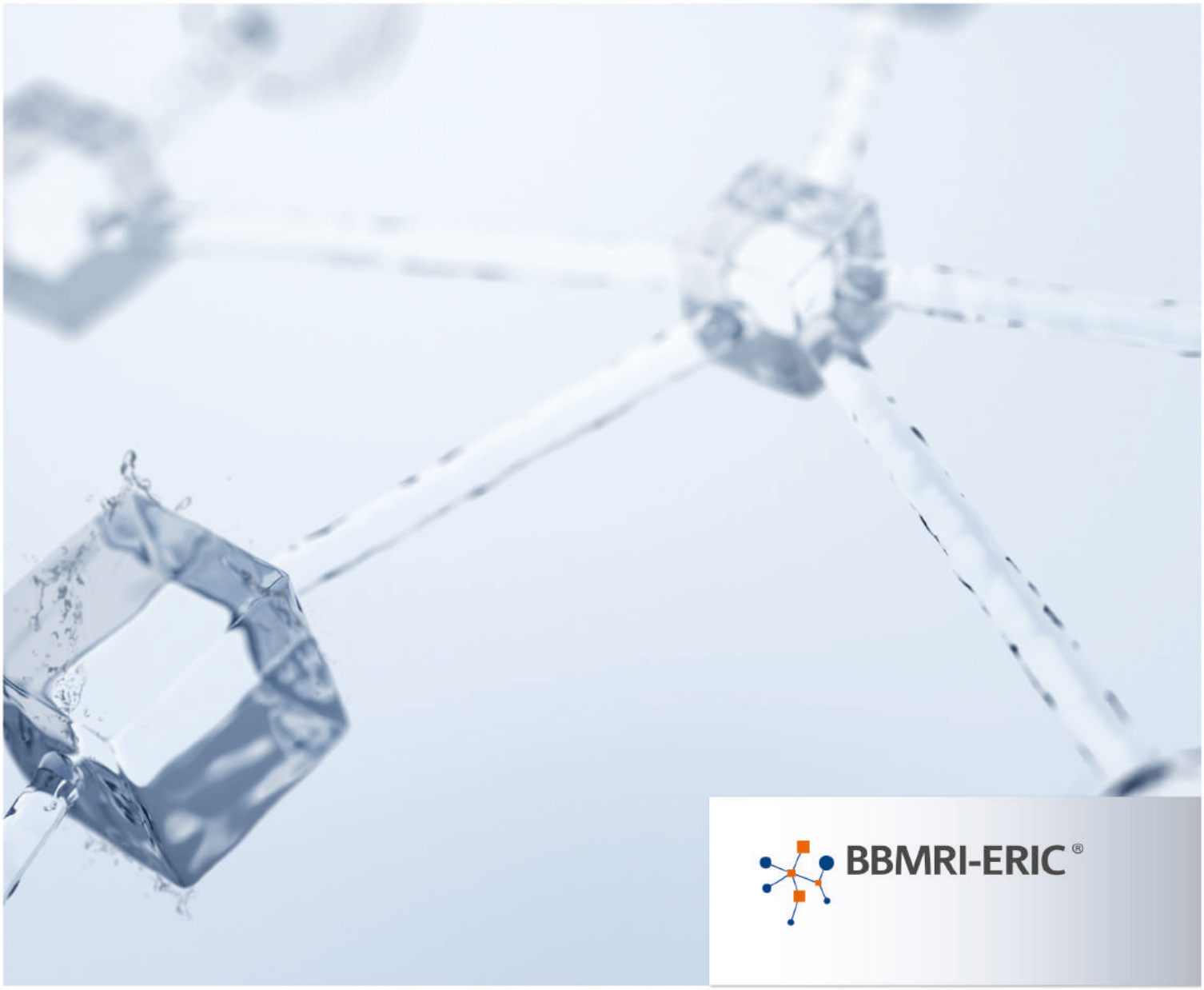

2017
ANNUAL REPORT

'Biobanks (and Biomolecular Resources Centres)' means collections, repositories and distribution centres of all types of human biological samples, such as blood, tissues, cells or DNA and/or related data such as associated clinical and research data, as well as biomolecular resources, including model- and micro-organisms that might contribute to the understanding of the physiology and diseases of humans.

BBMRI-ERIC Statutes, Article 1(1)

Executive Summary

Dear Delegates of the Assembly, dear National Node Directors, dear Sir/Madam,

Looking back at 2017, there were many highlights that demonstrate how we continue to build the research infrastructure of biobanks and biomolecular resources. I would of course like to share a few outstanding examples, however, what really stood out for me was the importance of access: many scientists are looking for high quality samples and we can provide access to over 500 biobanks storing over 100 million samples. By further improving our service capabilities, we are on track to fulfil our mission: to establish, operate and develop a pan-European, distributed research infrastructure of biobanks and biomolecular resources in order to facilitate access to resources and facilities as well as to support high quality biomolecular and medical research.

Transparency and Communication From the day I started as Director General, a top priority was to make sure there was a clear understanding of why we implement particular measures for our stakeholders. Introducing monthly progress reports as well as individual calls with National Nodes Directors helps both the team in Graz and our stakeholders to evaluate achievements and prepare future measures. This started with a visit to all individual Member States and Observers to learn about their vision, goals and strategies in depth. The input helps us to further improve our services to meet the needs of our funders and users in achieving our long-term vision to further build and strengthen value-added, sustainable biobanking.

Understanding the Environment For a service-oriented research infrastructure it is crucial to know who the stakeholders are and what they need. The Stakeholder Forum enables this mapping to be undertaken in greater detail, including requirements and needs of patient organisations, policymakers, learned societies, industry and academia. Having our own Engagement Officer since September 2017, located in Brussels, is now instrumental in achieving the next steps: becoming the tool for first-hand information exchange directly with all of our stakeholders. A great start has been made with the Stakeholder Forum and its added value has already been proven to further optimise our service capabilities.

Further Enabling Access The BBMRI-ERIC Directory is key in enabling our stakeholders to gain access to high quality samples from biobanks in our Member States. The launch of Directory version 4.0 brings further interesting new features that allow for detailed and more accurate representation of the biobanking infrastructure: both collections and biobank networks. In combination with the continuous efforts to implement quality management and self-assessment surveys, more information on the quality of the samples is now also available for some collections and will continue to be expanded.

Truly pan European datasets The key project for BBMRI is ADOPT BBMRI-ERIC; here, one major task is to collect 10,000 colorectal cancer datasets from 12 countries. This unprecedented resource is one example of the true strength of BBMRI-ERIC. With great combined efforts in this large-scale collaboration I am very pleased to share that a breakthrough has been achieved. Before the end of 2017, preparatory work for the data upload was finalised, combining IT, QM and ELSI expertise and services from the Graz team and the National Nodes. In early 2018 we collected half of the needed

data from over 30 participating biobanks. This unique resource will be available for fundamental and / or translational research in the continuous fight against cancer.

Europe Leads the Way in Global Event Supported by increased continuous contributions on various communication channels, the impact of the outreach activities has grown tremendously. One special event should be mentioned: the Global Biobank Week in Stockholm. It brought together almost 900 biobankers, scientists, policy makers and industry representatives from 53 different countries who together focussed on the theme of *Towards Harmony in Biobanking*. Here, Greg Simon, President of the Biden Cancer Initiative, gave a truly inspiring and thought-provoking keynote lecture highlighting that our attitude towards biobanks needs to change: *'A biobank is not a bank. It is a trust – a biotrust.'* This is a clear goal that BBMRI-ERIC is and will be working towards in the years ahead, continuing to support the National Nodes in achieving this together.

Guidance as Well as Education and Training In order to be able to provide appropriate guidance on ethical, legal and societal issues, the input of national experts is crucial. Since August 2017, a dedicated ELSI Helpdesk Coordinator ensures the promotion of this knowledge in a custom-based service and through science communication as well as education and training activities. A key activity as regards the latter is the BBMRI-coordinated project RItrain that designs a training programme for the leadership of European research infrastructures.

Code of Conduct On May 25th the GDPR data protection law will become effective. It is great to see that BBMRI-ERIC is taking the lead in writing a Code of Conduct for Health Research and that solid progress has been made throughout 2017. The aim is not only to contribute to the proper application of the regulation and to clarify and specify certain rules of the GDPR, but also to help demonstrate compliance by controllers and to help foster transparency and trust in the use of personal data in the area of health research. An ambitious project for which we hope to have a draft ready for a wider audience in Q2 2018.

Robust Financial Performance 2017 was another year of consistent, robust financial performance. Core funding supported the execution of the activities foreseen in the Work Programme. New projects were won, allowing us to have a greater impact on the European scientific landscape and new initiatives started to build the pipeline in the second part of the year to make sure solid funding is available in the coming years. Overall, the financials section of this report reveals a stable and healthy position.

To conclude, I am convinced that BBMRI-ERIC has the passion, skills and services to exceed expectations in building and strengthening value-added, sustainable biobanking. We can be proud of the achievements in 2017 that we made as a team. In the years ahead, BBMRI-ERIC will slowly shift to become part of a total workflow for health research and personalised medicine, where biobanks are the key drivers in enabling academia and industry to make new treatments possible.

Erik Steinfelder, Director General
7th May 2018

KEY ACHIEVEMENTS

JANUARY

- **SPIDIA4P Kick-off Meeting,** Hilden
- **EOSC-pilot Kick-off Meeting,** Amsterdam

FEBRUARY

- **Biobanks Europe Magazine No. 6 - special issue on quality** published
- **GDPR Code of Conduct initiative presented to stakeholders,** Brussels

MARCH

- **MC#16,** Trondheim
- **CliniMARK** Kick-off Meeting, Brussels
- **RItrain** competency profile published
- **Connection API** specification released

APRIL

- **EU-Africa Stakeholder Meeting,** Brussels
- **FAQ GDPR V2.0** published

MAY

- **AOM#11,** Lausanne
- **Joint MC/AoM Meeting,** Lausanne
- **MC#17,** Lausanne
- **RD-Connect Plenary Meeting,** Berlin

JUNE

- **ADOPT BBMRI-ERIC Mid-Term Review,** Brussels
- **CORBEL Mid-Term Review,** Brussels
- **Biobanks Europe Magazine No. 7** published
- **AARC 2 Kick-off Meeting,** Amsterdam
- **B3Africa AGM,** Uppsala
- **1st Code of Conduct Forum Meeting,** Brussels
- **Focus Group study of Directory 4.0**
- **DG RTD Ethics** Unit training on ethics assess-ment, Brussels

CONTINUOUS

- **Broadcasting** Quality webinars
- **Maintaining** Working Groups, Task Forces, Expert Groups
- **Maintaining** production services (Directory, Negotiator, Helpdesk)
- **Attending** project related working meetings & webinars
- **Participating** in NN meetings, conferences, workshops
- **Providing** ELSI guidance
- **Updating** the website, e-newsflash & new media

BBMRI-ERIC®

JULY

- **1st collections Quality labeled** in Directory
- **Start of ballot phase for ISO/ DIS 20387** Biobank Standard
- **Data protection policy for CRC-Cohort** developed
- **Code of Conduct Drafting Group** assessed existing codes

AUGUST

- **Erik Steinfelder starts** as Director General
- **Jasjote Grewal joined the team** as ELSI Helpdesk Coordinator

SEPTEMBER

- **Global Biobank Week,** Stockholm
- **Francesco Florindi joined the team** as Engagement Officer
- **RItrain AGM,** Porto
- **CETOCOEN Kick-off Meeting,** Brno

OCTOBER

- **MC#18,** Wroclaw
- **CORBEL AGM,** Amsterdam
- **Negotiator 1.0** exceeded 100 biobank registrations

NOVEMBER

- **AoM#12,** Vienna
- **ERIC Forum,** Graz
- **Access Policy** approved
- **Partner Charter** revision approved
- **Public Consultation:** Transformation Health and Care in the Digital Single Market submitted
- **Auditor Certificate** rewarded to Andrea Wutte, Quality Manager
- **RD-Connect** meeting on extending Negotiator for their use
- **BIBBOX 2.0** launched
- **Code of Conduct Drafting Group** decided on focus areas (legal basis, safeguards, responsibility of controller/ processor)

DECEMBER

- **Data in Question** survey on consent practices launched
- **Anna-Liisa Kuslap joined the team** as Secretary
- **Proposal participation** started (e.g., EOSC-life)
- **Directory 4.0** launched

MAKING NEW TREATMENTS POSSIBLE

Key Facts & Figures

- 550 unique visitors a month to the Directory, with 800 sessions
- 500+ biobanks included in the Directory
- 107 researchers signed up to use our Quality Management Service tools
- 25+ researchers received support by our ELSI Helpdesk since fall 2017
- 31.6% success rate in H2020 (13 active projects)

Figure 1.: The Headquarters team at the Global Biobank Week 2017, Stockholm

Pictured from left to right: Meghan McCaroll (Secretary), Petr Holub (Senior IT/Data Protection Manager), Outi Törnwall (EU Project Manager), Johanna Dungl (Communications Officer), Carmen Cristea (Finance Manager), Michaela Th. Mayrhofer (Chief Coordination and Policy Officer), Erik Steinfelder (Director General), Andrea Wutte (Quality Manager), Jasjote Grewal (ELSI Helpdesk Coordinator), Luc Deltombe (Communications Manager), Francesco Florindi (Engagement Officer). *Not pictured*: Jan-Eric Litton (Director General from January 2014 – July 2017), Markus Pasterk (Administrative Director).

Conferences and Meetings

In 2017, BBMRI-ERIC was represented at more than 130 events. Given the success rate in project participations, the largest share consists of 31 project meetings including Kick-off, WP and review meetings. The second largest category is conferences and symposia with a total of 14 different events including key note lectures, talks and paper presentations (e.g., the Global Biobank Week in Stockholm or the 3rd African Conference on EID and Biosecurity in Accra). 13 meetings were related to the EC such as DG RTD as well as other Research Infrastructures subsumed as EU, ERIC and ESFRI.

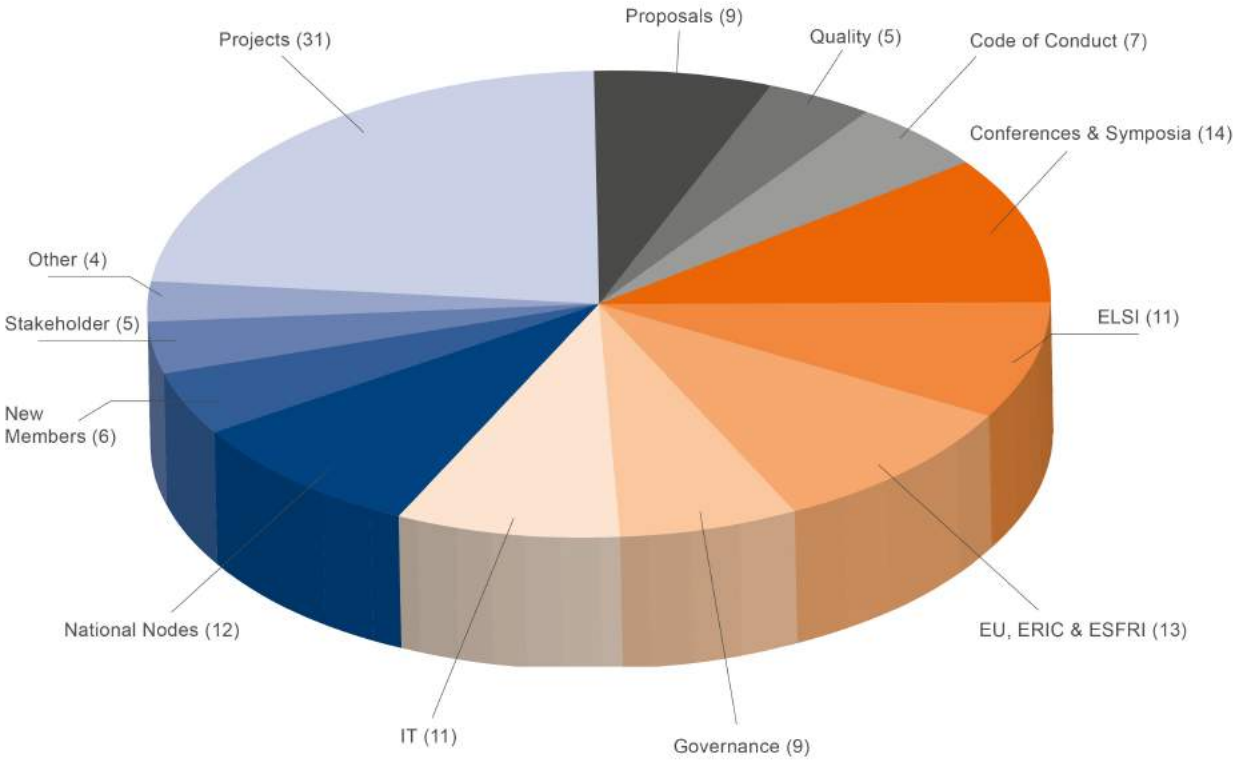

Figure 2.: Purpose and Scope

12 travels were related to workshops and annual meetings of the National Nodes, more than double the representation of 2016. 11 meetings were related to the Common Service ELSI and IT (including one joint meeting). Nine meetings were related to proposals (especially consortia forming and proposal writing) and governance (Assembly of Members, Management Committee, Finance Committee, Steering Committee, the Scientific Retreat and Selection Committee). Seven events were related to the Code of Conduct Initiative and five to Quality.

Five travels were related to BBMRI-ERIC's stakeholders, including the Stakeholder Forum, learned societies, associations and industry. Last but not least, four meetings were sub-summed under the category other and concerned managerial issues as well as outreach activities (e.g., European Biobank Week 2018). In an outlook for 2018, travels on projects will expectantly remain the same but activities in collaboration with the National Nodes and stakeholders as well as on outreach will increase.

