HOW CAN BIOBANKING DELIVER ON THE PROMISES OF PERSONALISED MEDICINE?

FRANCESCO FLORINDI
STRATEGY & PARTNERSHIP MANAGER
Members of the BBMRI-ERIC Stakeholder Forum

- Richard Stephens, NCRI, UK
- Maggie Wilcox, ICPV, UK
- Marleen Katee, PSC Patients, The Netherlands
- Sophia Turner, useMydata, UK
- Alastair Kent, UK

- Tieneke Schaaj-Visser, The Netherlands
- Cornelia Specht, Germany
- Lukasz Kozera, Poland
- Cornelia Stumptner, Austria
- Anu Jalanko, Finland
- Anna Durnova, Austria
- Joanna Vella, Malta
- Erik Steinfelder, HQ
- Michaela Th. Mayrhofer, HQ
- Patrick Miqueu, Institut Bordet
- Morten Oien, NTNU
- Ronny Baber, University Hospital Leipzig
TODAY’S QUESTIONS

- What is the role of biobanking in genomics & personalized medicine?
  What role BBMRI plays?

- Do patients/citizens trust biobanks?
  Do biobanks take patients/citizens perspective into account?

- Why should we care?
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
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

- Disease-oriented biobanks for investigation of molecular mechanisms of diseases, establishment of human disease relevance Population-based cohorts for identification of genetic risk factors
- Tissue banks for investigation of target expression in diseased and non-affected organs
- Tissue banks for validation of human diseases relevance of animal models
- Tissues, bodily fluids, cells collected in clinical trials for biomarker validation (companion diagnostics)
- Tissue banks to investigate target expression in large patient cohorts to support the design of clinical trials
- Archived tissues, cells, bodily fluids for biomarker discovery control cohorts

Phases:
- Target Id
- Target Val
- Hit
- Lead
- Lead Optim
- Preclinical
- Phase I
- Phase II
- Phase III

Steps:
- Research
- Discovery
- Development
IT'S ALL BASED ON TRUST
LET’S MEASURE THE LEVEL OF TRUST IN BIOBANKS IN THIS ROOM…

PLEASE OPEN YOUR 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?
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 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
THE WORLD'S BIGGEST BIOBANK DIRECTORY

MAKING NEW TREATMENTS POSSIBLE
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

BBMRI-ERIC QUALITY MANAGEMENT SERVICES FOR BASIC AND APPLIED RESEARCH

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

Andrea Wutte
Quality Manager
BBMRI-ERIC
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.
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.
Question 1: **Who do we serve?**
Answer: Define customer segments

Question 2: **What do we offer?**
Answer: Define customer value proposition

Question 3: **How do we do that?**
Answer: Define resource configuration
QUESTION 1: WHO DO WE SERVE?
STAKEHOLDER FORUM
THE SURVEY: BBMRI-ERIC STAKEHOLDERS

QUESTION 1: WHO DO WE SERVE?

Q4 Which are the stakeholders BBMRI-ERIC should engage with?

- Patients, 8
- Academia, 7
- Industry, 7
- Policy makers, 7
- Biobanks, 2
- Funders, 4
- HCPs, 5
- General public, 3
- Multistakeholder initiatives, 2
- Media, 1
2) DEFINE MOTIVATION

Green: supporter
Red: opponent
Orange: n/d or neutral

Ask yourself:

- What financial/emotional interest do they have in your work? Positive or negative?
- What information do they want from you?
- What is the best way of communicating your message to them?
- What is their current opinion of your work? Is it based on good information?
- Who influences their opinions generally, and who influences their opinion of you?
- Who else might be influenced by their opinions?
From engaging publics to engaging knowledges: Enacting “appropriateness” in the Austrian biobank infrastructure

Melanie Goisauri, Anna P Durnová

First Published October 16, 2018  Research Article
https://doi.org/10.1177/0963662518806451

Abstract

While there is consensus on the essential importance of public engagement in further developments of biobanking, the related investigation of public views predominantly focused on the concerns expressed by the publics, and the concrete formats of public engagement, without delving into the ways these concerns are constituted. In this article, we summarize recent research on public engagement in order to describe the constitution of respective concerns as “engagement of knowledges.” By shifting the focus of analysis from “publics” to “knowledges,” we draw attention to the interaction dynamic through which citizens embed the new knowledge they receive during expert interactions into the stock of knowledge they already possess.
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."

Why participate?

Biobanks - Medicine of the
From the bio-sample for
donor stories
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

Clinics (Warsaw, Gdansk, Wroclaw, Bialystok)
Biobank (PORT Wroclaw)
Data creation (PORT/Ardigen Krakow)
Data analysis (PORT/Ardigen)
Multiomics database creation (Ardigen)
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.
Should individual research results be returned to patients/citizens?
THE POWER OF OUR COMMUNITY: GRASPING PATIENTS PERSPECTIVES OVER TIME

Should individual research results be returned to patients/citizens?

Before the debate

<table>
<thead>
<tr>
<th>Response</th>
<th>Before</th>
<th>After</th>
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<tbody>
<tr>
<td>Yes</td>
<td>62.5%</td>
<td>50.7%</td>
</tr>
<tr>
<td>No</td>
<td>37.5%</td>
<td>49.3%</td>
</tr>
</tbody>
</table>
THE FUTURE OF BBMRI’S STAKEHOLDER FORUM

3 pillars

- Patients/citizens ✔
- Industry
- Healthcare professionals
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.

Medical Research Infrastructures: Solid foundations for Horizon Europe
NEVER SWIM ALONE 2.0
REACHING EUROPEAN AND GLOBAL STAKEHOLDERS
I'm losing sight of the Patient!

I'm right here!