Directory

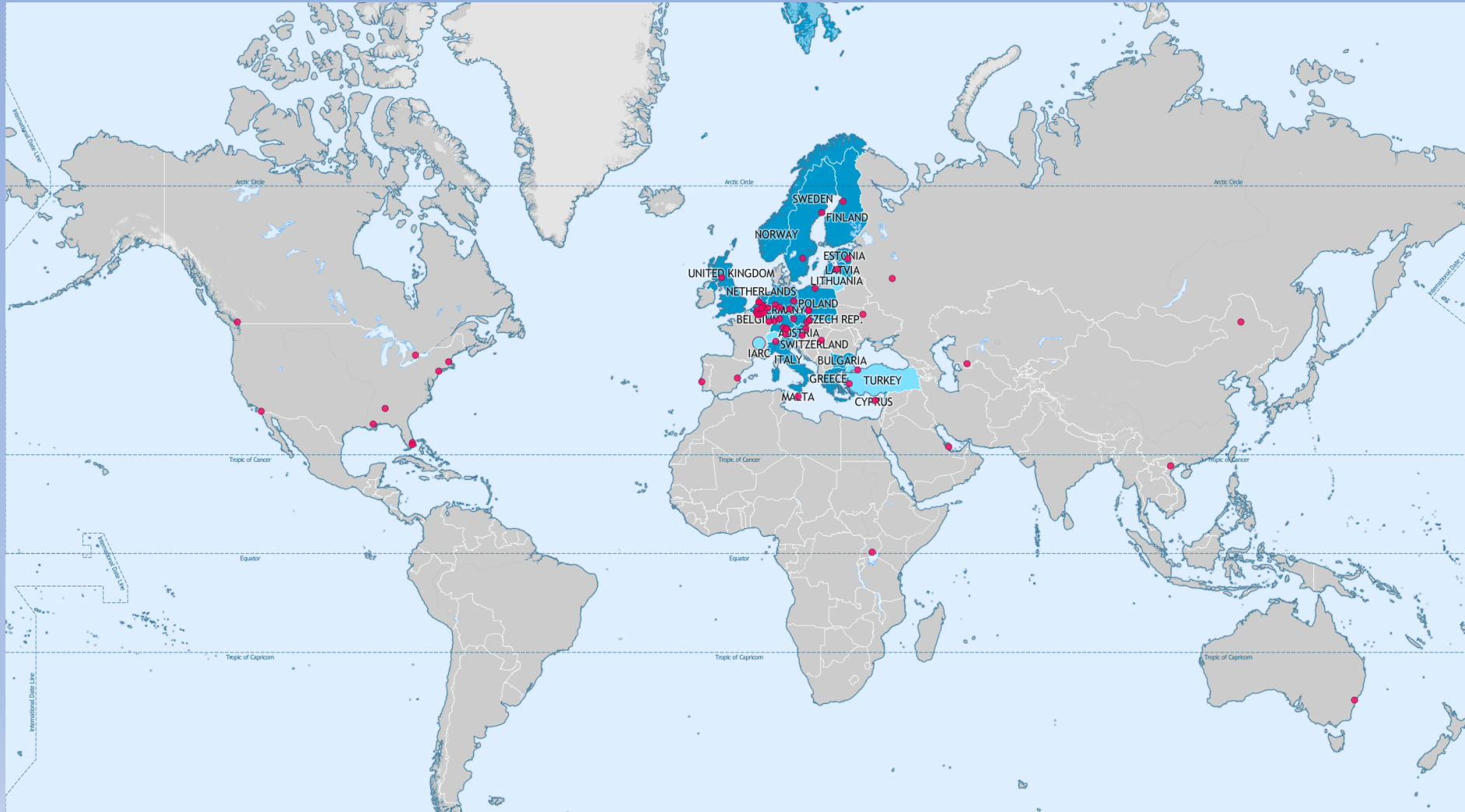
- > 700 biobanks
- *Estimated* >100,000,000 samples and associated data



Directory is open for **any** biobank to visualize **COVID or Rare Disease** samples & data for use!

