Annual Special Issue

10 Ideas Changing the World Right Now

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 AN IDEA
VIA AN FP7 PROJECT
TOWARDS
A RESEARCH INFRASTRUCTURE
- ESFRI Roadmap & FP7 project application (2006-2008)
- Preparatory Phase: FP7 project BBMRI (2008-2011)
- Interim Phase: ERIC application (2011-2013)
- Implementation Phase: ERIC status granted ... (2013-)
Article 3

Tasks and Activities

1. BBMRI-ERIC shall establish, operate and develop a pan-European distributed research infrastructure of Biobanks and Biomolecular Resources in order to facilitate the access to resources as well as facilities and to support high quality biomolecular and medical research. BBMRI-ERIC shall implement its Work Programme as adopted by the Assembly of Members.
8 Work Plans incl. 22 Work Streams

1) Central Executive Management Office in Graz, Austria
2) Biobank Outreach
3) BBMRI-ERIC Common services
4) Start pan-European and intern. fundraising efforts
5) Quality
6) Expert Centres
7) e-infrastructure
8) Finish work from BBMRI-PP

6 Work Plans incl. 15 Work Streams

1) A new gateway European Biobanks
2) Quality
3) Clinical Biobanks
4) Population-based Cohorts
5) Biobank Outreach
6) Expert Centres

10 Work Plans incl. 35 Work Streams

1) E-Infrastructure
2) Quality
3) Healthcare integrated biobanking
4) Population-based Cohorts
5) Common Services for BBMRI-ERIC
6) International standard developments
7) Bioimaging
8) Assessment and improvement of BBMRI-ERIC
9) Biobank outreach
10) Continued Work Streams
11) Projects active (9)

8 Work Plans incl. 28 Work Streams

1) E-Infrastructure
2) Quality
3) ELSI and Stakeholder Engagement
4) Biomolecular Resources
5) Cohorts
6) Biomedical Imaging
7) Outreach
8) Continued Activities
9) Budget
10) Project Active (12)
What is at stake?
It’s the quality, stupid!
There is increasing concern about the reliability of medical research, with recent articles suggesting that 85% of research funding is wasted.
Categories of Preclinical Irreproducibility

- Biological Reagents and Reference Materials (36.1% of total)
- Study Design (27.6% of total)
- Data Analysis and Reporting (25.5% of total)
- Laboratory Protocols (10.8% of total)

Estimated US Annual Preclinical Research Spend

- Reproducible
  - US$28.2B (50%)

- Irreproducible
  - US$28.2B (50%)
  - US$56.4B
BBMRI-ERIC recognizes quality grades of biobanks.

Self-Assessment

BBMRI-ERIC Directory
The central role of BBMRI-ERIC is to keep track and contribute to the biobank relevant international standard developments.

Act as an information hub by communicating Expert knowledge of the Working Group of ISO to the BBMRI-ERIC community and vice versa.

- **International Standard for Biobanks and Bioresources**
  ISO/TC 276 ‘Biotechnology’
  - **Terminology**
  - **Biobanks** human, animal, plant and microorganism resources for R&D
    - **Analytical Methods**
    - **Bioprocessing**
    - **Data processing and integration**

- **International Standard for Pre-examination processes**
  ISO/TC 212 ‘Clinical laboratory testing and in vitro diagnostic test systems’
Improving access?
626 biobanks
1363 collections
estimated > 100,000,000 samples
Integrated Structure

Researchers from public and private sectors

Users

Citizens/Patients

Cohort studies/Hospitals

BBMRI-ERIC

National nodes

Local Biobanks

BBMRI
Access: Simple View of IT Components

**Directory**
Findability: providing aggregated metadata on biobanks and their samples/data collections.

**Sample/Data Negotiator**
Accessibility: facilitating access to biobanks samples/data.

**Sample Locator**
Federated search of sample/donor-level data.
Result: sample availability estimate, candidate collections/biobanks.

Access Policy

Search highly aggregated data on biobanks and their sample/data collections.
Result: candidate collections/biobanks.

Governed by

Information on delivered service & research results
Directory: about 600 users/month
What about ELSI?
It is the elephant in the room full of stakeholders and their expectations.
patients/donors, citizens or the society at large

the media/policy makers

clinical staff, researchers or consortia

National Nodes and partner biobanks

ELSI experts

ethics committees

funding bodies

patients/donors
ELSI Helpdesk Coordinator (vacancy/ADOPT)

ELSI HELPDESK

What does it do?

BBMRI-ERIC provides support on ethical, legal and societal issues related to biobanking activities through its Common Service ELSI. Among other things, the ELSI-group is offering practical interpretation on new legislation. It also monitors relevant ethical and legal frameworks in development and communicates publications, research results, surveys, and informs about relevant meetings. We are also setting up a federated Helpdesk. The vision and aim is to make the Helpdesk available, feasible, practical, usable, reliable, verifiable and sustainable.

This Helpdesk will provide general information on topics that are crucial for biobanking, regarding for example informed consent, data protection and support on ethical questions. It will also offer customised help. The practical tools to help provide this service are currently under development together with IT experts.

Who is it for?

The Helpdesk offers support on ethical, legal and societal issues related to biobanking activities. It is primarily intended for users located in Member Countries of BBMRI-ERIC.
WMA Declaration on ethical considerations regarding health databases and biobanks

Council of Europe's Recommendation (2006)4 on research on biological materials of human origin

Day of Action & Position Paper on the GDPR, FAQs on the GDPR
The ultimate responsibility is to use samples & data appropriately, so that neither the expectations nor the efforts of the data/sample providers and users go to waste.
THANK YOU!
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