Communication and Outreach

Figure 3.: Highlights on Communication Activities in Numbers

H2020 Grant Distribution

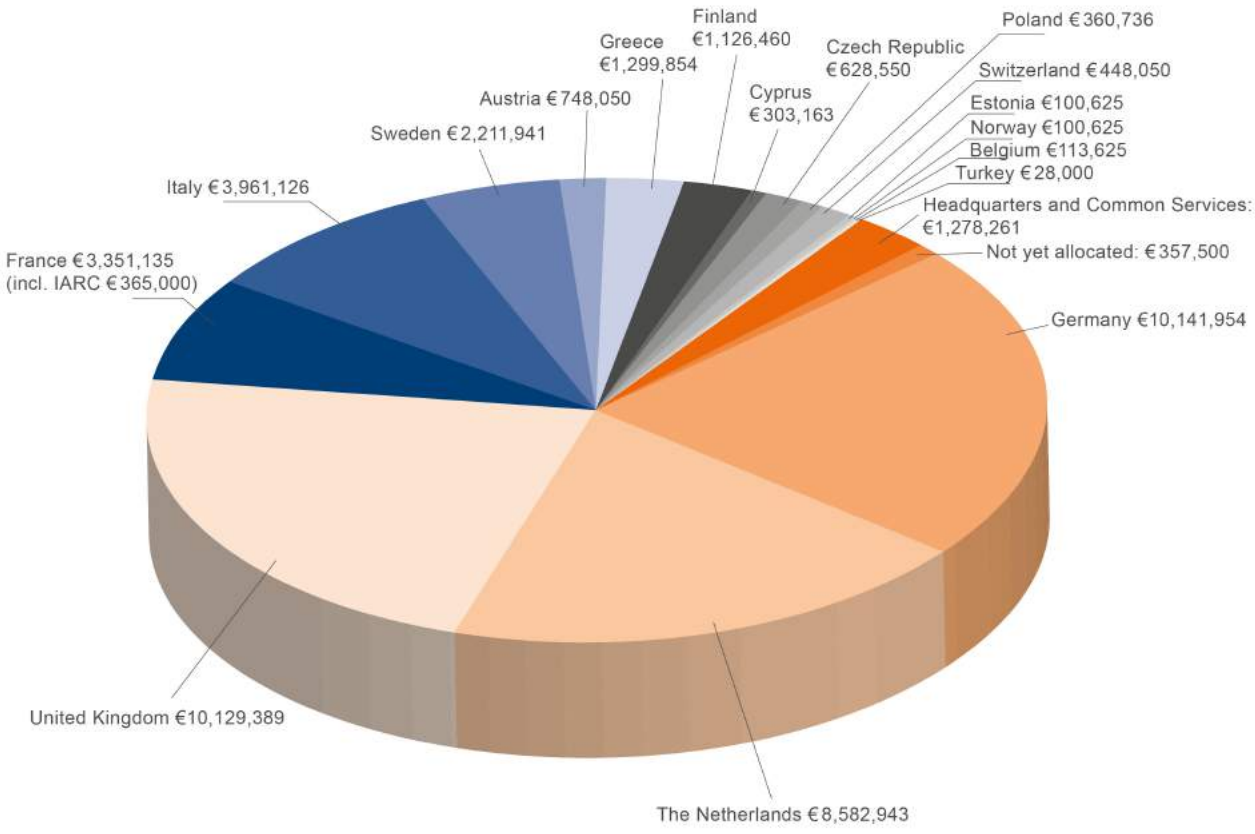

Figure 4.: Distribution of project grants where BBMRI-ERIC is partner per country

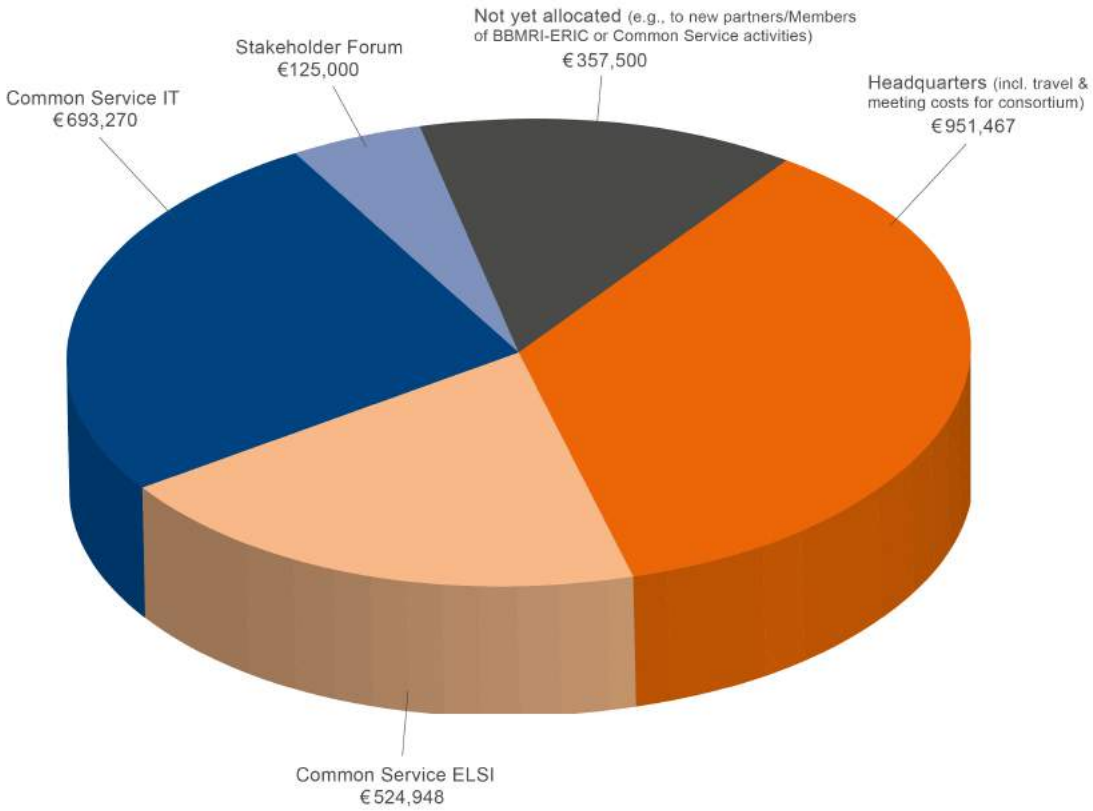

Figure 5.: BBMRI-ERIC's share of H2020 project grants

Collaboration Agreements

To date, agreements and Memoranda of Understandings have been signed with:

Part I.

Finance

Overview

The BBMRI-ERIC 2017 budget was drafted in accordance with the principles laid out in the Statues, with the sole purpose of facilitating and furthering the work and activities as detailed in the Work Programme 2017, approved by the Assembly of Members during its 8th session in November 2016. As a publicly funded organisation, BBMRI-ERIC aims to achieve the highest standards of transparency and accountability with regards to its allocation of funds, accounting and financial processes. BBMRI-ERIC's 4th Annual Financial Report is concluded in accordance with the principles laid out in the Statutes and submitted to the Assembly of Members for approval. The annual voluntary audit of the organisation's 2017 financial statement was performed by an external auditor, Ernst & Young Vienna, nominated during the Assembly of Members' 10th Session in November 2017, and the auditor's final report confirms the compliance with statutory provisions and generally accepted accounting standards. The audit report is submitted together with the financial statement for the Assembly's review and approval.

The Annual Financial Report gives a comprehensive overview of all the earnings and expenditures of the year 2017, pertaining to the operations of the Central Executive Management Office (Headquarters), Common Service ELSI, Common Service IT and Quality Management, as well as externally funded collaborative projects.

Procurement and Tax Exemption

According to the Statutes (Article 6), BBMRI-ERIC shall treat procurement candidates and tenders equally and without discrimination. During 2017, no major investments were made.

Profit & Loss Statement

In EUR	2015	2016	2017
Turnover	3.631.636	888.860	2.892.951
Other operating income	62.137	-	629
Material Expenses	-	-	-
Staff expenses	(887.215)	(1.554.036)	(1.689.010)
Amortization	(30.454)	(30.020)	(29.518)
Other operating expenses	(687.764)	(1.172.010)	(1.367.820)
Operating result	**2.088.340**	**(1.867.207)**	**(192.768)**
Other interest and similar income	16	-	-
Interest and similar expenses	-	(58)	(30)
Financial result	16	(58)	(30)
Loss from operating activities, Earnings before taxes	**2.088.356**	**(1.867.265)**	**(192.798)**
Taxes on income and revenue	(4)	-	-
Profit of the year	**2.088.352**	**(1.867.265)**	**(192.798)**
Reversal of profit reserves	-	1.867.265	192.798
Allocation to profit reserves	(2.034.352)	-	-
Profit carried forward from the previous years	313.775	367.775	367.775
Balance sheet profit	**367.775**	**367.775**	**367.775**
Check	-	-	-

Balance Sheet

In EUR	2015	2016	2017
Intangible Assets	3.840	2.560	1.280
Tangible Assets	112.120	87.759	73.274
Fixed Assets	**115.960**	**90.320**	**74.554**
Receivables and other Assets	93.179	145.488	199.669
Receivables arising from deliveries services	130	9.249	126.626
Other receivables and assets	93.049	136.239	73.043
Cash on hand and Bank deposits	3.625.026	1.970.135	2.189.624
Current Assets	**3.718.204**	**2.115.623**	**2.389.293**
Prepaid expenses, deferred charges	250	3.581	5.919
Assets	**3.834.415**	**2.209.523**	**2.469.766**
Reserves pursuant to the articles of association	2.193.362	326.097	133.300
Balance sheet profit	367.775	367.775	367.775
Capital and Reserves	**2.561.137**	**693.872**	**501.075**
Other accruals	24.669	52.800	128.178
Accruals	**24.669**	**52.800**	**128.178**
Liabilities arising from deliveries and services	31.407	54.179	58.187
Other liabilities	24.823	204.924	157.418
Liabilities	**56.230**	**259.104**	**215.604**
Deferred income	1.192.378	1.203.748	1.624.910
Liabilities and Owner´s Equity	**3.834.415**	**2.209.523**	**2.469.766**
Check	-	-	-

Cash Flow

In EUR	2016	2017
Profit of the year	(1.867.265)	(192.798)
Amortization	29.955	28.096
Cash Flow from the Result	**(1.837.309)**	**(164.702)**
Δ Receivables arising from deliveries services	(9.119)	(117.377)
Δ Other receivables and assets	(43.190)	63.196
Δ Liabilities arising from deliveries and services	22.772	4.007
Δ Other liabilities	180.102	(47.507)
Δ Prepaid expenses, deferred charges	(3.331)	(2.337)
Δ Accruals	39.500	496.540
Δ Working Capital	**186.733**	**396.523**
Cash Flow from Operations	**(1.650.576)**	**231.820**
Investing / Deinvesting	(4.315)	(12.331)
Cash Flow from Investing Activities	**(4.315)**	**(12.331)**
Δ Capital and Reserves		
Cash Flow from Financing Activities	-	-
Total Cash Flow	**(1.654.891)**	**219.490**
Cash Beginning	3.625.026	1.970.135
Δ	(1.654.891)	219.490
Cash End	3.625.026	1.970.135	2.189.624
Diff	-	-

BBMRI-ERIC, Graz

Report on the Audit of the
Financial Statements
as of December 31, 2017 (Translation)

Building a better working world

TRANSLATION

TABLE OF CONTENT

INDEX OF APPENDICES

TRANSLATION

To the Director General
BBMRI-ERIC,
Graz

We have completed the audit of the financial statements as of December 31, 2017 of

**Biobanking and BioMolecular resources Research Infrastructure –
European Research Infrastructure Consortium (BBMRI-ERIC), Graz**

(referred to as "the Company"),

and report on the result of our audit as follows:

1. AUDIT CONTRACT AND PERFORMANCE OF THE ENGAGEMENT

The Company, represented by the Director General, concluded an audit contract with us to audit the financial statements as of December 31, 2017, including the accounting system pursuant to Sections 269 et seqq. Austrian Company Code UGB.

The Company is a small corporation pursuant to Section 221 Austrian Company Code UGB.

The audit is a voluntary audit.

The audit included assessing whether the statutory requirements were adhered to concerning the preparation of the financial statements.

We conducted our audit in accordance with the legal requirements and generally accepted standards on auditing as applied in Austria. These standards require that we comply with International Standards on Auditing. An auditor conducting an audit obtains reasonable assurance about whether the financial statements are free from material misstatement. Absolute assurance is not attainable due to the inherent limitations of any accounting and internal control system and due to the sample-based test nature of an audit, there is an unavoidable risk that material misstatements in the financial statements remain undetected. Areas which are generally covered in special engagements were not included in our scope of work.

We performed the audit, with interruptions, in April 2018 mainly at the Company's premises in Graz. The audit was substantially completed at the date of this report.

Auditor responsible for the proper performance of the engagement is Mrs. Katharina Schrenk, Austrian Certified Public Accountant.

Our audit is based on the audit contract concluded with the Company. The "General Conditions of Contract for Audits of Financial Statements" issued by the Austrian Chamber of Public Accountants and Tax Advisors (refer to Appendix 2) form an integral part of the audit contract. These conditions of contract do not only apply to the Company and the auditor, but also to third parties. Section 275 Austrian Company Code UGB applies with regard to our responsibility and liability as auditors towards the Company and towards third parties.

2. BREAKDOWN AND DESCRIPTION OF SIGNIFICANT ITEMS IN THE FINANCIAL STATEMENTS

The breakdown and description of all significant financial statement items are included in the notes to the financial statements. Therefore, we refer to the respective disclosures made by the Director General in the notes to the financial statements.

3. SUMMARY OF AUDIT FINDINGS

3.1. Compliance of the accounting system and the financial statements

During our audit, we obtained evidence that the statutory requirements and generally accepted accounting principles in Austria have been complied with.

In line with our risk and controls based audit approach and to the extent we considered necessary for the purpose of expressing an opinion, we considered internal controls related to sub processes of the financial reporting process as part of our audit.

With regard to the compliance of the financial statements with all applicable statutory requirements we refer to the auditor's report.

3.2. Information provided

The Director General and the respective operative employees of BBMRI-ERIC provided all evidence and explanations requested by us. We obtained a representation letter signed by the Director General which we included in our working papers.

3.3. Reporting in accordance with Section 273 (2) and (3) Austrian Company Code UGB (exercising the duty to report)

During our audit we did not note any facts which indicate there could be substantial doubt about the Company's ability to continue as a going concern, or which indicate a material deterioration of the Company's performance or a material offence of the Director General or its employees against Austrian law or the Company's articles of association. We did not note any material weaknesses in the internal controls over the financial reporting process. The financial statements do not meet the requirements for the assumed need of reorganization in accordance with Section 22 Paragraph 1 Subsection 1 URG (Austrian Corporate Restructuring Act).

TRANSLATION

4. AUDITOR'S REPORT *)

Report on the Financial Statements

Audit Opinion

We have audited the financial statements of

**Biobanking and BioMolecular resources Research Infrastructure –
European Research Infrastructure Consortium (BBMRI-ERIC), Graz,**

These financial statements comprise the balance sheet as of December 31, 2017, the income statement for the fiscal year then ended and the notes.

Based on our audit the accompanying financial statements were prepared in accordance with the legal regulations and present fairly, in all material respects, the assets and the financial position of the Company as of December 31, 2017 and its financial performance for the year then ended in accordance with Austrian Generally Accepted Accounting Principles.

Basis for Opinion

We conducted our audit in accordance with Austrian Standards on Auditing. Those standards require that we comply with International Standards on Auditing (ISA). Our responsibilities under those regulations and standards are further described in the "Auditor's Responsibilities for the Audit of the Financial Statements" section of our report. We are independent of the Company in accordance with the Austrian General Accepted Accounting Principles and professional requirements and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Our responsibility and liability as auditor is guided by Section 275 par. 2 Austrian Company Code UGB (liability regulations for the audit of small and medium-sized companies) and is limited to a total of 2 million Euros towards the Company and towards third parties.

Responsibilities of Company's legal representative for the Financial Statements

The Company's legal representative is responsible for the preparation of the financial statements in accordance with Austrian Generally Accepted Accounting Principles, for them to present a true and fair view of the assets, the financial position and the financial performance of the Company and for such internal controls as management determines are necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Company or to cease operations, or has no realistic alternative but to do so.

Auditor's Responsibilities for the Audit of the Financial Statements

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Austrian Standards on Auditing, which require the application of ISA, always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

As part of an audit in accordance with Austrian Standards on Auditing, which require the application of ISA, we exercise professional judgment and maintain professional scepticism throughout the audit.

We also:

- identify and assess the risks of material misstatement of the financial statements, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinion. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.
- obtain an understanding of internal control relevant to the audit in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control.
- evaluate the appropriateness of accounting policies used and the reasonableness of accounting estimates and related disclosures made by management.

- conclude on the appropriateness of management's use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our auditor's report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify our opinion. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Company to cease to continue as a going concern.
- evaluate the overall presentation, structure and content of the financial statements, including the disclosures, and whether the financial statements represent the underlying transactions and events in a manner that achieves fair presentation.

Comments on the Management Report

Pursuant to Section 243 (4) UGB the audited company did not prepare a management report.

Vienna, April 27, 2018

Ernst & Young
Wirtschaftsprüfungsgesellschaft m.b.H.

Katharina Schrenk mp
Wirtschaftsprüferin / Certified Public Accountant

Gerald Steckbauer mp
Wirtschaftsprüfer / Certified Public Accountant

*) This report is a translation of the original report in German, which is solely valid. Publication or sharing with third parties of the financial statements together with our auditor's opinion is only allowed if the financial statements are identical with the German audited version. This audit opinion is only applicable to the German and complete financial statements with the management report. Section 281 paragraph 2 UGB (Austrian Company Code) applies to alternated versions.

Part II.

Activities

1. Work Plan: e-Infrastructure

1.1. Workstream: Development

Aim: The goal of this workstream was to focus on both the maintenance of tools already deployed and new developments to BBMRI-ERIC's IT infrastructure.

Achievements:

- Incremental development and deployment of the **BBMRI-ERIC Directory 3.1, 3.2, 3.3, and 3.4** with minor functionality improvements and updated data sets from the National/Organisational Nodes.
- The **BBMRI-ERIC Directory 4.0**[1] includes a redesigned *simplified user interface* for less experienced and non-technical users. The redesign was based on the feedback of focus groups conducted as a part of the BBMRI-ERIC Common Service IT. It also includes extensions to the data model, such as the ability to capture *the compliance of biobanks and sample collections with quality standards*. Semantic search capability has been developed to allow effective searches through complex hierarchies of diseases and their coding systems. The underlying Molgenis security model has been revamped to support fine-grained security rules, to enable direct editing of data by the National/Organisational Nodes. A rare disease section of the BBMRI-ERIC Directory has been implemented in collaboration with RD-Connect. The Directory has been extended to support simple persistent URLs for referencing both biobanks and collections in preparation for the implementation of BBMRI-ERIC's Persistent Identifier Policy.[2] The Directory now supports Docker images for the integration in the BIBBOX and for easier deployment of national directories/catalogues by the BBMRI-ERIC National/Organisational Nodes.
- **BBMRI-ERIC Negotiator 1.0**[3] has been continuously improved based on user feedback, including support for more efficient filing of requests by reusing the available project documentation and ethics vote. The Negotiator has been integrated with the BBMRI-ERIC Directory, in order to enable selection of biobanks and collections based on structured search criteria. It has also been integrated with the BBMRI-ERIC Authentication and Authorisation Infrastructure (AAI) so as to enable authentication of users using their home organisations. In collaboration with RD-Connect, a plan has been developed to extend the Negotiator to support multiple sources of requests, thus enabling its integration with resources other than the BBMRI-ERIC Directory–such as the RD-Connect Biobank and Registry Finder and RD-Connect Sample Catalogue.
- Development towards a **BBMRI-ERIC Sample/Data Locator**: a **Connector** API was selected in March 2017 (implementation of a prototype was tested in September 2017). The final implementation is expected to be delivered in mid-2018.

[1] http://www.bbmri-eric.eu/services/directory/
[2] Holub, P: *Policy for Assigning Persistent Identifiers (PIDs) in BBMRI-ERIC* (2017). doi:10.5281/zenodo.1241053.
[3] http://www.bbmri-eric.eu/services/sample-negotiator/

- The **BIBBOX 2.0**, a reference open-source software toolbox for operating biobanks, has been released with a new portal interface for easier management, with support for additional software components (e.g., Jupyter, OMERO.biobank) and better integrated management (vagrant/puppet management, common user and identifier management). BIBBOX has been piloted in the Biobank of Malta and with the Wrocławskie Centrum Badań EIT. ID mapping with BIBBOX has been aligned with B2Handle and prepared for ePIC PIDs (consistent with the BBMRI-ERIC Policy[4]).
- Updates to and maintenance of the **Colorectal Cancer Data Collection software (further abbreviated as CCDC)** for collection and storage of Colorectal Cancer Cohort (CRC-Cohort), which was developed in the context of the ADOPT BBMRI-ERIC project (incl. changes in the data model developed during 2017, based on feedback from participating biobanks). Development of **semantic and data harmonisation services** followed and these have also been piloted using Colorectal Cancer Cohort (CRC-Cohort). BiobankConnect/Molgenis has been extensively evaluated for the purpose of semantic data mapping and a MDR2Molgenis translation tool has been developed.
- The governance of **MIABIS** has been restructured in order to enable better scalability and a higher quality of further development, based on experience with designing the MIABIS 2.0 Core and Imaging modules. Two new focused Working Groups have been created, namely the Sample and Donor Data Working Group and the Standard Operating Procedures Metadata Working Group. A proposal has been prepared for an ontological MIABIS 2.0 Core based on OBIB ontology.

Outlook: Ongoing development and deployment of BBMRI-ERIC IT services, including finishing the BBMRI-ERIC Sample/Data Locator, updating existing services based on the usage patterns and user feedback.

1.2. Workstream: Operations

Aim: This workstream targets the sustainable operation of BBMRI-ERIC's IT infrastructure for both production and development purposes, as well as for use outside of BBMRI-ERIC's IT services (e.g., for the Common Service ELSI and rare diseases).

Achievements:

- **Operation of the common BBMRI-ERIC IT infrastructure**, which included upgrading server infrastructure and network uplink connection for the infrastructure provided by CNR (BBMRI.it), as well as developing a of backup strategy and failover transition between CNR infrastructure and infrastructure hosted by BBMRI-ERIC at Nessus in Vienna.
- **Operation of the BBMRI-ERIC Directory 3.x** series, which included data management and supporting the national nodes in delivering updated national data to the central Directory, development of data quality checks; and ensuring smooth operation of this service, which is the most utilised IT service provided by BBMRI-ERIC. Data management accounts for more than 50% of the operating costs of the Directory, which reflects the fact that the Directory's main value lies in its content.