BBMRI-ERIC Directory – COVID-19 samples & data

- 88 biobanks with 92.052 donors in COVID-relevant collections
- >490.000 COVID-related samples and associated data



ACCESS PROCEDURE

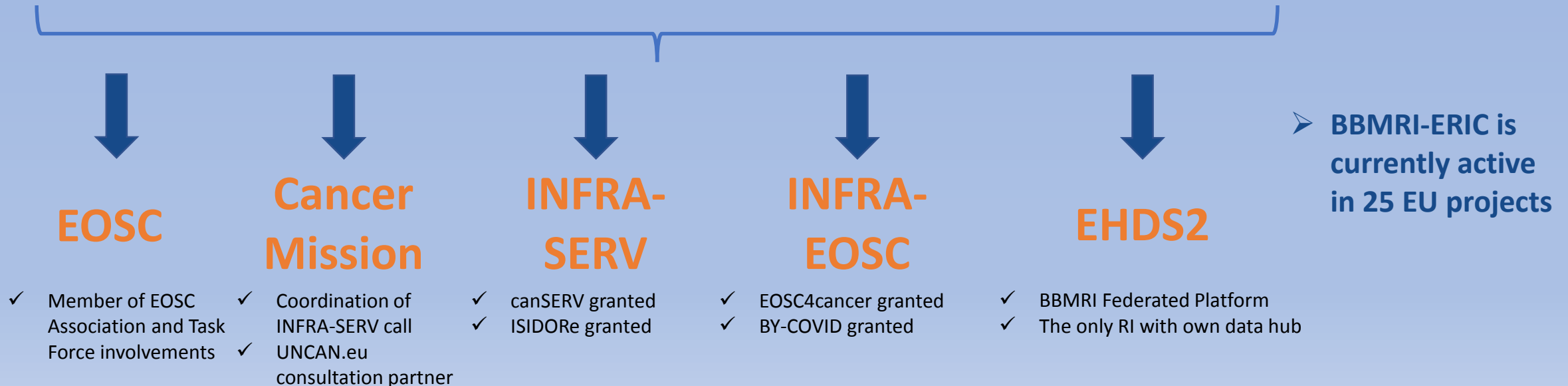
- ▶ **BBMRI-ERIC Directory:** <https://directory.bbmri-eric.eu/>
 - **COVID-19** cohorts
 - **Cancer** cohorts
 - **Rare Disease** cohorts
 - **Pediatrics** cohorts
 - other disease cohorts

- ▶ **BBMRI-ERIC/GBA Locator:** <https://samplelocator.bbmri.de/>
- ▶ **BBMRI-ERIC Negotiator:** <https://negotiator.bbmri-eric.eu/>
 - or directly via Directory and Locator services
- ▶ **BBMRI-ERIC Helpdesk:** negotiator@helpdesk.bbmri-eric.eu

Advancements in 2021

➤ Accelerated developments in 2021

- **Datafication:** new IT-Task Forces
- **Management & Operations:** HQ, NNs & biobanks for sustainability & growth
- **Formalized Education:** QM-Academy with CME-accredited trainings
- **GDPR compliance:** Code of Conduct for Health Research