[4] Holub, *Policy for Assigning Persistent Identifiers (PIDs) in BBMRI-ERIC.*

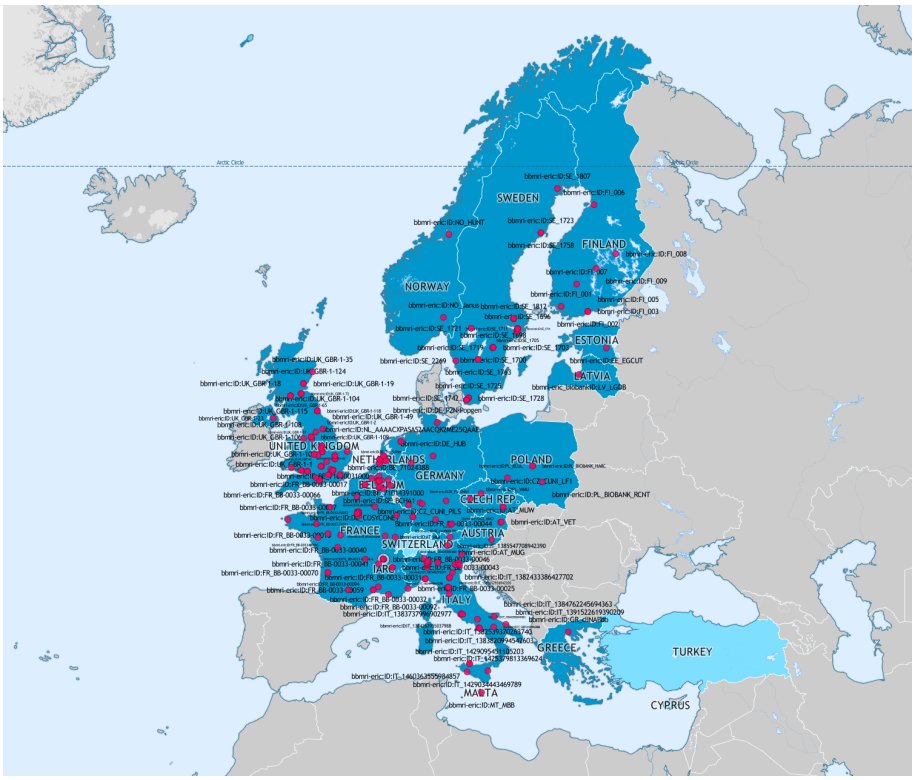

Figure 6.: Status of BBMRI-ERIC Partner Biobanks in the Directory 4.0.

- Operation of the **BBMRI-ERIC Negotiator** mainly involved onboarding BBMRI-ERIC Partner Biobanks into the system, so that once production requests start coming in through the Negotiator in 2018, a substantial portion of biobanks available through the Directory will be able to respond to these requests through the Negotiator.
- Operation of the **BBMRI-ERIC Authentication and Authorisation Infrastructure (AAI)** followed deployment of the infrastructure in 2016. The components were upgraded and a new Proxy Identity Provider component has been installed to enable user attribute aggregation. OpenID Connect interface has been installed to support integration with the Negotiator.
- **Operation of Helpdesk for BBMRI-ERIC** included reconfiguration of the ticketing RT system based on new user requirements, as well as end user support. The supported user communities include Common Service IT Helpdesk, ethical, legal, and societal issues (ELSI) Helpdesk, Rare Disease Helpdesk, Quality Helpdesk, and Colorectal Cancer Cohort (CRC-Cohort) Helpdesk.
- **User support and training** including outreach activities by Helpdesk RT system (training for ELSI and Rare Diseases groups), BIBBOX training and Global Biobank Week 2017, etc. Tuition materials have been developed for the BBMRI-ERIC Directory (manuals for users and data managers) and for the BBMRI-ERIC Negotiator (guidance for biobankers on how to register and work with the system).

Outlook: Operation of the IT infrastructure is a continuous process within BBMRI-ERIC and it is expected to continue uninterrupted in 2018, supporting the newly-developed or updated services.

1.3. Workstream: Interfaces with other e-Infrastructures and IT-related Projects

Aim: This workstream aims at coordinating BBMRI-ERIC's IT development with the development of European e-Infrastuctures[5] and relevant projects that are needed by BBMRI-ERIC but are outside of its primary scope.

Achievements:

- **Standardisation of provenance information for sharing both biological material and data** lead to the development and submission of an initial proposal Preliminary Work Item within ISO TC 276 WG 5 (which was approved as ISO/PWI 23494-1 in March 2018).
- **Development of long-term data stewardship/curation strategies** started with the delivery of the Persistent Identifier Policy for BBMRI-ERIC, in order to ensure long-term findability of biobanks and enable management of provenance information.
- Contributions to the development of the common Life Science AAI in collaboration with Life Science infrastructures in CORBEL and e-Infrastructures in the AARC2 project, co-led by ELIXIR, BBMRI-ERIC and INSTRUCT.

Outlook: All activities are aligned with BBMRI-ERIC's commitment to implement FAIR[6] and FAIR-Health[7] principles and will continue in 2018 and beyond (they are also part of the EOSC-Life and EJP RD project proposals).

[5] https://ec.europa.eu/programmes/horizon2020/en/h2020-section/e-infrastructures

[6] Wilkinson, MD, Dumontier, M, Aalbersberg, IJ *et al.:* The FAIR Guiding Principles for scientific data management and stewardship. *Scientific Data* **3** (2016).

[7] Holub, P, Kohlmayer, F, Prasser, F *et al.:* Enhancing Reuse of Data and Biological Material in Medical Research: From FAIR to FAIR-Health. *Biopreserv Biobank* **16**, 97–105 (2018).

2. Work Plan: Quality

2.1. Workstream: Quality Self-Assessment and Audit Systems

Aim: Following on from building a quality community and promoting and providing training in standards relevant to biobanks (and their associated clinical and scientific disciplines), this year's focus has been on application. The aim was to help biobanks on the way to self-assessing sample quality through the use of European standards (CEN Technical Specifications (CEN/TS)). By providing the BBMRI Self-Assessment Surveys (BBMRI SAS) and reviewing them through BBMRI.QM, it was shown that this evaluation and review process led to the visibility of quality-assessed sample collections in the BBMRI-ERIC Directory. This has been a successful launch into a new form of quality assessment for sample collections and biobanks.

Achievements:

- **Enhanced visibility of 9 quality-assessed sample collections** from 5 different biobanks (Auria Biobank, Biobank Graz, Biobank Vienna, Biobank MMCI, KI Biobank) from 4 National Nodes respectively (Finland, Austria, Czech Republic, Sweden) – Poster presentation at GBW 2017.
- **Introduction of the access queries reporting system** on BBMRI SAS, including metrics on how many requests have led to a quality mark in the BBMRI-ERIC Directory.
- **Concept development of a BBMRI-ERIC Audit Programme**, by establishing a Working Group for the development of a draft concept of a BBMRI Quality Service and Audit Programme.
- **Contribution to International Standard Development** through participation in plenary and working meetings of ISO/TC 276, commenting on ISO/DIS 20187 Biobanking – General requirements for biobanking.
- **25 web-based Expert Working Group meetings** were held on specific topics relating to groups 1, 2, 3, 4, 5 and 7.
- **A Biobanks Europe special issue** was published.
- **A focused session on quality was held at GBW in Stockholm, entitled 'Quality Assessment: a key factor for successful biobanks and reproducible science'** with 4 invited speakers from the National Nodes (DE, NL, AT, IT).

Figure 7.: Quality Management

Outlook: By Q2 2018, a comprehensive BBMRI.QM Service concept, including QM consultancy and audit services, will be drafted. This jointly developed BBMRI.QM Service should serve biobanks and their associated clinical and scientific disciplines in improving their QM systems and support their efforts in obtaining independent certification and accreditation by authorised national qualification bodies. This will allow for harmonisation and standardisation in Europe's clinical and scientific environment, providing the basis for scientific research and development.

3. Work Plan: Ethical, Legal and Societal Issues and Stakeholder Engagement

3.1. Workstream: Common Service ELSI

Aim: To provide relevant expertise, tools, services and policies concerning ethical, legal and societal issues related to biobanking and research infrastructure activities. Key assets of the Common Service are the experts from National Nodes and research institutions (organised into specific Task Forces), the ELSI Knowledge Base and the ELSI Helpdesk.[8]

Achievements:

- The **Task Force International Organisations' Policy Assessment & Monitoring** focuses on ELSI issues and European Institutions, notifying the BBMRI community about public consultations, as well as coordinating joint comments on key public consultations. To date, 11 joint replies have been concluded (e.g., WP29 opinion on informed consent).
- In May 2017, an updated version of the FAQs on the GDPR was issued by the **Task Force GDPR**. Some National Nodes (such as France, Greece and Poland) opted to translate the FAQs into their respective native languages. The focus of the task force currently lies in facilitating exchanges with regard to national implementation of the GDPR and envisaged consequences for the European biobanking community.
- The aim of the **Task Force Rule Making US** is to assess the implications of the development of a risk-based ethical review system for medical research in Europe, aiming to replace the approach undertaken in the US Common Rule. It will complete its task with a report and recommendations in Q1 2018.
- In September 2017, the **ELSI Helpdesk and Tools Task Forces** were combined into a single Task Force called ELSI Helpdesk & Knowledge Base, with the Helpdesk providing custom-based support to researchers, and the Knowledge Base promoting outcomes from activities conducted by other task forces.
- The **Task Force Societal Issues** issued the survey 'Data in Question', focusing on the challenges of obtaining and sharing biological samples and data for research purposes in biobanks. It is intended that the findings will assist in understanding where challenges, resulting from new practices, technologies and changes in European law, lie, and how they can be overcome. Initial results are expected at the end of Q1 2018.
- The **Task Force Sharing and Access** contributed to the BBMRI-ERIC Policy for Access to and Sharing of Samples and Data (a joint effort by CS ELSI and IT), which was adopted by the BBMRI-ERIC Assembly of Members in Q4 2017. Thereafter, the task force was dissolved.

[8] http://www.bbmri-eric.eu/services/common-service-elsi/

Continued activities included the assessment of the ethics check procedure, which was extended to include one case from the ELSI Helpdesk and two cases from the National Nodes in addition to the colon cancer case. Interim results suggest a re-framing of the ethics check as a service in the form of a self-assessment rather than a mandatory procedure. A conclusive report is expected early 2018.

In late 2017, the Common Service ELSI opened (1) a 'call for good examples' to showcase where and how biobanking makes a difference in scientific progress and for the benefit of citizens (Task Force Success Stories) and (2) started to scan for emerging or future ethical, legal and social issues relevant to different stakeholders involved in biobanking (Task Force Foresight and Stakeholder Forum)

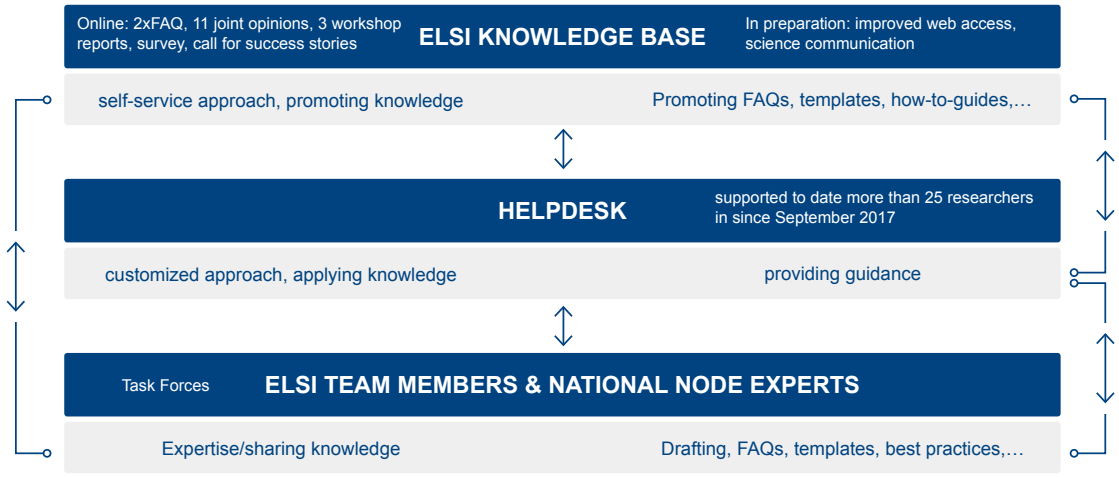

Figure 8.: Relationship between ELSI Helpdesk, Knowledge Base and experts

Outlook: First results of the call and the new Task Force will be available in Q2 2018. The work described above will continue, with a special focus on science communication, (best) practices in relation to returning research results, and engagement activities with citizens and the public forum; particularly in relation to the findings of the data in question surveys and success stories.

3.2. Workstream: Stakeholder Forum

Aim: The mission of the BBMRI-ERIC Stakeholder Forum Secretariat (SFS) is to facilitate project management and liaise services to the Stakeholder Forum (SF) and its individual chapters. The SF aims to provide a platform for discussion; exchange experience and knowledge; be a think-tank in the rapidly changing biobanking environment; and offering a forum for patient representatives and users to interact systematically with investigators and the industry, thereby providing advice and consultancy to the AoM and the Director General. In 2017, BBMRI-ERIC focused on strengthening its capacity to interact with stakeholders by hiring a dedicated Engagement Officer, and by updating its stakeholder engagement strategy.

Achievements:

- **Appointment of an Engagement Officer**: the selection process for the candidate was completed in April 2017. The selected candidate, Francesco Florindi, started in September 2017.
- **Identification and engagement of potential Stakeholder Forum participants**: a survey on stakeholder engagement was submitted to all BBMRI-ERIC Nodes. Data from the survey was used to update and expand the mapping of BBMRI-ERIC Stakeholders.
- **Setting up of an Industry Chapter:** between September and December 2017, the Engagement Officer focused on establishing informal connections with industry stakeholders by participating in several events, such as: (a) European Health Forum Gastein, 3rd – 7th October 2017 (b) IMI Stakeholder Forum, Brussels., 18th – 19th October 2017

  These meetings were instrumental in understanding some of industry's needs and perspectives towards biobanking, which will feed into the set-up of the SF industry chapter.
- **Setting up of a Learned Societies Chapter:** from the stakeholder survey submitted to the Nodes, it emerged that the main shared interest between biobanks and learned societies is collaboration in research projects. For these reasons, in Q4 2017, the Engagement Officer worked on 3 main tasks: - Liaising with learned societies, including federations of societies and research organisations (EORTC, OECI, League of European Research Universities, BioMed Alliance, various universities (Lund, NTNU, etc.)) to inform them about the BBMRI-ERIC SF. - Monitoring the development of the next European Commission's Framework Programme. The Engagement Officer produced a briefing document outlining the process of development of the next Framework Programme, including key deadlines; - Liaising with EMA regarding the Agency's framework of interaction with academia.[9]
- **Task Specific Meetings:** a Stakeholder Workshop was held at the Global Biobank Week. The workshop was an internal BBMRI-ERIC event, bringing together National Node experts dealing with stakeholder engagement. Results: 13 out of 19 National Nodes replied to a stakeholder engagement survey, providing data on the type and quality of stakeholder engagement they prefer, together with their perspectives and expectations of the BBMRI-ERIC stakeholder engagement strategy. A report of the event summarises the discussion at the Workshop and sets the main objectives for the work of the Stakeholder Forum in 2018 and 2019 (see Outlook).

All in all, BBMRI-ERIC should prioritise engagement with: the European Commission (in particular DG RTD, DG JUST, DG CNECT); industry (EFPIA); patients' organisations (in particular in the field of cancer and rare diseases); standardisation organisations (CEN, ISO) and EU agencies related to the implementation of the GDPR (EDPS); other research infrastructures; health and research ministries, together with EU governments' Permanent Representatives; selected learned societies with high interest in biobanking. BBMRI-ERIC's stakeholder engagement strategy should be updated to fit the needs expressed by the National Nodes, namely to provide a permanent platform to support the Nodes engagement work, provide the Nodes with best practices and training, identify synergies and set up common stakeholder engagement initiatives.

Outlook: The next Stakeholder Forum meeting (patients/consumers pillar) will take place in Q1 2018.

[9] http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/03/WC500224896.pdf

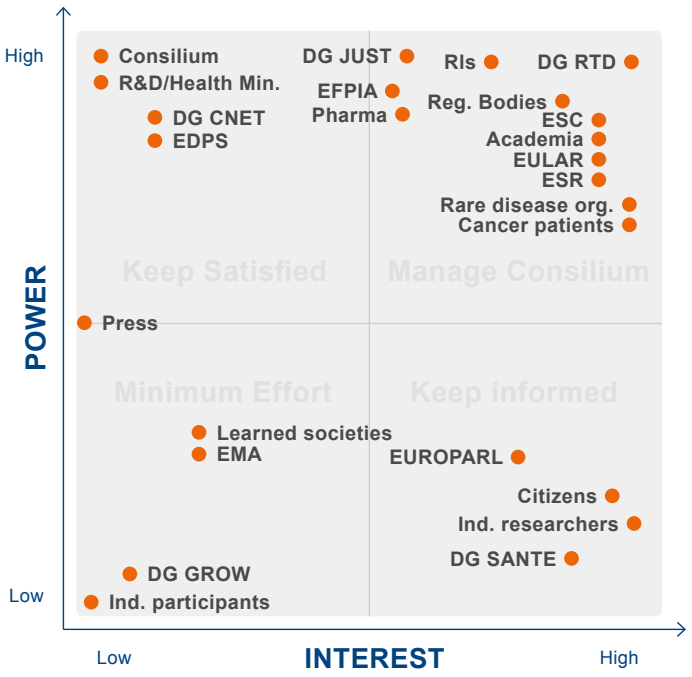

Figure 9.: Results of the stakeholder engagement survey submitted to National Nodes – identification and prioritisation of key stakeholders for BBMRI-ERIC

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4. Work Plan: Biomolecular Resources Service

4.1. Workstream: Biomolecular Resources Service

Aim: The intention of the Biomolecular Resources Service was to coordinate and connect services and expertise, in various locations throughout Europe, in the area of biomolecular resources.

Achievements:

- **Mapping of users and user needs** was executed in the context of ADOPT BBMRI-ERIC and BBMRI-LPC (page 115). The appointment of a Biomolecular Resources Officer was put on hold following the change of leadership.

4.2. Workstream: Technology Watch

Aim: Evaluating and aligning available technologies for biomolecular resources esp. in terms of cost, availability, speed and quality. It aims to map, evaluate and align the available technologies for biomolecular resources to meet the needs of users. The objective is to ensure broad access to advanced, unique and emerging technologies. Activities are linked to Workstream 8.2 of ADOPT BBMRI-ERIC and BBMRI-LPC (page 115).

Achievements:

- **Preparation for the launch of Technology Watch**: the Engagement Officer evaluated different methodologies and technologies (softwares) to identify the one best suited to performing the tasks.
- **Setting up of the Technology Watch monitoring system**: once the most suitable method was identified for collecting and sorting information on new technologies, the Engagement Officer proceeded to set up the system and acquire the software necessary to perform the tasks.

Outlook: By Q2 2018, Technology Watch will be fully operative. Frequent reports will be shared with both BBMRI-ERIC HQ and the National Nodes as appropriate.

5. Work Plan: Cohorts

5.1. Workstream: Catalogues

Aim: Integrating the BBMRI-LPC catalogues into the BBMRI-ERIC IT infrastructure.

Achievements:

- Given the extension of BBMRI-LPC (page 115) until October 2017, this work plan has been pursued exclusively within the FP7 project: http://www.bbmri-lpc-biobanks.eu/cohorts.html

Outlook: Integration of cohorts is not a priority in the Work Programme 2018 and may be executed in the context of H2020 projects.

5.2. Workstream: A Biobank Cost Calculator

Aim: Testing and integrating the Cost Calculator into BBMRI-ERIC.

Achievements:

- In the context of LPC, the Cost Calculator was employed by, but not integrated with, BBMRI-ERIC following the end of the FP7 project. It is part of the Work Programme 2018.

6. Work Plan: Biomedical Imaging

6.1. Workstream: Imaging Biobank Integration into BBMRI-ERIC Directory

Aim: Maintaining the collaboration between BBMRI-ERIC and the European Society of Radiology (ESR), to develop common data models for imaging and biobanking and ultimately integrate imaging biobanks into the BBMRI-ERIC Directory. In 2015, imaging biobanks were defined by the European Society of Radiology, through the "Position Paper on Imaging Biobanks", as "organised databases of medical images and associated imaging biomarkers (radiology and beyond) shared among multiple researchers, and linked to other biorepositories".