Stakeholder Forum

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

&

COMMUNITY ENGAGEMENT

- **RESEARCHERS & UNIVERSITIES**
- **CLINICIANS & CLINICS**
- **EXPERT CENTRES**

BIOBANKERS

PATIENTS

CLINICIANS

PARTNERS

POLITICIANS

RESEARCHERS

INDUSTRY



The Hellenic Network of Biobanks-BBMRI-GR

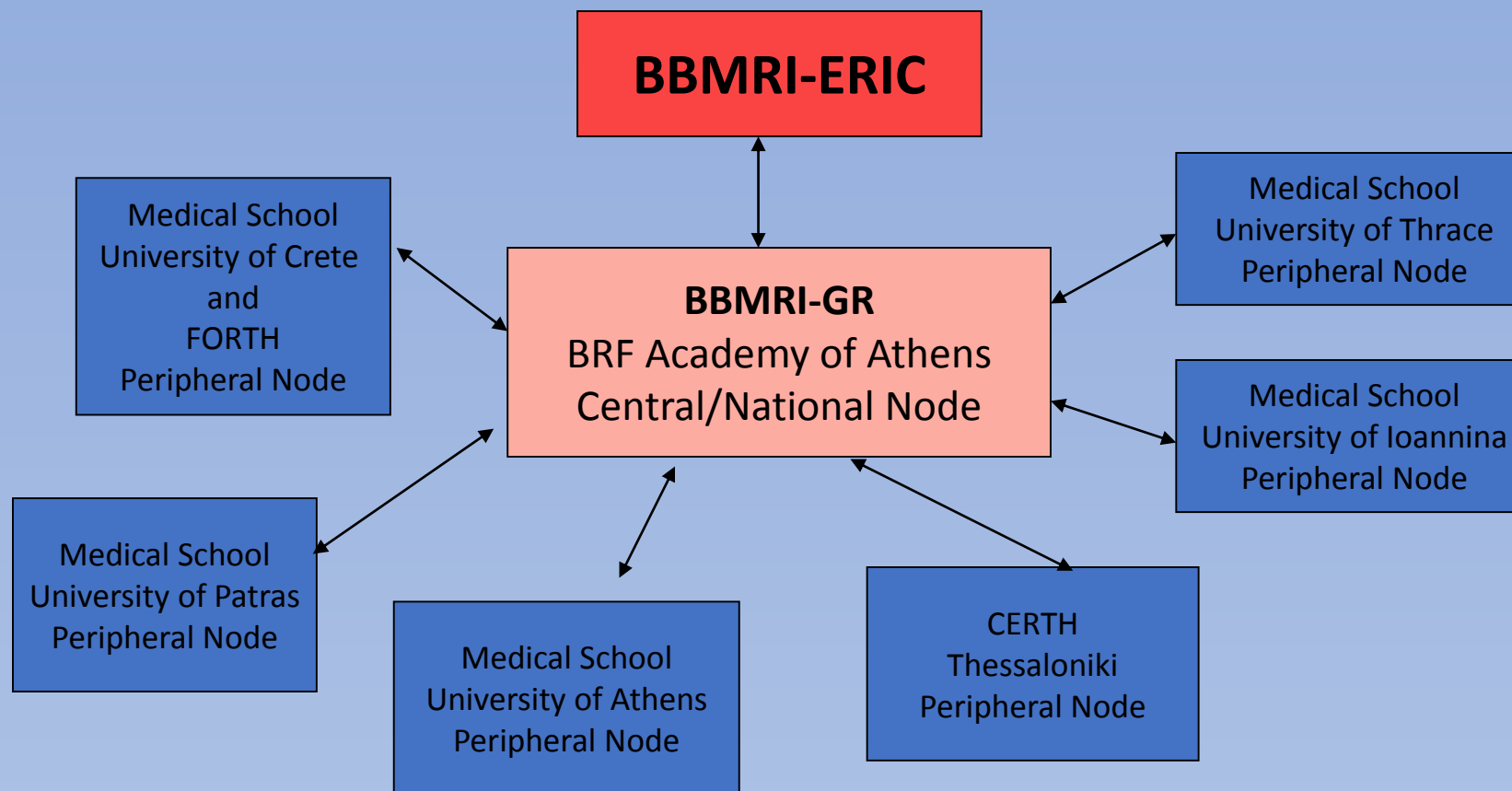
The BBMRI-GR Infrastructure

- BBMRI-GR is a integrating inclusive Research Infrastructure project for Greek human biobanks and collections.
- BBMRI-GR connects, Ministries, Research Centres, Universities, researchers, industry, hospitals and patients associations.
- BBMRI-GR is a national distributed infrastructure integrating biobanks distributed all over Greece. It covers the full spectrum of diseases e.g. neurodegenerative, cancer, hematological, lung disorders, rare diseases

BBMRI-GR

- BBMRI-GR is the interface with the BBMRI-ERIC, upgrading the Greek human specimens biobanks and collections to a new level of coordination and efficiency.
- BBMRI-GR is setting up a sustainable infrastructure which will provide new services, open access for users from public and private sector

Greek Network of Biobanks (BBMRI-GR)



BBMRI-GR. National Funding

- 2009

- Development of a national network
- Feasibility Study

- 2018

- Funding (500K€) for the development of BBMRI-GR

Implementation of BBMRI-GR

- Inventory of Biobanks of BBMRI-GR. Data and metadata related to the samples.
- Implementing Standard Operating Procedures (SOPs) in participating nodes.
- ELSI. Elaboration of Consent Forms. A conference on these issues will be organized.
- General Data Protection Regulation (GDPR). Implementation of the Regulation - GDPR for the protection of personal data for data encryption and access security
- Information Technology (IT) . Requirements analysis and specification. Design and original implementation of BIMS for the national network. Report on control, validation of operation and interoperability of the national network system of Biobanks.
- Networking, meetings and workshops in order to establish a community BBMRI-GR
- Collaboration with BBMRI-ERIC. Participation in the General Assembly, the Management Committee, the ELSI Group and the different *ad hoc* committees of BBMRI-ERIC.
- Pilot studies. Collaboration with industry
- Communication of the project. Collaboration with stakeholders e.g. Patients Organizations

BBMRI-GR. Outputs/Impact

- Exchange of data and samples, promotion of joint research programs and mobility of researchers at national and European level.
- Support to the activities on the personalized medicine in Greece
- Leveraging of funding opportunities for the sustainability of the BBMRI-GR
- Compliance with the Smart Specialization EU Regional Policy through the peripheral nodes.
- Societal impact, collaboration with different stakeholders, e.g. Industry, Patients Organizations, Ministries.