Achievements:

- The MIABIS-DICOM Working Group continued its operation: the model proposed in 2016 was internationally reviewed and a virtual meeting was organised on 4th October 2017, which decided on a further strategy for how to proceed.
- The ESR provided test data of an imaging biobank that has been integrated into the BBMRI-ERIC Directory.
- The ESR requested for additional data from 10 already established imaging biobanks to be included in the BBMRI-ERIC Directory.
- A link has been established with the Dutch imaging biobanks Working Group in order to develop consistent data model updates for the BBMRI-ERIC Directory.
- A programme of the ESR/BBMRI-ERIC leadership meeting and imaging biobank session has been prepared for European Congress of Radiology 2018.

Outlook: Integration of additional imaging biobanks into the BBMRI-ERIC Directory and establishment of a sustainable data curation model in collaboration with the ESR.

6.2. Workstream: Imaging e-Infrastructure

Aim: Allowing the generation of imaging biomarkers for use in research studies and supporting biological validation of existing and novel imaging biomarkers.

Achievements:

- BBMRI.it established a national **working group on Imaging Biobanks**. The WG involves several research groups in Italy. It continues to collaborate with the European Society of Radiology and has developed a collaboration with the University of Valencia.
- The WG aimed to **define Standard Operating Procedures (SOP's)** for image processing methods, to obtain quantitative data capable of providing information on pato-physiological phenomena (radiomics).
- To this aim, an **oncological imaging biobank** has been established, including multiple cancer types.[10] To date, the biobank includes 160 studies of magnetic resonance in colorectal, breast and prostate cancers. The main ongoing activity is the extraction of biomarkers from imaging data; a complex framework that includes image segmentation, analysis and radiomic features extraction.

Outlook: The next step will be to link imaging biomarkers with other 'omics' biobank data from the same patients in order to achieve consistency and interoperability across European biobanks. This will be achieved by collaborating closely with EATRIS.

[10] Neri, E & Regge, D: Imaging biobanks in oncology: European perspective. *Future Oncol* **13**, 433–441 (2017).

7. Work Plan: Outreach

7.1. Workstream: Communication

Aim: This workstream aims to provide the biobanking community with relevant information,while also raising awareness of biobanking outside the community.

Achievements:

- **Website**: One of the most frequently visited pages on the website is the news and events page featuring regular updates from the National Nodes.
- **Social Media**: All news articles on the BBMRI-ERIC website were shared on social media, i.e., Twitter and LinkedIn. Later in the year, events were also posted. Twitter was used to share more dynamic content, such as updates during important events like Global Biobank Week 2017.
- **Monthly Newsletter**: BBMRI-ERIC has a monthly newsletter with close to 5,000 subscribers. This mailing list is also used to send out important updates a few times a year, for example when online registration for our conference opens.
- **Internal Mailing Lists**: As for internal communication, there are mailing lists that are used to address specific target groups such as the Assembly of Members etc.

As far as print material is concerned, BBMRI-ERIC continued to use a variety of print material featuring its corporate identity, e.g., notepads, letterheads, flyers, folders, conference bags, business cards, compliment cards, and, most notably, Biobanks Europe, a print magazine.

2017 saw two new issues of Biobanks Europe. Issue No. 6/2017, a special issue on quality, notably attracted a lot of interest from the biobanking community. Regarding online communication, there was a significant increase in news articles on the website, along with more frequent updates on Twitter and LinkedIn. This increase in social media activity resulted in high gains in follower numbers on both platforms. The number of newsletter subscribers saw a steady increase from 4,707 to 4,823 throughout the year. With a total of 23,602 users, website traffic was more or less the same compared to the previous year.

Scientific Publications

- Hainait P, Vaught J, Zatloukal K, Pasterk M (Eds): Biobanking of Human Biospecimens. Principles and Practice. Springer.
- Jiménez RC, Kuzak M, Alhamdoosh M, Holup P, et al.: Four simple recommendations to encourage best practices in research software [version 1; referees: 3 approved]. F1000Res. 2017; 6: pii: ELIXIR-876.
- Litton JE: We must urgently clarify data-protection rules. Nature 541, 437 (26 January 2017)

- Paterson RRM, Lima N, Brooksbank C, Guarini E, Pasterk M, Lavitrano M, RItrain project consortium: Microbiology Managers: Managerial Training in the RItrain Project. Trends Microbiol. 2017 Jun;25(6):425–428.

Press Reports

- ISC, Global Biobank Week: Toward Harmony in Biobanking (13 Jan 2017)
- CORDIS, BBMRI-ERIC seminar: 'BBMRI-ERIC's role and contribution to the implementation of the Cloud' (17 Jan 2017)
- Research Europe: Science advice panel struggles to find feet (9 Feb 2017)
- ISC, Summary Report on the BBMRI-ERIC Working Meeting on Health and Life Sciences GDPR Code of Conduct (22 Feb 2017)
- ISC, BBMRI-ERIC's contribution to health research capacity building in Africa (Mar 2017)
- Heise.de, Das Genom ist nicht genug (29 Mar 2017)
- Meteoweb.eu, Salute: l'Incontinentia Pigmenti puo essere trasmessa anche dai padre (25 Aug 2017)
- Nowiny24.pl, Uniwersytet Rzeszowski we współpracy z firmą Softsystem tworzą Podkarpacki Biobank (7 Sep 2017)
- Mirai-intex.com, MIRAI Intex participated in the Global Biobank Week (26 Sep 2017)
- Europe Biobank Week 2018 (28 Nov 2017)

Outlook: The 2018 Work Programme has a specific focus on marketing and communications. The main tasks include creating a new corporate identity, developing a more detailed content strategy, creating a press kit and launching PR campaigns. KPIs have been defined to measure the outcomes.

7.2. Workstream: Education and Training

Aim: This Workstream aimed to develop an Education and Training policy framework for Biobank employees in Europe and beyond. It is cross linked with the tasks and deliverables of H2020 Project CORBEL and RItrain.

Achievements:

- **Policy Framework**: The Working Party Education and Training Policy did not meet in 2017.
- **European Master Curriculum**: During 2017 we introduced the idea of a joint European Master in biobanking, bringing together representatives from the majority of universities which currently run such programmes (Medical University of Graz, AT; Catholic University of Lyon, FR; University of Nice, FR; Catholic University of Valencia, SP and Kings College London, UK). These institutions are now discussing collaboration through different funding models like COST or ERASMUS.

- **CORBEL**: The main target audience of the H2020 project CORBEL training programme are technical operators in biological and medical research infrastructure hubs and nodes. The content of the curriculum is based on the development of the CORBEL competency profile.[11] Several pilot training activities have been successfully delivered:
  - A short training course, 'Data Visualisation for Biology: a practical workshop on design, techniques and tools';
  - Two webinars, 'Identifying and Networking with Industry: How to Market Your Research' and 'User Experience Design for more user-friendly applications' respectively, by speakers from EATRIS and EMBL-EBI;
  - Two staff exchanges by ECRIN/BBMRI (General Data Protection Regulation (GDPR) issues and ELSI Helpdesk) and CCMAR (User Access and Service Provision).
  - Additionally, the CORBEL training activities have been extended by a fellowship scheme, which supports technical operators to attend training courses relevant to CORBEL but not organised by the consortium. Lastly, further prioritisations for training needs and improvements on training modules (e.g., communication) were discussed.
- **RItrain**: In the context of the H2020 project RItrain, the focus is to train managers of RI. The Executive MBA at University Milano-Bicocca successfully started in September 2017. 115 applications from 25 countries allowed the selection of 25 candidates (including two people from BBMRI National Nodes). Moreover, several staff exchanges have been organised to date and some 20 webinars recorded (e.g., 'The RI environment' by Eero Vuorio). In addition, several educational webinars were organised (e.g., quality) and staff participated in several teaching activities (e.g., Markus Pasterk and Mats Hansson as Visiting Professors for the Executive MBA in Milano or lecturers for the online Masters in Biobanking Management at the Medical University Graz).

Figure 10.: H2020 RItrain project partners

Outlook: CORBEL and RItrain continue to run during 2018 and will provide further opportunities for employees of biobanks to train as operators as well as managers. Training programmes and awareness-raising webinars on key topics (esp. GDPR) will be intensified.

[11] European Virus Archive goes global, https://zenodo.org/record/154085#.WYGGb4jys2w

7.3. Workstream: Global Biobank Week: Towards Harmony in Biobanking

Aim: The aim of the annual biobanking conference is to bring together members of the biobanking community and provide them with a forum to discuss current issues and the latest developments in biobanking. The theme of the 2017 conference was 'Towards Harmony in Biobanking'.

Achievements: Global Biobank Week 2017, the first biobanking conference on a global scale, took place in Stockholm between 13th – 15th September 2017. Co-organised by BBMRI-ERIC, BBMRI.se, ESBB and ISBER, the event attracted a total of 857 participants from 53 different countries, including 162 vendors exhibiting state-of-the-art biobanking technology. The programme offered many different options, including two workshops on the pre-conference day, a total of 23 scientific sessions, poster presentations and social events such as a networking dinner and site visits.

Outlook: The next edition of Global Biobank Week is set to take place in 2019. In the meantime, BBMRI-ERIC and ESBB will be organising another edition of Europe Biobank Week, which will take place in Antwerp from 4th – 7th September 2018.

Figure 11.: Key Note Lecture by Gregory C. Simon, President of the Biden Cancer Initiative

7.4. Workstream: Code of Conduct for Health Research

Aim: The EU General Data Protection Regulation (GDPR) specifies in Article 40 that 'the Member States, the supervisory authorities, the Board and the Commission shall encourage the drawing up of codes of conduct intended to contribute to the proper application of this Regulation, taking account of the specific features of the various processing sectors and the specific needs of micro, small and medium-sized enterprises.'

Under the coordination of BBMRI-ERIC, a Code of Conduct for Health Research is being developed to be as comprehensive as possible in order to (a) guide researchers and administrative staff, (b) reduce unnecessary fear relating to compliance and (c) enhance data sharing for the purpose of stimulating progress in research. The ultimate aim is to reach a sector-specific code that explains how the GDPR applies in practice. With regards to clinical trials, it will focus on the secondary use of data that is not regulated within the Clinical Trials Directive. The code has to be comprehensive to non-legal experts.

Achievements: By late 2017, 130 individuals representing 80 organisations in the field of health research had indicated their interest and support for the Code of Conduct for Health Research. Indicating interest in the initiative does not mean that an individual or organisation endorses the Code. It means that they see benefit in the development of such a code and are interested in partaking in the process. It is set up as a non-exclusive initiative. It welcomes representatives from sector-specific organisations who are interested in a Code of Conduct for Health Research and are committed to its development. It differentiates three levels of involvement:

- **The Code of Conduct Forum**: comprises all individuals and organisations interested in the code's development.
- **The Code of Conduct Drafting Group**: consists of 10 legal and data protection experts who represent health research, patient advocacy groups, industry and BMS research infrastructures as well as learned societies.
- **The Code of Conduct Reference Groups**: include experts to be consulted on an ad-hoc basis to inform the drafting of specific sections.

A regular dialogue with key policy makers including DG Justice, EDPS and national DPAs has been set up. Two Forum meetings and several drafting group meetings have been held to date. The initiative has been introduced to a wider audience via webinars and conference participations as well as in a specific session at the CDPC 2018.[12]

The key topics of the code are on the lawfulness of processing (esp. Art.9(j) related to 6 and 89), the responsibility of the controller/processor and their relationship (esp. Arts. 24, 28) and the appropriate safeguards (esp. pseudonymisation). The code shall be drafted in a non-legalistic language following the typical workflow structure of a researcher and shall explain rules by using practical examples and representative scenarios.

[12] https://www.youtube.com/watch?v=kE_uf2H1uc8

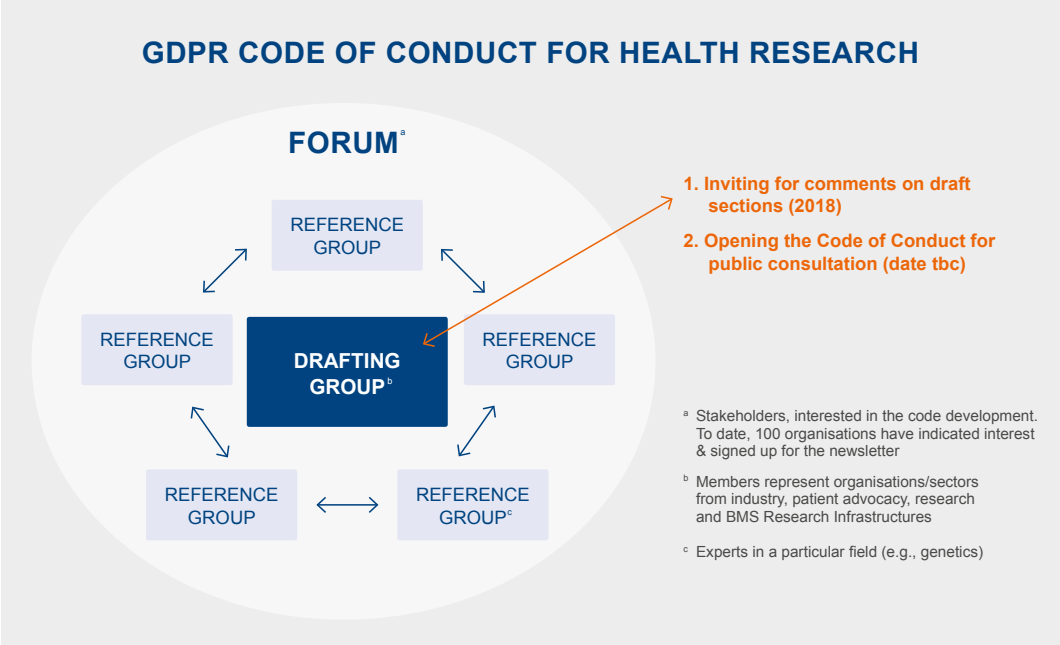

Figure 12.: Levels of involvement in the Code of Conduct for Health Research initiative

Outlook: In late 2018, sections of the draft code will be shared to the Forum for comments. A key element of the code will be the governance structure. This will be developed in Q3 2018. The complete draft code will be open for public consultation (date tbd). Once consensus on the final document is reached, organisations will be invited to support the code in line with Article 40 of the EU GDPR. To date, the exact process of submitting the code under the EU GDPR to the European Commission is unclear. The WP 29 has set up a working group to define this process. It is expected to be known before the summer.

8. Work Plan: Continued Workstreams

8.1. Workstream: Expert Centres

BBMRI-ERIC Associated Expert Centres/Trusted Partners[13] are non-profit organisations representing a novel public-private partnership model. BBMRI-ERIC performed the first audit at CBmed GmbH.[14] The audit for ATMA-EC[15] is foreseen in 2018. A dialogue with EXCEMET[16] is ongoing.

8.2. Workstream: Biomarker Verification and Validation

BBMRI-ERIC Associated Expert Centres/Trusted Partners CBmed (Austria) and ATMA-EC (Italy) are active in biomarker development and validation, particularly in the context of Herkules[17] and of ADOPT BBMRI-ERIC[18] projects. In 2017, BBMRI.it organised two workshops with the participation of major European experts from the Biobanks and Molecular Pathobiology WG of the Organisation of European Cancer Institutes (OECI), the ATMA-EC and the Molecular Pathology WG of the European Society of Pathology (ESP). The WGs resulted in the development of SOPs and guidelines for next generation sequencing (NGS) protocols using clinical tissues (including FFPE tissues) and for protocols of ccfDNA testing from liquid biopsies-plasma.

8.3. Workstream: Healthcare Integrated Biobanking

The establishment of a collection of 10,000 datasets/samples derived from patients suffering from colorectal cancer has been selected as use-case in the framing of the ADOPT BBMRI-ERIC project. For this purpose, a Working Group including 43 participants from all National Nodes has been established. The WG deals with issues relating to disease-oriented biobanks. A second interdisciplinary WG including biobankers, clinicians, disease registry experts, researchers and IT experts has been set up to develop a formal model including entities and their attributes, for collection of sample's datasets. The WGs continue to establish and share SOPs related to liquid biopsies, FFPE and frozen tissues.

[13] Wutte, A & Litton, JE: *BBMRI-ERIC-Associated Expert Centres/Trusted Partners V2.0* 2015. doi:10.5281/zenodo.164634.
[14] http://www.cbmed.org/en/index.php
[15] http://atma-ec.com/
[16] http://www.excemet.org
[17] Activities are liaised with the HERCULES project (EP 667403). It is developed to characterise effective combinatorial targeting of high-grade serous ovarian cancer. It is coordinated by Helsinki University and presents two phases: the first based on discovery and the second on verification and clinical validation of new biomarkers on two large populations, one Scandinavian and one Italian.
[18] Within ADOPT BBMRI-ERIC's WP6, a joint initiative on imaging biomarker has been initiated. A call for a digital pathology competition based on digital slides and clinical data related to the ADOPT BBMRI-ERIC colorectal cancer cohort has been prepared. The competition should follow the model of the Camelyon competitions. All national nodes of BBMRI-ERIC are invited to participate in the organisation.

8.4. Workstream: Archived Tissues

The Quality Expert Working Group 2 for quality management for formaline-fixed paraffin-embedded (FFPE) tissues has been active since 2016. In 2017, it conducted five webinars. It continues to collaborate with the European Standardisation Committee and others, such as the European Society of Pathology, the Organisation of European Cancer Institutes and the H2020 project SPIDIA4P.

8.5. Workstream: Liquid Biopsies

The Quality Expert Working Group 3 for human whole blood molecular analysis held three webinars in 2017. Its output is used in the context of the H2020 project SPIDIA4P to develop CEN/ISO standards for sample pre-analytics.

8.6. Workstream: Immortalised Cell Lines

A working group on immortalised cell lines has been active since 2017 in Italy. It continues to collaborate with the International Cell Line Authentication Committee. It contributes to the Register of mis-identified cell lines and to the Cellosaurus, a knowledge resource on cell lines containing information on more than 100,000 human and animal cell lines.

8.7. Workstream: Microbiome

The MicroPred proposal (H2020-SC1-2018-Singel-Stage) was prepared by bringing together leading biobanks hosting microbiome samples and/or data. The output of the project should feed into the work of the H2020 project SPIDIA4P aimed at developing CEN and ISO standards on microbiome pre-analytics.

8.8. Workstream: Rare Diseases

A rare disease section of the Directory has been implemented in collaboration with RD-Connect. A RD Helpdesk has been implemented in collaboration with ADOPT BBMRI-ERIC. The BBMRI RD Working Group continued the established routine of teleconferences every 3 months in order to reduce fragmentation and work jointly with the National Nodes, RD-CONNECT and BOND ERN.[19] The use case on OI was conducted in collaboration with ELIXIR to make all data contained in biobanks and registries FAIR.

[19] European Reference Network for bone dieases, more details see https://ec.europa.eu/health/sites/health/files/ern/docs/ernbond_factsheet_en.pdf.

8.9. Workstream: Infectious Material

In 2017, a dialogue with EVAg continued but has not led to concrete actions thus far.

8.10. Workstream: Headquarters

The BBMRI-ERIC Headquarters is based in Graz and is responsible for the executive management of BBMRI-ERIC and respective project participations. In August 2017, Erik Steinfelder succeeded Jan-Eric Litton as Director General.

8.11. Workstream: Scientific Retreat

A joint Assembly of Members and Management Committee meeting was held in Lausanne for an indepth discussion on IT, ELSI and Stakeholders.

8.12. Workstream: Assessment and Improvement of BBMRI-ERIC

In 2016, BBMRI-ERIC delivered a list of possible performance measures. In 2017, key performance indicators were selected and will be implemented in Q1 2018.

8.13. Workstream: Fund-raising Activities

BBMRI-ERIC continued its activities to receive additional funding for its core activities. BBMRI-ERIC participated in research project consortia as a participant/contributor or an associated organisation that supports research consortia with a letter of intent. Since 2014, BBMRI-ERIC has been involved in 42 H2020 calls in total (thereof: three as coordinator/co-coordinator). **The success rate is 31.6%.** BBMRI-ERIC is non-discriminatory as regards the scope of the project, whether scientific or infrastructural.

Part III.

Activities of National/Organisational Nodes

9. Members and Observers

BBMRI.at (Member)

Country

Year joining BBMRI-ERIC: 2013
GDP: €306.4 billion
Population: 8.6 million
Number of biobanks and stand-alone collections as specified in the Directory 4.0: 4 biobanks

National Node

Start date: 1 December 2013
Director: Kurt Zatloukal
Total staff (FTE/year and headcount): 7.5 FTE/year and 36 persons on the 2016 payroll (employment ranging from 5–100% and 1–12 months)
Total funding (period): €3.5 million
Funding body: Federal Ministry of Science, Research and Economy (BMWFW) (GZ 10.470/0016-II/3/2013)
Legal entity of/hosting institution of National Node: Medical University of Graz
Partners (total 7): *Medical University of Graz*; *Medical University of Vienna*; *Medical University of Innsbruck*; *University of Veterinary Medicine, Vienna*; *Paracelsus Medical Private University, Salzburg*; *Life Science Governance Institute, Vienna (until Oct 2016), and University of Vienna (since Nov 2016)*; and *Alpen-Adria-University Klagenfurt*.
Web: http://www.bbmri.at
National Catalogues: http://catalog.bbmri.at/

About

With its partner universities and biobanks, BBMRI.at establishes and further develops the Austrian biobanking research infrastructure and integrates it into BBMRI-ERIC. It increases the close co- operation and harmonisation between Austrian biobanks with respect to sample, data and quality management and engages its stakeholders, particularly citizens/patients and industry stakeholders. This is a prerequisite for facilitating access to biological samples and data for academic and industrial research and for fostering their use.

Specific Strengths

- Solid community of BBMRI.at partners
- Expert contribution to and development of CEN/TS and International Organization for Standardization (ISO) standards (e.g., CEN/TC 140, ISO Technical Committee (ISO/TC) 212, ISO/TC 276)
- Pioneering role in BBMRI-ERIC's quality management (QM) activities of BBMRI-ERIC: Development of a Self-Assessment Tool to assess conformity with CEN/TS and its joint development for pan-European use with the BBMRI-ERIC QM expert group; organisation of hands-on training courses for pre-analytical sample processing, building biobanks, as well as a MSc (Master of Science) in Biobanking; commitment of partner biobanks to, and conduction of, BBMRI.at QM cross audits (since 2017)
- Biobank Graz[20] – one of the largest biobanks in Europe, awarded with several prizes
- BBMRI.at Biobank Catalogue with all partner biobanks and their collections (since 2013)
- Conducting Citizen Expert Panels and hosting workshops with citizens/patients and experts (from the ethics committee, patient organisations, biobanks)
- Engagement of the public (particularly children) through workshops and events
- VetBiobank[21] with non-human/animal biospecimens and data
- Translational Science Forum with industry representatives
- 1st BBMRI-ERIC expert centre for biomarkers (CBmed)
- Standardised Biomaterial Material Transfer Agreement (MTA) templates (human, animal) jointly developed by interdisciplinary experts from universities and industry

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

e-Infrastructure

- All BBMRI.at biobanks in the BBMRI.at Catalogue and BBMRI-ERIC Directory 4.0
- First BBMRI-ERIC node to declare sample quality (i.e., meeting the CEN/TS requirements) in its national catalogue and feed it into the BBMRI-ERIC Directory
- Establishment of a national digital pathology infrastructure to complement biobank tissue samples with digital image information
- Further development of BiBBoX, a repository for biobank open source software (together with projects, such as B3Africa and ADOPT BBMRI-ERIC)
- Active participation in the BBMRI-ERIC Common Service IT
- Close collaboration with BBMRI-ERIC on the implementation of the General Data Protection Regulation (GDPR) in biobanking

Quality

- Expert contribution to and development of CEN/TS and ISO standards (e.g., FFPE – in situ staining/detection) in the context of the SPIDIA4P project
- Start of the BBMRI.at internal cross audits – first audit performed at partner Biobank Graz
- Among the first nodes with biobank sample collections meeting CEN/TS requirements
- Support of BBMRI-ERIC Quality Manager Andrea Wutte with launching and further developing the BBMRI-ERIC Self Assessment Survey and planning the BBMRI-ERIC QM Audit Programme
- Continued implementation of CEN/TS in biobanking workflows in BBMRI.at biobanks

[20] https://www.medunigraz.at/biobank/
[21] http://www.vetmeduni.ac.at/de/vetcore/research/researchunits/vetbiobank/

- Education and training activities on sample quality management at local and international level

Clinical Biobanks

- Contribution to the development of a set of data on colon cancer collections in ADOPT
- Development of a show case to use the colon cancer cohort for imaging biomarkers of colon cancer in ADOPT BBMRI-ERIC
- Participation in the Austrian Platform for Personalised Medicine (ÖPPM)
- Participation in the 2nd ERINHA preparatory phase (biobanking in high security labs)

Population-based Cohorts

- Cooperation with the Human Biomonitoring Platform Austria, a member of the European Human Biomonitoring Initiative for harmonising human biomonitoring initiatives (HBM4EU)[22]

ELSI

- Organisation of three Citizen Expert Panels (Vienna, Graz, Innsbruck)
- Definition of technical, ethical, legal and governance-related requirements for the implementation of the General Data Protection Regulation
- Participation in the BBMRI-ERIC Common Service ELSI (Task Force Societal Issues) as ELSI experts
- Public activities, such as workshops and events (e.g., junior researcher days for children from kindergartens, primary and secondary schools)

Expert Centres

- Engagement in the implementation of CEN/TS at expert centres [23] in collaboration with SPIDIA4P
- Further development of the Expert Centre model for other research infrastructures (in COR-BEL (page 118))

Education & Training

- Several local and international training sessions were held: on sample quality management and biobanking (e.g., 'Implementation of sample quality standards CEN/TS' (MUI), 'Pre-analytical Sample Processing according to CEN/TS' (MUG), 'Master (MSc) in Biobanking' (MUG), 'How to build a biobank' (MUG); and on IT and data management (e.g., training course on open source biobanking software)

[22] http://www.umweltbundesamt.at/en/news_events_reports/news_eaa/en_news_2017/news_en_170203/
[23] http://www.cbmed.at/en/index.php

BBMRI.be (Member)

Country

Year joining BBMRI-ERIC: 2013
GDP: €455.1 billion
Population: 11.4 million
Number of biobanks and stand-alone collections as specified in the Directory 4.0: 13 biobanks

National Node

Start date: 1 January 2013
Director: Annelies Debucquoy (Deputy: Karin Haustermans/Sofie Bekaert/Etienne Marbaix)
Total staff (FTE/year and headcount): 1.25 FTE/year and 4 members of staff
Total funding (period): The different biobank networks are funded by several funding bodies. The Belgian Science Policy Office (BELSPO) contributes to the annual BBMRI-ERIC membership fee. The Belgian Cancer Registry is financed by the Belgian Ministry of Public Health for the setup of the Coordination Office and the BBMRI.be IT platform. The Belgian Virtual Tumorbank (BVT) and 11 local partner biobanks receive funding from the Belgian Ministry of Public Health from 2009 onwards for an indefinite period. BWB is supported by DG06 (Walloon region) and Innoviris (Brussels capital region). The Flemish Biobank Initiative is financed by IWT and by the Flemish Government.
Funding body: BELSPO, Belgian Ministry of Public Health, DG06, Innoviris, IWT and Flemish Government
Legal entity of/hosting institution of National Node: Belgian Cancer Registry **Partners (total 13):** *Brugmann University Hospital*; *University Hospital of Liege*; *University Hospital of Mont-Godinne*; *Institut de Pathologie et de Génétique*; *St-Luc University Hospital*; *Erasme Hospital*; *Jules Bordet Institute*; *University Hospital of Ghent*; *University Hospital of Antwerp*; *University of Hasselt*; *University Hospital Leuven*; *University Hospital Charleroi*; *University Hospital Brussels*.
Web: http://www.bbmri.be
National Catalogues:
http://www.virtualtumourbank.kankerregister.be/
http://www.biotheque-wallonie-bruxelles.be/
https://vlaamsebiobank.cmi-vzw.be/

About

Belgium's scientific participation in BBMRI-ERIC is exerted by a National Node, which collaborates closely with the Central Executive Management Office and involves the three Belgian network biobank initiatives: the Belgian Virtual Tumorbank project, assigned to the Belgian Cancer Registry (BVT-BCR; Federal Initiative); the Bibliotheque de la Fédération Wallonie-Bruxelles (BWB; Walloon Initiative); and the Flemish Biobank Network (Flemish Initiative). Altogether, this network connects 13 biobanks that are linked to public institutions such as hospitals, universities and research centres.

Specific Strengths

- Large number of clinical biobanks with high quality samples and associated data.
- Three sample locators with sample-level data available; one with oncological samples and two with samples and data collected from patients with a broad range of diseases (e.g., hepatotropic viruses, diabetes, inflammatory bowel disease, rheumatoid arthritis, etc.).
- Five working groups have been established on a national level, with experts in the different fields: ELSI, IT, Quality, Stakeholder Involvement, Networking & Valorisation

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

e-Infrastructure

- BBMRI.be has three sample locators available with sample-level data. Preparations are being made to set up a national IT platform which will bring together the 3 different catalogues. This national catalogue will also be part of the BBMRI-ERIC sample locator;
- All BBMRI.be biobanks are included in the BBMRI-ERIC Directory. In 2017, several BBMRI.be biobanks updated their data in accordance with the new dataset of Directory 3.0.
- Several members of BBMRI.be have actively participated with the MIABIS WG in the development of the standard minimal dataset that will be used for BBMRI-ERIC's Sample Locator.

Quality

- During 2017, the situation and needs in the domain of quality management in biobanks in Belgium were assessed by means of two surveys. The surveys showed that there is an extreme degree of variability as to which guidelines / standards are used in the biobanks. Based on the results of the surveys, it was decided that the activities of the BBMRI.be Quality Working group in 2018 will mainly focus on the BBMRI-ERIC quality handbook and the ISO/DIS 20387.
- During 2017, five BBMRI.be biobanks completed the self-assessment survey developed by BBMRI-ERIC. Three BBMRI.be Quality experts are participating in the draft of the BBMRI-ERIC audit program that is being developed.

Clinical Biobanks

- The BBMRI.be network harbours 13 clinical biobanks with a variety of collections.
- Seven of the BBMRI.be biobanks are participating in the colorectal data collection of ADOPT BBMRI-ERIC (page 113)

Population-based Cohorts

- Currently, BBMRI.be has no biobanks specialised in population-based cohorts. There are however some biobanks that have some population-based collections (e.g., Twin Study, Mother-child studies).
- Negotiations with two Belgian biobanks with population-based cohorts to be included within BBMRI.be are ongoing.

ELSI

- During 2017, the ELSI WG of BBMRI.be was mainly involved in the development of the new Belgian Biobank Law. Feedback was given on the Royal Decree draft and a practical guidance document for this new Belgian Biobank Law is being developed.

- The Belgian ELSI experts have participated in the drafting process of the GDPR Code of Conduct. Several BBMRI.be members attended meetings about the General Data Protection Regulation (7/06/2017: The Code of Conduct Forum meeting, Brussels; 6/11/2017: GDPR Code of Conduct for Health Research and implications for FP9 (Brussels).

Expert Centres

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Education & Training

- At the different Belgian universities, several biobank-related courses are organised as part of the Master of Science in Biomedical Sciences and the Bachelor in Biomedical Laboratory Technology with a focus on courses about quality and ELSI, e.g., Quality Management for Biomedical Laboratories; Good Laboratory Practice; Bio-Ethics in Experimental Medicine; Proteomics, Genomics, Metabolomics.
- First BBMRI.be Annual meeting (21st September 2017)
- Biobank managers meeting (14th November 2017): meeting organised by the Belgian Cancer Registry to update biobank managers about new rules and regulations in the biobanking field and give training concerning the registration of tumour samples in the Belgian Virtual Tumorbank

Other

- Stakeholder Involvement: In 2017, the Stakeholder Involvement Working Group of BBMRI.be was involved in two initiatives: (1) Multistakeholder dialogue in prioritising hepatology research and biobanking project (2) Reverse Science Café. Members of BBMRI.be also participated in the Stakeholder Forum that was organised in September 2017.

BBMRI.ch (Observer)

Country

Year joining BBMRI-ERIC: 2015
GDP: €485.13 billion
Population: 8.1 million
Number of biobanks and stand-alone collections as specified in the Directory 2.0: 0 biobanks

National Node

Start date: 1 January 2015
Director: Cristine Currat
Total staff (FTE/year and headcount): 5.8 FTE/year
Total funding (period): €3.2 million (2015–2018), 800k CHF
Funding body: Swiss National Science Foundation (SNSF)
Legal entity of/hosting institution of National Node: Swiss Biobanking Platform Association
Partners (total): Bern University Hospital (Inselspital), Centre Hospitalier Universitaire Vaudois (CHUV), Geneva University Hospitals (HUG), University Hospital Basel (USB), University Hospital Zurich (USZ), Ecole Polytechnique Fédérale de Lausanne (EPFL), Swiss Academy of Medical Science (SAMS), Swiss Institute of Bioinformatics (SIB), Swiss Personalized Health Network (SPHN), Swiss Society for Microbiology, Swiss Tropical & Public Health Institute, Vetsuisse Faculty University Bern & Zurich
Web: http://www.bbmri.ch or http://www.swissbiobanking.ch
National Catalogues: under construction

About

Swiss Biobanking Platform (SBP) is the national coordination platform for biobanks in human and non-human domains. It is an initiative of the SNSF, which responds to increasing requests from biomedical sciences researchers in terms of quality control, access, transparency and the interconnectedness of biobanks (BB) and their basic data for research purposes. SBP aims to centralise information on human and non-human BB and data collections, which have been established to serve specific scientific questions, and to ensure broad access to these data for research purposes. It holds a register of BB and data collections in Switzerland. It provides up-to-date technical know-how and training for biobanking and IT management (e.g., 'good biobanking practices', know-how on sampling, samples conservation and treatment of information), information and counselling on legal and ethical aspects of biobanking, as well as information on repositories abroad. As a BBMRI national node, SBP ensures harmonisation of biobanking practices with international and EU standards, provides information on BB networks abroad and other related activities.

Specific Strengths

Support and harmonisation of biobanking activities within the five University Hospitals through:

- Recommendations for biobanking activities based on quality, BB governance, interoperability and public engagement
- Advisory function in other Swiss initiatives, such as the Swiss Personalized Health Network (SPHN) and Swiss Academy of Medical Science (SAMS)
- Harmonisation and interoperability: development of common datasets for liquid, tissue and microbiological samples, to ensure that the documentation of sample history follows common standards and to enhance visibility
- BB Information Management System (BIMS) strategy: professionalisation and interconnection for biobanks with or without BIMS
- Support in legal and ethical issues

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

e-Infrastructure SBP BIMS strategy:

- Providing a business model analysing the benefit of a unique BIMS for Switzerland or a common language to
- Adopting solutions for BB with or without BIMS requiring a Standard Data Format (based on a standardised dataset for liquid, tissue and microbiological samples)
- Adopting solutions for BB interested in using SBP BIMS modules, where this Standard Data Format is integrated

SBP e-Catalog strategy:

- Identifying and piloting data and solutions through different SNSF BioLink projects (projects intended for investigators who wish to network their BB using IT systems)
- Linking the Swiss directory to the BBMRI directory in collaboration with BBMRI Common Service IT
- Liaising with SPHN in view of having one reference source on BB

Quality Active participation in BBMRI-ERIC quality expert working groups

- SBP Quality strategy
- Member of the Swiss Association for Standardization expert group for the future ISO biobanking norm: expertise and developments from the BBMRI Working Groups Quality can be brought into this expert group
- Developing quality management services and SBP labels
- Providing an evaluation tool (SBP Toolbox) to monitor continuous improvement of BB
- Delivering a scoring system for governance and QMS
- Offering audit services

SBP Toolbox

- A tool to guide Swiss BB and BB Infrastructures on governance and QMS, based on good biobanking practices and complementary to the BBMRI-ERIC self-assessment tool
- Basis for the SBP directory
- Offers the possibility to generate a harmonised BB regulation
- Scoring on ethical and legal compliance with federal/international law and the Taipei declaration, as well as on quality compliance with international ISO norms
- The scoring end product is communicated to its customer with an audit plan and with a process to adhere to the different SBP labels

Clinical Biobanks Active participation in BBMRI-ERIC ADOPT:

- Contribution to the development of a dataset on colon cancer collection by recruiting a Swiss BB providing 300 cases

Population-based Cohorts SBP Proof of concept

- Cooperation with the national Human Biomonitoring Project (HBM) of the Federal Office of Health: this pilot tests the feasibility of recruiting a large cohort of citizens (100 000 participants)
- Objectives of the pilot have been defined between SBP and HBM

ELSI Active participation in BBMRI-ERIC ELSI Task Forces SBP Governance strategy:

- Creation of a Governance Advisory Board regrouping representatives of instances involved in ELSI issues to advise on biobanking governance issues
- Guidance on the three critical pillars in the setup of a good BB governance: BB regulation, material transfer agreement (MTA), and general consent
- Development of a Swiss BB regulation template and a Swiss MTA template
- Governance evaluation through the SPB Toolbox (see above) to assess the BB compliance with applicable law and ethical standards

SBP Public engagement strategy

- Involvement of patient organisations and society representatives as consulting bodies
- SBP stakeholders, like BB or hospitals, can consult the group by submitting a request to SBP

National consent for research

- SBP is mandated by the SAMS to evaluate version 1 of the national consent documents released in July 2017

GDPR evaluation for Switzerland:

- Development of document on how to implement GDPR at a national level

Expert Centres

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Education & Training

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BBMRI.cy (Observer)

Country

Year joining BBMRI-ERIC: 2016
GDP: €17.37 billion
Population: 848,300
Number of biobanks and stand-alone collections as specified in the Directory 2.0: 2 biobanks

National Node

Start date: Not yet established
Director: –
Total staff (FTE/year and headcount): –
Total funding (period): –
Funding body: –
Legal entity of/hosting institution of National Node: Ministry of Health (tbc) **Partners (total 2):** *University of Cyprus, The Cyprus Institute of Neurology and Genetics*
Web: –
National Catalogues: http://www.ucy.ac.cy/mmrc and http://www.cing.ac.cy Last update: 2017

About – University of Cyprus

BBMRI.cy is still in its initial stages, mainly because of limited state funding. There is minimal state support and it operates on research grants, also partially funded by the hosting organisation, the University of Cyprus. Nevertheless, the biobanking community in Cyprus is making serious efforts to convince state authorities of the need to provide permanent annual support for maintaining this research infrastructure. During the past few years, biobanking has led to positive results with regard to upgrading research and diagnostic procedures in inherited disorders. It is a positive sign that more people are interested in using the small, high-quality repositories created so far. Considering that the Biobank is presently focused on inherited disorders, the achievements are obvious in terms of novel discoveries and the introduction of new diagnostics. The Biobank operates within the Molecular Medicine Research Center, an independent research unit and infrastructure at UCY.

Specific Strengths

- The two biobanks operating in Cyprus specialise in inherited disorders and are mainly funded through research projects. In the case of the University of Cyprus/Molecular Medicine Research Center (UCY/MMRC) Biobank, there is substantial internal funding for maintaining the operation of the infrastructure. There is cooperation with public hospitals and doctors in the private domain.
- The infrastructure enables genetics/genomics work including next generation sequencing technology and cell biology work.

- The personnel have specific expertise and a strong track record in inherited kidney disorders with European and global presence.
- The MMRC has strong links with the nephrology medical community and close contacts and collaborations with patients' organisations as major stakeholders in our field of activity.

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

We have expertise regarding inherited kidney disorders and inherited cancers. The particularities of the Cypriot gene pool have allowed Cypriot researchers to generate data that has an impact not only on the local, but also the global population. However, being Observers and without adequate independent funding it is difficult to contribute substantially to the BBMRI-ERIC pan-European effort.

e-Infrastructure

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Quality

- We have not yet been able to implement specific quality measures through ISO certification, but we make every effort to maintain high quality material.