Future. Biobanks as mediators

- Pan-European infrastructures aim to resolve the tension between the local and the global, and, to do so, connections are made, for instance, through bioresource directories.
- Connections are **also stressed** in the BBMRI-ERIC Report (BBMRI-ERIC 2013, 22) where it is said that biobanks are expected to act as an **“intermediary”** between donors/participants, scientists, patients, hospitals, and so on.
- If recognition of biobanks’ **mediator position** is **central** to reaching their purpose, increasing their visibility **becomes a need** in order to make the assemblage work. For this reason, it was not surprising that the title of the current Action Plan of the BBMRI-ERIC 2019–2021 is **“increasing the visibility of biobanks and sample collections”** (BBMRI-ERIC 2019)

Biobanks as mediators

- However, intermediary is not an innocent term, there are nuances between intermediaries and mediators (Serres and Latour 1995; Latour 2005).
- Is biobanks' only purpose to allow access to samples and data or do they also redefine what they collect and share? An intermediary, according to Latour (2005, 39), “transports meaning or force without transformation”, working **as a black box** or a unit; while mediators are “endowed with the capacity to translate what they transport, to redefine it, redeploy it, and also to betray it” (Latour 1993, 81).
- Mediators can betray, but also care. In fact, biobanks tend to be endorsed as caretakers of the samples and their associated data. **Biobanks' curating practices and knowledge production on biospecimens shape and redefine how science is made.**

Michel Serres with Bruno Latour. *Conversations on Science, Culture, and Time*, 1995, The University of Michigan Press

Bruno Latour, *We have never been modern*, 1993, Harvard University Press

Bruno Latour. *Reassembling the Social. An Introduction to Actor-Network Theory*. Oxford, UK: Oxford University Press, 2005

Biobanks as mediators

- As mediators and not mere intermediaries, biobanks in the BBMRI-ERIC network express the aforementioned “thinking bigger.” In this case, “thinking bigger” does not entail “making it bigger” as in physics, like in the case of a Large Collider, but doing it bigger by digitally scaling up infrastructures, collaborations, and networked services. **Connections are what enable this “thinking bigger” and make it global.**
- **Biobanks act as mediators** when their central purpose is to curate, distribute samples and their associated data, instead of just accumulating them.
- Regarding biobanks as mediators, there are three different practices that characterize biobanks under the BBMRI-ERIC logic: globalizing, sharing, and localizing

Globalizing

- **Globalizing is made of connectivity and virtualization.** The pan-European network of biobanks builds on the connection of several distributed infrastructures, bearing upon directories, datasets, freezers, samples, computers, workers, lab devices, donors/participants, etc. **It is this infrastructural assemblage that enables global effects.**
- **Informatics capabilities, standards, and harmonization processes** enabled a network of freezers with biospecimens and their associated data. **Connections are what make the network global.**
- The biobanks network as global phenomena must have the capacity to exist across diverse social and cultural situations.

Sharing

- While the word “exchange” tends to refer to a more evident bidirectional relationship, in biobanking, the relationships consist more **of gift-giving, which engages with highly mediated modes of reciprocity.**
- The BBMRI-ERIC report reads: Typically, biobanks are viewed as a “**public good**”: a **shared** resource to which individuals contribute through their blood donations and that will, eventually, result in a **reciprocal benefit** in the form of better and more effective medical treatment options. (BBMRI-ERIC Report 2013, 38)