Clinical Biobanks

- The UCY/MMRC Biobank has been specialising in polycystic kidney disease and other monogenic rare kidney disorders. Based on research funding, over the past several years there has been a focus on inherited glomerulopathies with the follow-up of two cohorts, one with Alport syndrome and thin basement membrane nephropathy and one with C3 glomerulopathy/CFHR5 nephropathy, with positive results and high impact publications. A third unique cohort is for medullary cystic kidney disease 1 (more recently renamed MUC1 kidney disease), with more than 160 patients, mostly in the south-western part of the island. Importantly, these specific cohorts are characterised by the inheritance of founder mutations. These cohorts and additional archived records have already attracted the interest of local and external academic organisations, as well as a pharmaceutical company, in order to use the biological material in innovative research aimed at identifying new genes and new targets for therapy.

Population-based Cohorts

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ELSI

- ELSI is mainly monitored by the Cyprus National Bioethics Committee, which must evaluate and approve every research project that includes human beings and/or human biological material. Also, researchers need to obtain permission from the Cyprus Commissioner for the Protection of Personal Data.

Expert Centres

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Education & Training

- The MMRC Center is a popular training destination for younger researchers and hosts several fellows every summer
- As part of the UCY, it constantly hosts students completing their diploma BSc theses or their MSc and PhD dissertations

About – The Cyprus Institute of Neurology and Genetics

Aim: To establish and operate a national biobanking infrastructure that will provide well-annotated biological samples for the needs of the Cypriot clinical and academic research community. To assimilate and integrate existing collections into the biobank in order to provide valuable resources for fostering innovative research. To align the national biobank with EU protocols and procedures and to connect the Cyprus research community with the EU, through BBMRI.

Specific Strengths

- The Cyprus Institute of Neurology and Genetics has pioneered the application of genetics and molecular biology to investigate the genetic causes for a plethora of common and rare inherited diseases. As a result of this 25-year presence, CING has developed the largest collection of biological samples and databases. These are now being assimilated to create an enviable biobank featuring a population-specific biological resource.
- CING has developed unique infrastructures and has already established a high throughput of genomic and proteomic technologies. The biobank adds substantial value to the infrastructures already available at CING and supports the conducting of high-calibre research on a national level.
- CING has direct links with many national stakeholders
- Organises meetings with patient advocacy associations

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

CING receives an annual subsidy from the Cyprus Ministry of Health to deliver specialised services in neurology, covering 10,000 patients and 75,000 laboratory diagnostic tests which cover molecular diagnostics for a range of common and rare disorders. In this context, CING operates as a national and regional referral centre in the above areas of specialisation.

- CING has capacity, critical mass
- CING has unique expertise in neurology, clinical genetics and biomedical sciences
- Advanced IT infrastructure
- Efficient and successful networking with both public and private health sectors

e-Infrastructure

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Quality

- Quality assurance schemes in operation
- All laboratory services are ISO15189-accredited

Clinical Biobanks

- Several collections of biological samples already available at CING

Population-based Cohorts

- CING has the largest collection of DNA samples
- CING has population-wide samples and data at its disposal, representing disorders such as thalassemia, diabetes, and cancer, amongst many others.

ELSI

- The operation and establishment of CING Biobank has been approved by the Cyprus National Bioethics Committee. The operation of the CING Biobank has also been notified to the Cyprus Commissioner for the protection of personal data.

Expert Centres

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Education & Training

- CING has established the Cyprus School of Molecular Medicine (CSMM)
- CSMM offers postgraduate programmes at MSc and PhD level
- CSMM carries out executive training programmes targeting professionals such as doctors and scientists
- Programmes include workshops/training in biobank procedures

BBMRI.cz (Member)

Country

Year joining BBMRI-ERIC: 2013
GDP: €152.6 billion (2015)
Population: 10.5 million
Number of biobanks and stand-alone collections as specified in the Directory 4.0: 6 biobanks.

National Node

Start date: 7 October 2010
Director: Dalibor Valík
Total staff (FTE/year and headcount): 3.75 FTE/year and 119 employees per the network and hospital-affiliated specialist staff
Total funding (period): €5 million (2010–2016)
Funding body: Ministry of Education, Youth and Sports (MEYS)
Legal entity of/hosting institution of National Node: Masaryk Memorial Cancer Institute
Partners (total 5): *Masaryk Memorial Cancer Institute*; *First Faculty of Medicine, Charles University, Prague*; *Faculty of Medicine, Charles University, Hradec Králové*; *Faculty of Medicine, Charles University, Pilsen*; *Faculty of Medicine, Palacký University, Olomouc*
Web: http://www.bbmri.cz
National Catalogues: https://index.bbmri.cz (web version under preparation)

About

The Biobank of clinical samples is an existing large infrastructure founded and maintained by the Masaryk Memorial Cancer Institute (MMCI) and functionally bound to the Centre for Basic and Translational Cancer Research, RECAMO. In 2000, Masaryk Memorial Cancer Institute (MMCI) formally instituted a biobanking unit spanning its two departments, the Department of Pathology and the Department of Experimental and Clinical Biochemistry, and started to support it with institutional funding. This was complemented by the hospital-integrated IT bank of biological material (BBM) module linking clinical and laboratory data to biobanking aliquots in 2004. From then on, institutional development continued until 2009, when MMCI applied to the first call of the Research Infrastructure funding with the project 'Bank of Clinical Specimens' focused on cancer BBMRI.cz, which was granted and initiated in October 2010. The aim of the Czech BBMRI.cz infrastructure was to operate a network of medical research biobanks that preserve biological samples from cancer patients long-term and under secured, standardised and accredited conditions. Otherwise, such material would be permanently lost for future biological and medical research. This process led to the establishment of a network of cancer research biobanks comprised of the BBM MMCI, the BBM of the 1st Faculty of Medicine at Charles University (BBM 1FM CU), the BBM of the Faculty of Medicine at Hradec Králové Charles University (FM HK CU), the BBM of the Faculty of Medicine at Pilsen Charles University (FM CU Pilsen), and the BBM of the Faculty of Medicine at Palacký University in Olomouc, (FM PU Olomouc). These biobanks are integrally linked to key healthcare providers in the Czech Republic and operate as the BBMRI.cz research infrastructure.

Specific Strengths

- BBMRI.cz's development ambitions include assuming leadership in the field of research-oriented clinical biobanking in the Czech Republic, including setting up a network of regional biobanks to focus on the premorbid period in cancer in the context of regional exposure in the Czech Republic. At the academia-industry interface, BBMRI.cz will increase its role as a leading partner for innovative industrial activities to enhance the introduction of new potential medicinal products, in order to provide an improved service to the patient community in the Czech Republic. BBMRI.cz's direct socio-economic impacts are related to the definition of key health policy documents in the Czech Republic, such as clinical practice guidelines on the use of clinical laboratory and predictive testing in oncology. Indirect impacts may focus on the medical applications of biomarkers to be discovered and characterised with the use of collected biological material connected to clinical data and tested through a comprehensive system of clinical trials. Searching for relevant biomarkers specific to certain diseases using archived human tissues is a critical component in the design of innovative medicinal products and diagnostic procedures in human diseases.

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

e-Infrastructure Activities focused on three basic areas in 2016:

- (1) connection of the biobank information system and related hospital information systems in which sample and patient data are saved
- (2) ongoing development of the central structure of the BBMRI.cz Index, in particular based on feedback of biobank operativity
- (3) integration of the infrastructure into BBMRI-ERIC IT infrastructure

Integration efforts towards the established BBMRI-ERIC infrastructure have been continuously carried out alongside further connections between national partners. Information about Czech biobanks is sent in to the Directory service, which creates a metadata repository of European biobanks and thus represents the first step towards the integration of their IT systems.

Quality

- The source laboratories for the BBMRI.cz network (i.e., the labs sampling part of the patient biological material for biobanking storage) are currently accredited either by CAI according to the ISO 15189 standard or by NASKL according to the ISO standard 15189. Supervision of the biobanking and sampling processes is carried out by qualified medical staff.

Clinical Biobanks

- The overall organisational concept and implementation of the BBMRI.cz system were described and published in 2012.[24] The overall research infrastructure is realised through the organisational structures of partner institutions as described therein.

[24] Holub, P, Greplová, K, Knoflíčková, D, Nenutil, R & Valík, D: The biobanking research infrastructure BBMRI_CZ: a critical tool to enhance translational cancer research. *Klin Onkol* **25 Suppl 2**, 78–81 (2012).

Population-based Cohorts

- At present, BBMRI.cz primarily focuses on cancer research, however, a future focus on populational cohorts is envisaged for the near future. This trend is dictated by the fact that, for personalised medicine, long-term cohorts may be a significant source of knowledge.

ELSI

- BBMRI.cz has a nominee in the Common Service ELSI, Mr. Radek Halouzka.

Expert Centres

- In BBMRI-ERIC terminology, we have not yet implemented the EC/Trusted Partner mechanism.

Education & Training

- Students benefit from the expertise of staff linked to the research infrastructure (pathologists, molecular biologists, experts in laboratory medicine (I.), of a subject of choice or other special educational activities focused on biobanking (II.). We support the training of IT students – they are 'pilot' students at the interface of IT services and medical activities – and we harness this expertise to develop a 'school of interdisciplinary medical collaboration'.

BBMRI.de (Member)

Country

Year joining BBMRI-ERIC: 2013
GDP: €2.7 trillion
Population: 82 million
Number of biobanks and stand-alone collections as specified in the Directory 4.0: 21

National Node

Start date: 1 November 2013
Director: Michael Hummel
Total staff (FTE/year and headcount): 2 FTE/year
Total funding (period): €1.5 million (11/2013–4/2017)
Funding body: Federal Ministry of Education and Research (BMBF)
Legal entity of/hosting institution of National Node: Charité – Universitätsmedizin Berlin
Partners (total +15)
Web: http://www.bbmri.de
National Catalogues: https://www.biobanken.de/

About

The German Biobank Node (GBN) acts a central contact point for all biobank stakeholders in Germany and represents the German biobank community within BBMRI-ERIC. The German Biobank Alliance (GBA) represents the stringent realisation of the concepts developed by the German Biobank Node (GBN) in its first funding phase. To this end, eleven German biobank sites fulfilled the criteria and were selected by reviewers for a new funding period. The central executive management office of the GBN has the challenging task of shaping, to coordinating and guiding this biobank alliance over the next years to come. IT networking, common quality standards and measurements and ELSI regulations are particular focuses of the activities supplemented by public accountability and stakeholder management. In addition, GBN is responsible for the linkage of GBA to the BBMRI-ERIC infrastructure, fostering an extensive exchange and harmonisation between GBN and BBMRI-ERIC in order to allow cross-border exchange of biomaterial and related data.

Specific Strengths

BBMRI-ERIC

- Expert contribution to the CEN/TC Technical Specifications and related standards.
- Leadership of the BBMRI-ERIC Common Service IT.
- Strong involvement in the development of BBMRI-ERIC IT Gateway for Health
- Expert contribution to Common Service ELSI activities, also with respect to the new GDPR.

BBMRI.de

- Harmonisation of procedures between 11 centralised biobank sites on IT, quality of samples and data and ELSI level.
- IT network to enable cross-biobank queries for samples and data
- Stakeholder management addressing key stakeholder groups of biobanks and GBN.
- Common user satisfaction survey conducted by all biobanks for quality assurance.
- In GBA < 5,060,000 liquid samples and < 10,590,000 tissue samples are available on request.

e-Infrastructure Activities focused on three basic areas in 2016:

- Development of an IT infrastructure that enables access to samples and data on national and international levels. The data remain locally at the respective biobank site and are accessible via federated search tools.
- Generation of aggregated biobank information by the IT network for the BBMRI-ERIC Directory and the German Biobank Registry.
- Conduction of detailed Stakeholder analyses to assure the generation of sustainable solutions, tailored to the user's needs.
- The coordinator of BBMRI.de, Michael Hummel, is Director of the BBMRI-ERIC Common Service IT and therefore involved in and responsible for all of BBMRI-ERIC's ongoing IT activities.

Quality

- Established QM system with generic SOPs implemented to > 80% in GBA biobanks.
- Conduction of ring trials for liquid and tissue samples in all GBA biobanks.
- Development of an audit program including auditor training/qualification and friendly annual audits in alignment with the new DIN/ISO standards and with BBMRI activities.
- Conduction of a biomarker validation study aiming to validate potential markers as reference markers to sample quality.
- Support and active contribution to the BBMRI-ERIC service 'Quality'

Clinical Biobanks

- Definition of the colon cancer dataset and significant contribution of patient data to ADOPT BBMRI-ERIC (page 113) Colon Cancer Data Collection (CCDC; total of 10,000 patients).

Population-based Cohorts

- The two major population-based cohorts are the German National Cohort and KORA- Cooperative health research in the Region of Augsburg, which are both part of the BBMRI-LPC.
- Being part of the BBMRI-LPC, these cohorts provided free access to biomaterial and associated data to selected research projects.

ELSI

- Regular contributions to the activities of the Common Service ELSI.
- Development of a workshop series regarding ethical, legal and societal issues in the context of biobanking.
- Organisation of the first ELSI-Workshop concerning incidental findings in research projects and hurdles in returning these findings to the biomaterial donor.

Expert Centres

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Education & Training

- Development of an e-learning training platform for technical personnel in biobanks.
- Provision of exchange platform and practical training courses for technical personnel from biobanks.
- Multiple workshops on ELSI, Quality Management, IT and stakeholder engagement.
- Organisation of the annual national Biobank-symposium with approx. 250 participants.

BBMRI.ee (Member)

Country

Year joining BBMRI-ERIC: 2015
GDP: €17.4 billion
Population: 1.325 million
Number of biobanks and stand-alone collections as specified in the Directory 4.0: 5 biobanks

National Node

Start date: 1 January 2013
Director: Andres Metspalu
Total staff (FTE/year and headcount): 3.3 FTE/year and 1, total: 480/year and 45
Total funding (period): €36,887 (2016), total 3.5 million (2016)
Funding body: Estonian Research Council (ETAG), Foundation Archimedes
Legal entity of/hosting institution of National Node: Estonian Genome Center, University of Tartu
Partners (total 8): *Estonian Ministry of Education and Research*; *Estonian Genome Center, University of Tartu*; *Estonian Biocenter*, *Tartu University Hospital*; *The North Estonia Medical Centre*; *East-Tallinn Central Hospital*; *Competence Centre on Reproductive Medicine & Biology*; *National Institute for Health Development*
Web: http://www.bbmri.ee
National Catalogue:

About

In its role as a BBMRI-ERIC Member, the Estonian Ministry of Education and Research has nominated the Estonian Genome Centre, University of Tartu (EGCUT), to represent Estonia in BBMRI-ERIC activities as its national node. The Estonian Genome Center and the Estonian Biocentre joined on 01.01.2018 and formed new department—the Institute of Genomics, University of Tartu (GIUT). The new department[25] combines sample sets from both national biobanks, but also ancient DNA from all around the world. The Estonian national biobank (EGCUT) is a population-based, prospective and longitudinal biobank. The EGCUT maintains and manages the biobank by storing the samples of DNA, plasma and buffy coat, and periodically renewing and updating the health information. The Estonian Biobank cohort is a volunteer-based sample of the Estonian resident adult population (aged ≥18 years). The current number of participants, which is close to 52,000, represents a large proportion, i.e., 5% of the Estonian adult population, making it ideally suited for population-based studies. The number of samples will increase by 100,000 and all 150,000 donors will be genotyped by the same Illumina GSA assay for 2019. The entire EGCUT database makes it possible to carry out research to find links between genes, environmental factors, lifestyle habits and their contribution to complex diseases or other traits. One of EGCUT's aim is to facilitate the development of personalised medicine in Estonia by implementing the genomic data among all other medically-relevant information on the patient in medical care. In Estonia, the national node activities were funded by a

[25] http://www.biobank.ee

grant from the Estonian Centre for Genomics (Estonian Roadmap grant no 3.2.0304.11-0312) in the period of 2011–December 2015. Funding for the second period (2016–2020) has also been obtained, but the node activities are no longer supported through the roadmap grant.

Specific Strengths

- The biobank is actively used by researchers worldwide, with hundreds of projects underway.
- Transparent and simple rules for access to biobank samples and data.
- All legal and societal issues of biobanking are well covered by a special law: The Human Genes Research Act of Estonia.[26]
- By 2019, the whole cohort of EGCUT (152,303 individuals) will be fully genotyped (Illumina GSA chip).
- Data are continuously updated through periodic linking to national electronic databases and registries.
- Since 2017, the biobank has piloted giving feedback and counselling about individual genetic risk, based on scientific research, to participants of the biobank who express interest in it. This research program is a first step in the implementation of the objectives of the Estonian National Personalised Medicine Programme, which was developed under the leadership of the Ministry of Social Affairs in the period 2015–2018 and was extended to 2025.
- At the end of 2017, the Estonian government announced that it had allocated €5 million ($5.9 million) to support the genotyping of 100,000 people. Starting in 2018, the biobank will recruit additional 100,000 participants. Illumina's Global Screening Array will be used to genotype the new samples. All DNA extraction and genotyping will be done at the Estonian Genome Centre's core facility. Most samples for the new study will be recruited via regular medical check-ups, as well as visits to any place where blood is drawn. Additional medical information will be obtained from the electronic medical records of the participants. As part of the new phase of the project, the biobank will not only collect genetic data on participants, but report back on genetic risks via Estonia's national health information system.
- GI does not manage a population-based biobank, however it is also a leading research institution in the field of genomics, consisting of workgroups such as biostatistics (headed by Dr. Krista Fischer), bioinformatics (headed by Dr. Reedik Mägi), medical genetics (headed by Dr. Neeme Tõnisson), epi- and pharmacogenetics (headed by Dr. Lili Milani, archeogenetics (headed by Dr. Kristiina Tambets) and genomics (headed by Dr. Tõnu Esko). There is a team of 106 people (100 FTE) working at the research unit, at the biobank and at the sequencing and genotyping core lab (headed by Dr. Lili Milani), as well as support staff.
- The University of Tartu is member of the EIT (European Institute of Innovation and Technology)[27] Health consortium, which focuses on implementing research results into medical practice. The national biobank is involved in the 'EIT Health Pointlab' project, which builds up support systems for collaboration between biobanks and industry in order to develop new products and services.

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

e-Infrastructure

- The majority of Estonian biobanks are included in the Directory 4.0.

[26] https://www.riigiteataja.ee/en/eli/531102013003/consolide
[27] https://eit.europa.eu

- According to the tasks from the ADOPT BBMRI-ERIC grant, we will help with validating the new algorithms for performing fine searches in the new database.

Quality

- EGCUT uses ISO 9000-2008. Also, the sequencing and genotyping core lab is an Illumina CSPro (Certified Service Provider) one. All biological samples are collected and processed following standardised LIMS-assisted protocols with various checkpoints and are stored in LN2. Storage conditions are logged and monitored, and LN2 refilling is automated.
- As a training centre for Eastern European biobanks in the EU, thanks to BBMRI-LPC, and as a model for new emerging biobanks, the Estonian Node is willing to share its SOPs for designing a quality standard international biobank.

Clinical Biobanks

- Collection of data for BBMRI-LPC directory
- Contribution to the development of a set of data on colon cancer collections (ADOPT BBMRI-ERIC project)

Population-based Cohorts

- The biggest Estonian biobank is a population-based biobank (52,000 samples), which is also the National Node representative: The Estonian Genome Centre, University of Tartu.

ELSI

- The EGCUT representative is member of the BBMRI-ERIC ELSI expert group and the Ethical Committee of the University of Tartu. She helped to compile the draft for the BBMRI-ERIC Ethics Check.
- The ELSI representative from EGCUT has shared Estonia's experiences regarding consent and biobank legislation. EGCUT has been using broad consent forms since the recruitment of biobank participants started in 2002. The Estonian Human Genes Research Act is a piece of legislation that regulates the maintenance and use of biobanks as well as the re-contacting of participants. It permits the retrieval of additional information from national registries and gives participants the right to receive individual research results.

Expert Centres

- As the Estonian node of BBMRI-ERIC is responsible for providing training to emerging biobanks within the BBMRI-LPC project, it has turned into a training centre for several Eastern European and Asian biobanks. Some countries (Switzerland, South Korea, Qatar, Vietnam, Japan, USA, India, Moldova, Georgia, Russia, Ukraine, Balkan countries, etc.) have sent a representative to the Estonian node to study the processes inside the national biobank in order to improve or set up their own biobank later on.
- The Estonian Genome Centre has been nominated as Centre of Excellence for Genomics and Translational Medicine [28] (funding from the European Regional Development Fund (ERDF) for 2016–2023) and is an object of the Estonian Roadmap (funded through the grant 'Estonian Centre for Genomics', 2017–2022).

[28] https://sisu.ut.ee/gentransmed/home-0

Education & Training

- Organised several courses and conferences: WS 'Functional annotation of genome-wide variants'[29] in the Centre for Integrative Genomics, Lausanne, Switzerland; Course 'European Mathematical Genetics Meeting'[30] in Tartu, Estonia; Geneforum 2017[31] ; • WS 'Estimated (disease) risk for coronary atherosclerosis using lifestyle factors and genetic markers'[32] Tartu, Estonia; PhD courses at University of Tartu: P1GV.00.002 Statistical Methods in Genetics (3 EAP) and P1GV.00.003 Genetic and Genomic Epidemiology (3 EAP)

Our representatives were also involved in the organising committee of 'Europe Biobank Week' 13.-15.09.2017, where BBMRI.ee had a booth.

[29] http://epermed.ut.ee/workshop-functional-annotation-genome-wide-variants
[30] https://www.geenivaramu.ee/en/emgm2017
[31] http://www.geneforum.ee/GF2017
[32] http://epermed.ut.ee/MD_WS_2017

BBMRI.fi (Member)

Country

Year joining BBMRI-ERIC: 2013
GDP: €191.5 billion
Population: 5.4 million
Number of biobanks and stand-alone collections as specified in the Directory 4.0: 9 biobanks

National Node

Start date: 15 March 2011
Director: Anu Jalanko
Total staff (FTE/year and headcount): 2.5 FTE/year for coordination activities
Total funding (period): €1.8 million (2015–2018), of which €312,000 for BBMRI.fi coordination and€1,200,000 for equipment for biobanks
Funding body: Ministry of Education and Culture / Academy of Finland
Legal entity of/hosting institution of National Node: National Institute for Health and Welfare
Partners (total 9): THL Biobank (National Institute for Health and Welfare THL); Auria Biobank (University of Turku (UTU), Hospital districts of Southwest Finland, Satakunta and Vaasa); Hematological Biobank (FHRB Biobank) (Finnish hematology association, Finnish Red Cross Blood Service, Institute for Molecular Medicine Finland FIMM (University of Helsinki(UH)); Helsinki Biobank (Hospital districts HUS, CAREA and Eksote and UH); Northern Finland Biobank Borealis (Oulu University Hospital, University of Oulu (UO), NordLab and the healthcare districts of Kainuu, Lapland, Central Ostrobotnia and Länsi-Pohja); Finnish Clinical Biobank Tampere (FCBT) (Pirkanmaa Hospital District (PSHP), University of Tampere (UTA), the joint municipal authority of the Etelä-Pohjanmaa hospital district (EPSHP) and the joint municipal authority of the Kanta-Häme hospital district (KHSHP); Biobank of Eastern Finland (Hospital District of Northern Savo, University of Eastern Finland (UEF) and the joint municipal authorities of Itä-Savo (Sosteri), Etelä-Savo (Essote) and North Karelia (SiunSote)); Central Finland Biobank (University of Jyväskylä (UJ) and Central Finland Health Care District (KSSHP)), FRC Blood Service Biobank (Finnish Red Cross Blood Service)
Web: http://www.bbmri.fi
National Catalogue: http://www.bbmri.fi and https://kite.fimm.fi

About

BBMRI.fi is the Finnish national node of BBMRI-ERIC and was one of the first national research infrastructures in Finland. BBMRI.fi provides access to collections of Finnish clinical and population biobank samples and associated data according to the Finnish Biobank Act. BBMRI.fi network participants include 9 biobanks and their background organisations, these being all relevant universities, hospital districts and THL. BBMRI.fi promotes the collaboration of national biobanks and the biobank consent and access procedures have been harmonised nationally. BBMRI.fi biobanks further harmonise operations in several national working groups and national projects. The main

aims of the BBMRI.fi network are well in line with BBMRI-ERIC and the three major areas include biobank IT infrastructure development, quality management and ethical and legal issues. During 2015–2017 the Finnish BBMRI.fi biobanks provided access and participated in more than 300 biobank research projects, many of which were of international significance. The collection of prospective biobank samples and new biobank consents has developed remarkably within the same period. The national network will see a new level of development in the near future, as the hospital biobank background organisations have established a cooperative, Biobanks Finland Joint Operator (FINBB), to produce services for biobanks. BBMRI.fi and FINBB initiated a close collaboration in 2017 and aim to integrate their operations.

Specific Strengths

- A unique strength of Finnish biobanks lies in the data associated to the samples, which includes biological data including different omics data, hospital EMR data and lifestyle data as well as follow-up data from national registries. This puts BBMRI.fi in a strong position internationally.
- A major achievement for all Finnish biobanks has been their participation in the public-private FinnGen research project aiming to collect GWAs and national health register data from 500,000 participants by 2022.[33] Samples and genome data will remain in the ownership of Finnish biobanks, significantly increasing their potential for discovery in the future.
- Biobanks play major roles within the national operating environment. Biobanks are well embedded in the national government strategy, including the government bill for secondary use of health data, the Genome Strategy, the Health Sector Growth Strategy for Research and Innovation Activities (involving three ministries), and the National Health Data Hub, led by Sitra and the Ministry of Social Affairs and Health.
- Finnish Biobanks' strong collaboration activities have been well evaluated by national funding bodies and BBMRI.fi biobanks have received joint funding from the Academy of Finland, Sitra, Business Finland and the Ministry of Social Affairs and Health.
- BBMRI.fi received excellent scores in the mid-term evaluation of the Finnish infrastructure roadmap. Being the only infrastructure that stores and distributes samples and data from human patients at the national level, it has a specific role in enabling the operation of other infrastructures in Finland.

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

e-Infrastructure

- BBMRI.fi participated in initial testing of the new BBMRI-ERIC services – BBMRI-ERIC Directory, BBMRI-ERIC Negotiator, and MDR – and provided test data sets as well as feedback that has been incorporated into the updated versions of these tools. The main focus of the 2017 Common Service IT work has been in defining a common terminology for sharing individual-level data on samples and sample donors under BBMRI-ERIC's new MIABIS governance model, with THL leading the effort. The work started with defining use cases and obtaining approval for the scope of the work, then continued with forming a multinational group of experts to work on the data model and attribute components. The final proposal was presented to BBMRI-ERIC's MC in November 2017.

[33] https://www.finngen.fi/

- National activities include joint development and testing of biobank databases and, in 2017, a Sitra-funded BBMRI.fi Isaacus project piloting the integration of biobank data between all biobanks. Additionally, the Academy of Finland and Business Finland funded joint biobank projects for the harmonisation of cohort data and digitalisation of clinical data and images.

Quality

- BBMRI.fi biobanks are actively participating in BBMRI-ERIC's quality expert working groups. The first BBMRI-ERIC Self-Assessment Survey was executed by the Finnish Auria Biobank.

Clinical Biobanks

- The 6 large clinical biobanks host EMR data and FFPE samples from almost 3 million participants and are currently actively collecting new samples directly from the hospital flow. The backround organisations of the 6 clinical biobanks have established the FINBB cooperative to promote the one stop shop of Finnish biobank resources. FINBB operates integrally with BBMRI.fi.

Population-based Cohorts

- Major Finnish population cohorts are located in the BBMRI.fi member THL Biobank and BBMRI.fi has been a very close collaborator with the BBMRI-LPC project. The genome data of Finnish population cohorts are utilised actively in several international genome projects.

ELSI

- BBMRI.fi organised an annual nationwide ELSI seminar for sharing cases, practices and discussion with the ethics committee. BBMRI.fi ELSI experts were intensively engaged in new legal initiatives for the Secondary Use of Health Data, Genome Centre and renewing the Biobank Act. Consultation services were provided for Finnish biobanks (i.e., hands-on guidance). Finnish experts participated in Common Service ELSI activities, including the preparation of the GDPR Code of Conduct and the TF Societal working group.

Expert Centres

- Finnish Biobanks have several collaboration projects with pharma but so far, no BBMRI-ERIC associated Expert Centres.

Education & Training

- The yearly Get Together, the national ELSI clinic and the BBMRI.fi IT day for biobank operators have been organised to promote the harmonisation of biobank activities. Additionally, the BBMRI.fi Working Group for Biobank Development actively promotes harmonisation of biobank processes and sharing of documents and materials. Biobank experts actively lecture in national seminars and graduate school courses.

Other

- BBMRI.fi acts as the co-coordinator of ADOPT BBMRI-ERIC WP6 Biomarker Development. BBMRI.fi experts had several oral presentations in the Global Biobank Week 2018.

BBMRI.fr (Member)

Country

Year joining BBMRI-ERIC: 2013
GDP: €2.6 trillion
Population: 67.19 million
Number of biobanks and stand-alone collections as specified in the Directory 4.0: 95 biobanks

National Node

Start date: 1 September 2011
Director: Georges Dagher & Michael Hisbergues (since 03/2017)
Total staff (FTE/year and headcount): 13 FTE/year and 10
Total funding (period): €17 million over a ten-year period (2011–2020)
Funding body: National Research Agency (ANR)
Legal entity of/hosting institution of National Node: Institut national de la santé et de la recherche médicale (Inserm)
Partners (total 6): *CNRS*; *Inra*; *Institut Pasteur*; *CEA*; *CNCR*; *Université Claude Bernard (Lyon)*; *GRAM*
Web: http://www.biobanques.eu
National Catalogues: http://www.biobanques.eu/en/biobanks-directory

About

BIOBANQUES/BBMRI.fr is a distributed infrastructure dedicated to biomedical research. It aims to: (1) foster translational research and biomarker development, (2) elicit national and international consortia and (3) develop public-private-partnerships. It builds on a landscape of 88 biobanks distributed all over France including disease-oriented studies and population-based cohorts. It covers the entire spectrum of human diseases with more than 700 on-going biological and clinical research programs, including 45 follow-up prospective surveys of a population of 300,000 individuals included in the studies. It interfaces with BBMRI-ERIC, thus constituting the French National Node of the pan-European research infrastructure. It also interfaces with MIRRI, thus constituting the French node for the pan-European research infrastructure for microorganisms. The national infrastructure BIOBANQUES is included in the French roadmap 2016 for research infrastructures, which comprises 95 French entities that have listed their contribution to the European strategic roadmap (ESFRI). They are divided into four categories:

- International Organisations (IO)
- Very Large Research Infrastructures (VLRI)
- Research Infrastructures (RI, 65)

As for projects, BIOBANQUES is part of the 25 French health and biology research infrastructures with funding of about €17 million over a ten-year period (2011–2020). At an international level, it is part of BBMRI-ERIC.

Specific Strengths

- The network of biobanks has been active since 2000 and consists of 95 biobanks.

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

e-Infrastructure

- Participation in the MIABIS meetings.
- Inclusion of all French biobanks in the BBMRI-ERIC Directory 4.0.
- Implementation of IT tools (i.e., BBMRI-ERIC Negotiator) in the French network (in progress)

Quality

- In order to follow the contribution of biobanks to published results, BIOBANQUES implemented a unique identifier for biobanks (Bioresource Research Impact Factor, BRIF) at all 95 biobanks in France.
- Additional key activities: (1) Setting up and coordinating a Working Group at the international level (ISO/TC 276) to develop a set of international standards for biobanks, and the new ISO 20387 norm on general requirements for biobanking which will be implemented in 2018. The infrastructure is also implicated in the European SPIDIA-4P project aiming to tackle the standardisation and improvement of pre-analytical procedures for in vitro diagnostics, leading to a set of 14 technical standards (CEN/TS); (2) Training of Quality Managers: i.e., advising biobanks on quality control and quality management issues; replying to 37 requests from biobanks, including 10 internal audits.

Clinical Biobanks

- Contribution to dataset development in the colon cancer collection (ADOPT BBMRI-ERIC) by promoting the recruitment of samples and data collection (10,000 samples) from 17 French cancer centres.
- Active contribution to the enhancement of the connection between basic research through the clinic by using biomarkers as use cases (ADOPT BBMRI-ERIC WP6 D6.4 questionnaires on OMICS technology platforms).

Population-based Cohorts

- Most of the French Biological Resource Centres in the network participate in collecting and storing samples/clinical data arising from 14 national population/patient-based cohorts.

ELSI

- Active following and dissemination (http://www.biobanques.eu and shared with the BBMRI-ERIC) of the National legal changes regarding research involving human beings (Loi Jardé of 2012 and implementing acts) and related aspects on the procurement, storage, use and sharing of human biological samples for research purposes.
- Contribution to public consultations from the National Data Protection Authority (CNIL) on the implementation of the EU General Data Protection Regulation (GDPR). The topics of the consultations were transparency and tools for international personal data transfers.
- Operation of the ELSI Helpdesk: responding to 20 requests for support and guidance.

- Active participation of BBMRI.fr in the setting up and operations of the Task Force on International Organisation Policy Assessment and Monitoring (IO Policy TF), through experts' feedbacks and coordination. This TF contributed to 4 major public consultations from different international organisations (Art.29 DPWP; EAHL; EC).
- Contribution of BBMRI.fr to the testing of the Ethics Check procedure, in collaboration with the ERIC HQ, BBMRI.fi and BBMRI.se.

Expert Centres

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Education & Training

- Organisation of a Masters course in biobanking in France. The University of Nice delivers the qualification in partnership with the Catholic University of Lyon.
- Since 2012, 169 people (practitioners, managers, coordinator or technicians) have received training in implementing the NFS 96-900 norm of quality management in biobanks. Three training sessions per year are co-organised with the Inserm and one with QUARES (French association for quality in research and higher education).
- Contribution to Masters courses for lawyers and contribution to PhD courses for biomedical researchers and medical doctors on data protection.
- Involvement in the TUBA (TUmorBAnks) project coordinated by the Toulouse Faculty of Law. Contribution to the annual meeting TUMOR BANKS: Public regulation of BRC in oncology.
- Contribution of the French node to the first scientific meeting of the Group of Interest on Biobanks (PIs E. Rial-Sebbag and A.M. Duguet) of the European Association of Health Law in Bergen, September 2017.
- Training session FCrin. (G. Chassang and E. Rial-Sebbag), Ethics in H2020 Research Programmes.

Other

- European Institute of Technology (EIT Health), Paris, France; Gauthier Chassang presented a seminar on Data Protection law.
- Global Biobank Week 2017, Stockholm, Sweden; G. Chassang and E. Rial-Sebbag, The WMA Declaration of Taipei (2016): a new regulatory benchmark for health research databases and biobanks at international level, European Association of Health Law Annual Conference, Bergen, Norway, Sept. 2017 (to be published in the Medical Law Journal).

BBMRI.gr (Member)

Country

Year joining BBMRI-ERIC: 2013
GDP: €194.6 billion (2015)
Population: 11.03 million
Number of biobanks and stand-alone collections as specified in the Directory 4.0: 1 biobank

National Node

Start date: 1 January 2013
Director: Dimitris Thanos
Total staff (FTE/year and headcount): 2.5 FTE
Total funding (period): –
Funding body: –
Legal entity of/hosting institution of National Node: Biomedical Research Foundation of the Academy of Athens (BRFAA)
Partners (total 10): *Foundation for Research and Technology Hellas (FORTH)*; *Center for Research and Technology Hellas (CERTH)*; *University of Athens*; *University of Patras*; *University of Crete*; *University of Ioannina*; *University of Thessaly*; *Demokritian University of Thrace*; *Evangellismos Hospital*; *Metaxa Hospital*
Web: http://www.bbmri.gr
National Catalogues: –

About

BBMRI.gr aims to establish a state-of-the-art distributed biobanking infrastructure in Greece and to achieve closer cooperation and harmonisation between biobanks. For this purpose, a network comprising almost all medical schools and two independent public hospitals is being established. BBMRI.gr considers the formation of a functional network as a prerequisite to facilitating access and fostering the use of biological samples and data for academic and industrial research. Biological samples and data collected in biobanks are valuable resources for innovations in personalised medicine, as well as the development of biomarkers, diagnostics and therapeutics. BBMRI.gr is an active partner in a Flagship National Initiative on Precision Medicine, recently launched in Greece. BBMRI.gr is included in the Greek Roadmap's Research Infrastructures. The nodes of the BBMRI.gr participate in several national and European research projects. Following a recent ministerial decision, BBMRI.gr will receive an amount of €500,000, as seed funding.

Specific Strengths

Existing collections in specified areas:

- Disease-oriented biobanks: lymphomas, Parkinson's disease, childhood obesity
- Population biobank: umbilical cord samples

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

Participation in the Education Committee and the Common Service ELSI

e-Infrastructure

- Under construction, based on recently awarded national funding

Quality

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Clinical Biobanks

- Existing collections on lymphomas, Parkinson's disease, childhood obesity

Population-based Cohorts

- Umbilical cord samples

ELSI BBMRI.gr is actively engaged regarding the increase of public awareness on biobanking and relevant ELSI issues (e.g., data protection, breach of privacy, incidental findings, etc.). Through the active participation of Dr Olga Tzortzatou, who was appointed as the Greece's National Node ELSI expert of the Common Service ELSI, the Node contributed to drafting the FAQs on the GDPR. A communication channel regarding the GDPR's effect on research and on the role of the scientific community in the implementation of the GDPR, was opened with the Greek Data Protection Authority. On Tuesday 20th June 2017, at the premises of the Biomedical Research Foundation of the Academy of Athens (BRFAA), BBMRI-ERIC in collaboration with BRFAA and supported by the EU Project ADOPT BBMRI-ERIC, prepared an intensive one-day workshop titled: 'Biobanking: Ethical and Legal Issues'. This was an initiative which emerged out of the work conducted within the BBMRI-ERIC Common Service ELSI, and more specifically the GDPR Task Force, which examines the legal and ethical issues related to personal data protection within the framework of biobanking research, in view of the implementation of the General Data Protection Regulation (GDPR).

This workshop, was the first attempt in Greece to organise such an event regarding ethical and legal issues in the field of biobanking research. Although it did not achieve the anticipated audience numbers, it succeeded in offering researchers from Greece the opportunity to engage in a dialogue with legal and ethics experts and get informed about the national DPA requirements and how the GDPR may affect their research after May 2018. Furthermore, this initiative was welcomed by Greek law practitioners and members of the governmental committee for the implementation of the GDPR, creating a communication channel between BBMRI.gr and the latter. Hopefully the outcomes if this initiative will reach more of the general public through the dissemination of the present report as well as the presentations already uploaded to the BRFAA website..[34] Additionally, BBMRI.gr took the initiative to proceed with the translation of the FAQ's on GDPR prepared by the BBMRI-ERIC ELSI GDPR TF into Greek, thereby contributing to Greek researchers' awareness of key issues for biomedical research with regards to the new provisions inserted by the GDPR.

[34] http://www.bioacademy.gr/news-details/XsaNtDXU/video-biobanking-ethical-legal-issues-conference

Expert Centres

- The Greek Genome Centre has been operational for two years now and aims to become a prototype expert centre for Greece and beyond. Detailed information about the equipment available and its capabilities can be found in the enclosed document (GGC info). A formal application as an Expert Centre/Trusted Partner is being considered.

Education & Training

- There are no biobanking courses organised in Greece. We anticipate that interested fellows will be encouraged to enrol in courses suggested/organised by BBMRI-ERIC and promote participation nationwide.

BBMRI.it (Member)

Country

Year joining BBMRI-ERIC: 2013
GDP: €1.6 trillion
Population: 60.4 million
Number of biobanks and stand-alone collections as specified in the Directory 4.0: 65

National Node

Start date: 8 October 2013
Director: Marialuisa Lavitrano
Total staff (FTE/year and headcount): 10 FTE and 18
Total funding (period): €4.2 million (2013–2018)
Funding body: Ministry of Education, Universities and Research (MIUR). The Ministry of Health contributes towards the annual BBMRI-ERIC membership fee.
Legal entity of/hosting institution of National Node: University Milano Bicocca, Milano
Partners (total 0): –
Web: http://www.bbmri.it
National Catalogues: http://www.bbmri.it/network-board

About

Established in 2013, the Italian Node of BBMRI (BBMRI.it) is a distributed infrastructure consisting of biobanks and biological resource centres located throughout Italy, and a large community of researchers involved in disease-oriented projects that rely on the use of collections of biological resources. BBMRI.it includes the National Institute of Health, CNR, 18 universities, 23 research hospitals (IRCCS), 40 hospitals, 8 associations of patients and 90 biobanks, biological resources centres and collections organised in thematic networks and regional networks with a matrix architecture. BBMRI.it has developed a web portal, while Common Services for ICT, quality and ELSI have been set up to support the network. The Common Service IT adopted the BBMRI-ERIC standards and created the national IT infrastructure, developing tools to improve the interoperability of research databases. The Common Service Quality has been implemented, with the objective of monitoring biobanks and biomolecular resources, providing information on guidelines/best practices, harmonising operational procedures, developing criteria for the accreditation and certification of biobanks, implementing the quality management system criteria of BBMRI-ERIC within the Italian network, and promoting training on quality issues. The Common Service ELSI works as an instrument at the service of all stakeholders, from biobanks to ethics committees. It acts as a liaison between the National Node and the European infrastructure regarding current ELSI issues.