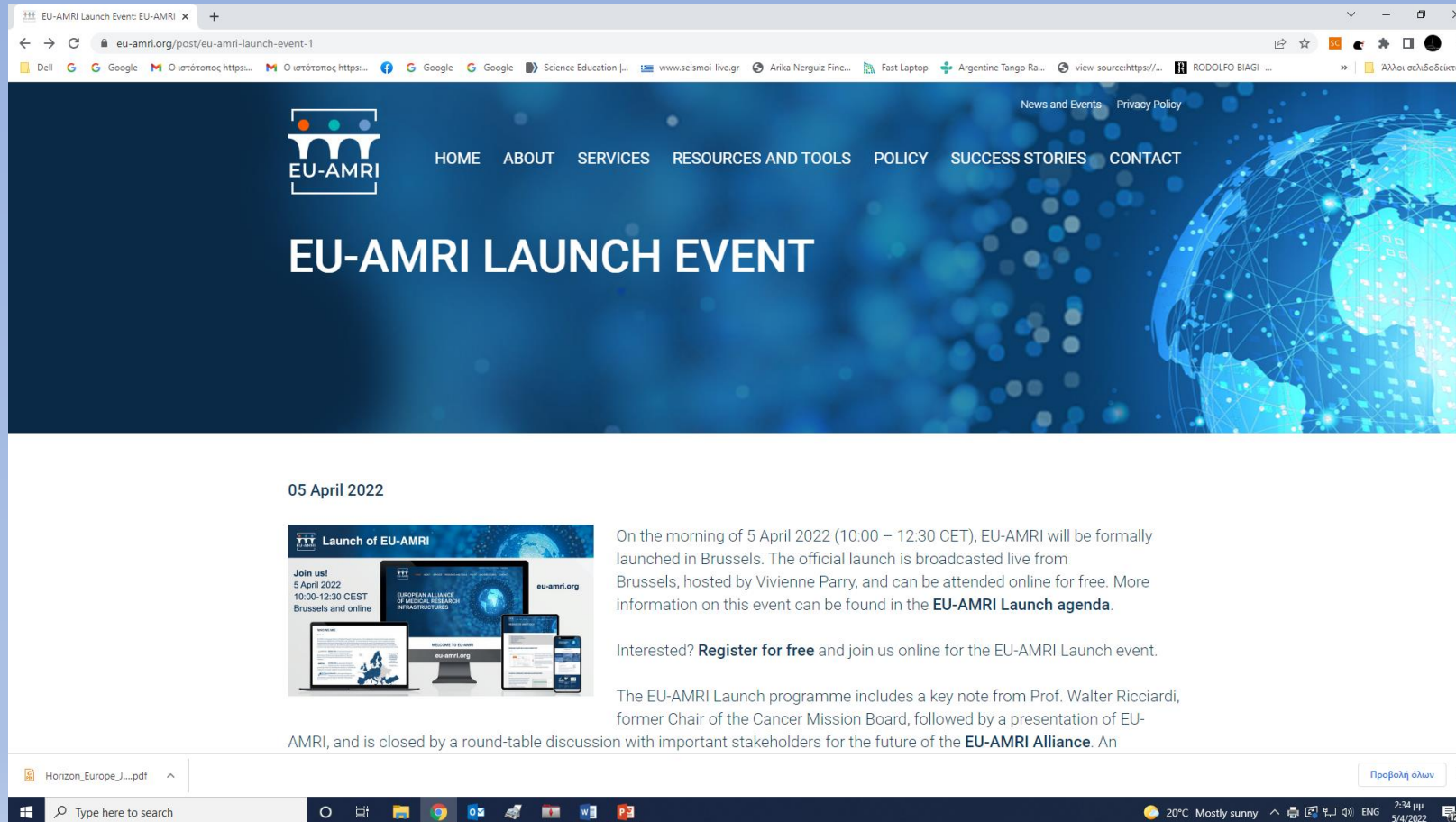
Localizing

- Contrasting with the virtualization of samples and sharing practices, we conceptualize **biobanks as nodes**, from which data flows internationally through local researchers and institutions.
- **Node implies an anatomic differentiated material mass**—for instance, biobanks' deposits, lab gloves, computer servers, and the material form of biospecimens are the aspects that can be readily differentiated from the whole research infrastructure.
- **The anatomical entity behind the notion of node provides physicality and avoids approaching digitization as lacking materiality.**
- Also, biobanks in the BBMRI-ERIC infrastructure and framework fit with **the global node concept**.
- **Nodes localize materials** . Without lab technicians processing the samples, server stations, office workers at the donor call centers, or security personnel attending around the clock to beepers connected to the frozen deposits, there is no biobank nor, hence, a network of biobanks.
- It is necessary to note that the BBMRI-ERIC defined the entities that coordinate **biobanks in different countries as nodes** and not biobanks themselves.

Biobanks as Global Nodes

- An analysis of the BBMRI-ERIC, defining biobanks as nodes, is going a step further, defining a biobank **as a node of a global network—a global sharing node**.
- The term **global sharing nodes** accommodates current biobank practices and enables us to grasp what biobanks are presented to do and become after the establishment of the BBMRI-ERIC infrastructure in Europe.
- Situating biobanks in the network **as global sharing nodes indicates** their reconfigurations, after the establishment of the BBMRI-ERIC in 2013

The Future



The Future



Medical Research Infrastructures: Solid foundations for Horizon Europe

BBMRI-ERIC, EATRIS-ERIC and ECRIN-ERIC are ESFRI medical research infrastructures (RI) with an ERIC status (European Research Infrastructure Consortia¹), established as **high quality service providers** for academia and industry. Through our services, we support discovery, translational and clinical research, underpinning a common objective – **creating, developing and delivering new value to European patients.**

Thank you!

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