Specific Strengths

- Number and quality of Italian biobanks (population, genetic, disease-oriented and archived tissues biobanks) with high-quality samples and associated data

- Link between biomedical research and clinical care in the IRCCS network (Research and Care Hospitals)
- Development of Common Services and Information Desks (IT, Quality, ELSI)
- Close collaboration with patient associations, the scientific community and the bio-industries
- Thematic networks of excellence (i.e., Telethon Network of Genetic Biobanks, NIPAB network of archived tissues biobanks)
- Expert contributions to CEN/TC Technical Specifications (CEN/TS) and ISO standards
- Development of a Self-Assessment Tool to assess compliance with quality and ELSI requirements included in the BBMRI-ERIC Partner Charter
- Development of a matrix for the informed consent process in biobanking
- Development of a matrix for ethical evaluation of studies involving human tissues
- BBMRI-ERIC Expert Centre ATMA for imaging and molecular biomarkers validation
- VetBiobank with non-human/animal biospecimens and data
- Expert contributions to Common Service ELSI and IT activities

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

e-Infrastructure

- Involvement in development and coordination of the BBMRI-ERIC WP7 Common Service IT
- Integration of the Italian Biobanks' catalogue data into the BBMRI-ERIC Directory.
- Helpdesk software support to the BBMRI-ERIC ELSI and Common Service IT and e-Infrastructures projects
- Supporting the e-mailing list and News for the Italian National Node BBMRI-IT
- Hosting the database for CRCC Colon Cancer data
- Hosting the virtual machine for all of the WP's developing team in BBMRI-ERIC Common Services
- Hosting the BIBIBOX VM's

Quality

- Several BBMRI.it experts contributed to QM-CEN/TS and ISO WGs
- Involvement in the 2.1 Workstream: Quality Self-Assessment and Audit Systems Expert Working Groups
- Coordination of the 8.6 Workstream: Immortalised Cell Lines
- Implementation of the CEN/TS within the biobanking workflow
- BBMRI.it has implemented the Common Service Quality (CSQ) to monitor biobanks and biomolecular resources; to provide information, through the help desk, on guidelines and best practices; to harmonise operational procedures; to develop criteria for the accreditation and certification of biobanks; to implement the quality management system criteria of BBMRI-ERIC in the Italian network; to improve interoperability and to promote training on issues of quality. CSQ provides support to Italian hospitals, universities and research institutes that are planning to build new facilities, and support existing research collections on the path to a fully established quality management system
- Update of the self-assessment questionnaire for biobanks, taking into account the new European and International scenarios
- BBMRI.it is involved in ISO/TC 276 activity, and has organised the ISO/TC 276/WG Meetings in Rome (25^{th} November 2017 – 1^{st} December 2017)

- Development of a national working group on quality (37 participants from 27 research institutions, 7 conference calls), production of the quality note book presented at the National Italian Biobank Day (15th November 2017)
- Development of national working group on the sustainability of biobanks (30 participants from 22 research institutions), production of a document and proposal for a national table of charges for biobank services, presented at the National Italian Biobank Day (15th November 2017)

Clinical Biobanks

- BBMRI.it leads the Archived Tissues, Liquid Biopsies and Immortalised Cell Lines Work Groups
- BBMRI.it co-coordinates the Healthcare Integrated Biobanking Work Plan
- BBMRI.it leads Work Packages 2 and 7 in ADOPT BBMRI-ERIC

Population-based Cohorts

- National network of biobanks specialised in population-based cohorts
- Participation in the BBMRI-LPC project

ELSI

- Management of the Common Service ELSI (M. Lavitrano is co-director of Common Service ELSI)
- Co-chairing of Task Force Societal
- Co-chairing Good Examples Task Force
- Horizon scanning Task Force: Configuration and launch of the 'What do you see on the horizon in biobanking?' survey during Global Biobank Week 2017
- IO Policy Task Force: Contact for EFP, EFPIA, EUREC, UNESCO
- Active participation in EFPIA round table on the value of health data (LONDON)
- Biobanking and successful stories (public information and public engagement): coordination of the collecting of stories
- Development of the survey 'Data in question. ELSI challenges in biobank-based-research'
- Configuration of the call 'How biobanking makes difference in society'
- Attendance at the following Common Service ELSI meetings: Towards Mutual RECognition, GDPR, CoC
- Early dialogue and involvement of Italian biobanks in the discussion and feedback on the WMA Consultation on Ethical Considerations Regarding Health Databases and Biobanks and GDPR
- Involvement of Italian ethical committees in the Ethics Review of European Biobank Research meeting (qualitative interviews with committee presidents)
- Contribution to the development of the BBMRI-ERIC Ethics Check
- Patient engagement and co-production of ELS tools: National pilot working group with the cancer community, in dialogue with ECPC – including POs, biobanks, Research Ethics Committees (REC) and ELSI experts – working towards a good practice of informed consent.
- Collaboration with FAVO and the European Cancer Patient Coalition (ECPC) on Modelling Together Understanding and Cancer Patients' Participation in Research Biobanking
- ELSI and quality requirements of biobanking as a shared framework for REC ethical evaluation
- Public engagement with clinicians and with RD and Cancer patients' communities: how to promote and ensure public information for a global awareness of and contribution towards biobanking processes
- ELSI requirements for 'profit biobanking' of samples collected during/as a result of a clinical trial
- Italian Data Protection Authority, Guidelines for Protection Officers

- A co-built digital dynamic framework for public information: how to modulate the information on biobanking and research, starting with the needs of the individual
- Public engagement: 'Biobanking concerns me' and Open Doors in a biobank. European Biotech Week 2017 as a training ground for public engagement
- Several public activities

Expert Centres

- The ATMA Expert Centre (ATMA-EC) to accelerate clinical research with a focus on imaging and molecular biomarker verification and validation. ATMA-EC is supported by BBMRI.it.

Education & Training

- Executive Masters in Management of Research Infrastructures[35] at the University Milano-Bicocca: Develop your skills in leading research infrastructures with global impact
- Participation in European Biotech Week 2017 (25^{th} September 2017 – 1^{st} October 2017) through a public engagement initiative: 90 different events in several Italian Regions, targeted towards the younger generation, patients and families, citizens, researchers, health professionals and journalists. Informational materials were produced and made available for schools
- Organisation of hands-on courses and participation in several courses
- Organisation of five national working groups
- BBMRI.it Quality Notebook
- BBMRI.it Sustainability and Charges for Biobanking Services
- Booklet 'Porte aperte nelle biobanche' in the context of the European Biotech Week, in collaboration with Regione Liguria, Genoa
- Biobanks-themed card game for a school programme on raising awareness of biobanking

[35] http://emmri.unimib.it/

BBMRI.lv (Member)

Country

Year joining BBMRI-ERIC: 2016
GDP: €22 billion
Population: 2 million
Number of biobanks and stand-alone collections as specified in the Directory 4.0: 1 biobanks

National Node

Start date: 25 August 2016
Director: Janis Klovins
Total staff (FTE/year and headcount): 4.0 FTE/year and 5
Total funding (period): €119,521 (2017)
Funding body: The National Health Service (direct administrative institution subordinate to the Ministry of Health of the Republic of Latvia)
Legal entity of/hosting institution of National Node: Latvian Biomedical Research and Study centre
Partners (total 7): *University of Latvia: Faculty of Medicine, Faculty of Biology*, *Institute of Clinical and Prophylactic Medicine of University of Latvia*, *Riga East University Hospital*, *P. Stradins Clinical University Hospital*, *Riga Stradins University*, and *Oncology Institute of Riga Stradins University*.
Web: http://bmc.biomed.lu.lv/en/about-us/related-organisations/lgdb/
National Catalogue:

About

BBMRI.lv is a biobank network that unites and coordinates the efforts of biobanking research communities in Latvia. Currently, the main task for the national network is to help biomaterial collectors and users to set up quality-related standards (for sample collection, processing, storage and application) within a framework of ELSI related issues (regarding international and national regulations and norms). This facilitates cooperation on a national level and furthers research activities in Latvia, contributing to BBMRI.lv's goal of promoting the availability of biomaterial for international health studies.

Specific Strengths

- The Genome Database of the Latvian population contains disease-specific and population-based cohorts, as well as associated data, in specific project-based cohorts for which extensive clinical information is available.
- During 2017, the National Node built up a framework that enables users to obtain medical information from states medical information systems, which opens up opportunities for large epidemiological studies.

- BBMRI.lv coordinates biosample collection and research activities in Latvia (collaboration with hospitals, universities and research institutes), facilitating networking and infrastructure availability on national level and contributing to the recognition of small national collections on a European scale.

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

e-Infrastructure

- Three experts nominated for the BBMRI-ERIC Common Service IT.

Quality

- Two experts nominated for the BBMRI-ERIC quality expert working groups.

Clinical Biobanks

- The Genome Database of the Latvian population stores biomaterial and associated clinical and phenotypic information for cardiovascular (over 15,000), endocrine (over 7,000), oncological (over 3,000) and other diseases.

Population-based Cohorts

- The Genome Database of the Latvian population contains a population-based collection (3,807 recruited as volunteers, invited based on information from the Latvian Population Registry).

ELSI

- One expert nominated for the BBMRI-ERIC Common Service ELSI.

Expert Centres

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Education & Training Within the framework of the BBMRI-LPC, two national courses and one international course were organised:

- Within the frameworks of BBMRI-LPC, two national courses and one international course were organised in 2015 and 2016. No activities in 2017.

BBMRI.mt (Member)

Country

Year joining BBMRI-ERIC: 2013
GDP: €7 billion
Population: 450,000
Number of biobanks and stand-alone collections as specified in the Directory 4.0: 1 biobank

National Node

Start date: 1 January 2013
Director: Alex Felice
Total staff (FTE/year and headcount): 4.7 FTE/year, 6
Total funding (period): €170,000
Funding body: Institutional Funds
Legal entity of/hosting institution of National Node: University of Malta
Partners (total 0):
Web: http://www.um.edu.mt/biobank
National Catalogue: http://www.eurobiobank.org/en/services/CatalogueHome.html

About

The Malta Biobank was developed jointly between the University of Malta and the Malta Deparment of Health, in the context of the Thalassaemia project and the national haemoglobin neonatal screening programme. It is the Malta National Node (BBMRI.mt) in BBMRI-ERIC and is one of the founders of the inter-faculty Centre of Molecular Medicine and Biobanking at the University of Malta. The Malta Biobank is the first biobank set up in Malta in 2010. It holds a population bank and a clinical bank with specific collections. The Population Bank is a discovery tool for biobanking / population-led research and has a very large collection of random Maltese neonates, pooled neonatal samples, a Twin Bank and a cohort of healthy senior citizens. The business model of the Clinical Bank is based on a collaboration between the University of Malta, the Department of Health and Mater Dei Hospital's departments including Pathology, Paediatrics, Neurology and Oncology. It is a founding partner in EuroBioBank, RD-Connect, and was an associate partner in EURenOmics (FP7). It also forms part of the Electronic Infrastructure for Thalassaemia Research Network (ITHANET) (FP6). BBMRI.mt is strategically positioned to engage neighbouring Mediterranean countries in biobanking through BBMRI-ERIC's Euro-Mediterranean Engagement Working Group (WG3).

Specific Strengths

- Rare diseases, science communication and public engagement
- BBMRI.mt was instrumental in placing Rare Diseases on the agenda of Malta's Presidency of the Council of the EU in 2017 (Malta EU2017). A series of high-level meetings about Rare Diseases was organised in parallel with the informal meeting of EU Health Ministers.
- Third National Colloquium on research in Rare Disease.

- Over the past six years, The Malta Biobank (BBMRI.mt) has been presented to Members of Parliament at the event 'Science in the House', and to members of the general public at 'Science in the City', an annual scientific event organised in Valletta on European Researcher's Night.
- ELSI expert contribution in Task Force for Societal issues.
- Expert contribution to CEN/TC Technical Specifications and related standards.

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

e-Infrastructure

- The Malta biobank (BBRMI.mt) is included in BBMRI-ERIC Directory 4.0.
- BBMRI.mt is a full partner in the RD-Connect work package 3 'Biobanks'.
- The Malta Biobank sample catalogue is accessible from the EuroBioBank website and will form part of the RD-Connect Sample Catalogue.
- Molgenis software for sample catalogue management is being used, which improves interoperability with other projects and nodes (both locally and abroad). The Malta Biobank is visible on the RD-Connect Registry and Biobank Finder.
- Some samples available in the Malta Biobank will be linked to patient registries on the RD-Connect platform.
- PhenoTips was installed at the Malta Biobank.
- BIBBOX was installed at the University of Malta. The site http://test-malta.bibbox.org was created as a trial version to be able to download and configure applications and for research.
- Open Specimens software for sample management was recently installed in the Malta Biobank and is under configuration.
- SeedDMS Document Management System was also installed for biobank file storage.
- Launched 'Connecting for Health – Building IT Communication Pathways for Citizen Participation in Biomedical and Genomic Research', a two-year project funded by Vodafone Foundation Malta via the Research and Innovation Development Trust (RIDT) of the University of Malta.

Quality

- BBMRI.mt participated in the Quality Management System (QMS) Self-Assessment Survey (QMS v5).
- Continued to develop the Quality Management System (QMS) of the Malta Biobank (BBRMI.mt) in line with the requirements of international standards.
- Some banked sample collections were evaluated against the recently published CEN/Technical Specifications for pre-examination processes using the BBMRI-ERIC Self-Assessment Surveys.
- Six experts contributed to the BBMRI-ERIC Quality Management Working Groups, including WG6 on the audit programme.

Clinical Biobanks

- The RD-Connect genome phenome analysis platform was used to analyse the whole exome sequencing data of Maltese patients for BBMRI-LPC projects (Identification of Molecular Pathology of Undiagnosed Patients with Mitochondrial Disorders by Whole Exome Sequencing – MITOMUTWES; Undiagnosed Cases of Congenital and Dystrophic Neuromuscular Diseases – UND-MND).
- The phenotypic data of the patients for the BBMRI-LPC projects was uploaded on PhenoTips.

- GlobinBank: All twenty-seven thalassaemia patients (homozygous and compound heterozygotes) have been sequenced using the Illumina TruSight One Sequencing Panel on the MiSeq. The data have now been deposited at the Malta Biobank and the collection of all genome data along with the clinical and medical phenotypes is in progress.
- A further four un-related Maltese families with members carrying the KLF1 p.K288X mutation have been identified and shall be studied further in the context of globin gene control.
- A Haemophilia A collection with samples from 18 patients was set up. The DNA was tested for the most common mutations, intron 22 inversion and intron 1 inversion. 2 DNA samples were also tested using the illumina NGS protocol.
- Renal: Analysis of 10 whole-genome sequencing datasets of patients with congenital anomalies of the kidney and urinary tract (CAKUT).
- ADOPT: contributed 300 cases to the Colorectal Cancer collection dataset.
- Diabetes: The ongoing project aims to identify and characterise the genetic epidemiology of monogenic diabetes in Malta. To date, around 30 families with suspected monogenic diabetes have been recruited. The first phase of the study has revealed a number of rare and novel mutations in various genes implicated in monogenic diabetes.

Population-based Cohorts

- A new random Maltese population collection was set up, which includes ancestry data to study the lineage markers (N=798). The European DNA Profiling Group (EDNAP) Mitochondrial DNA Population Database (EMPOP) protocol was used to amplify and sequence a subset of 300 samples with a minimum of four EMPOP sequencing primers according to forensic quality guidelines. So far, 256 full mitochondrial control region sequences have been typed, of which 168 are unique. A total of 150 Y-haplotypes were obtained from the 214 samples genotyped for the Y23-STR markers.
- The Malta Human Genome Project (MHGP) is further developing the Population Bank. A new Maltese population cohort (1% of the population – 4000 samples) is being set up based on Maltese family structures. Thus far, 0.1% of the Maltese new-born collection has been subject to Whole Genome Sequencing in a pooled anonymised fashion using the Illumina HiSeq2500 platform. All data are currently being analysed in order to produce the very first Maltese Reference Genome.
- Analysis of patient samples in the Globin Bank has resulted in interesting population and phenotypic data of the population. Mutation frequencies were calculated and analysed over time.
- Research: Expression levels of haemoglobin variants in new-borns will be used to find which factors affect globin gene expression. The project is still ongoing. A deletion at the globin locus (previously unreported in the Maltese population) was identified in several new-borns.

ELSI

- Contributed as member of the task force for Societal Issues
- Survey design: Biobanks in Question: ELSI challenges in Biobank based research;
- Poster presentation: Biobanks in Question: ELSI challenges in Biobank based research with Melanie Goisauf (BBMRI.at) at Global Biobank Week 2017, Stockholm
- Contributed to stakeholder workshop, September 2017, Stockholm
- Contributions via expert centre: contributed to BBMRI joint reply to GDPR WP29 guidelines; contributed to BBMRI-ERIC comments on consultations WP259 and WP260 (consent & transparency)
- Contributions via Helpdesk: commented on template consent form from Swiss Biobanking Platform

- Dr Bridget Ellul is a member of the Bioethics Research Programme, Faculty of Medicine and Surgery and the Medicine and Law Programme, Faculty of Laws. She is also a member of the Health Ethics Committee, which assesses clinical trials, and a member of the Research Ethics Committee, Faculty of Dental Surgery.

Expert Centres

- The Malta Biobank forms part of the new inter-faculty Centre of Molecular Medicine and Bio-Banking at the University of Malta. It may apply as an Expert Centre/Trusted Partner.

Education & Training

- Participated in the EMBL-EBI Roadshow, organised by TrainMALTA, (RITrain), 2nd – 3rd February 2017, University of Malta.
- The third National Colloquium on Research in Rare Disease was organised on 23rd February 2017 on the occasion of Rare Disease Day.
- High-level meetings organised in parallel with the informal meeting of EU Health Ministers as part of the Maltese Presidency agenda of the Council of the EU: 'Integrating Research and Healthcare for Rare Diseases: a structured cooperation with high community added value', 20th March 2017, Valletta; 'Development and Access of Medicines for Rare Diseases', 21st March 2017, Valletta
- Participated in the annual RD-Connect meeting in Berlin between 1st – 3rd May 2017.
- Attended the 50th European Society of Human Genetics (ESHG) conference and workshops between the 27th and 30th May in Copenhagen, Denmark.
- Attended TrainMALTA's (RITrain) 2nd Networking event, 1st – 2nd June 2017, Cambridge.
- Joanna won the Joint Research Centre (JRC) Young Scientist Award and was invited to the Joint Research Centre between the 14th – 16th June 2017 in Ispra, Italy, to present her ongoing PhD research about Genomics in Rare Diseases to the JRC Director General Vladimir Sucha, the JRC Board of Governors and the JRC Rare Diseases group.
- Attended the 27th International Society of Forensic Genetics Congress, 30th August 2017 – 2nd September 2017, Seoul, South Korea.
- Attended Global Biobank Week and the workshop 'How to set up a Modern Biobank', 13th – 15th September 2017, Stockholm.
- Attended the summer school in Model Systems, organised by TrainMALTA (RITrain), 18th – 23rd September 2017, University of Malta.
- Attended the Genomics in Medicine: Policy meeting, organised by TrainMALTA (RITrain) and held on the 29th September 2017 at Valletta Campus.
- A Health and Rare Disease research area was organised at Science in the City (European Researcher's Night) on the 29th September 2017, Valletta.
- Attended a three-week research visit at the Pasteur institute of Lille, France and at the European Genomic Institute for Diabetes, 18th November 2017 – 5th December 2017.
- Participated in the IARC-BCNet symposium 'From Biobank Infrastructure to Research: How BCNet Member Biobanks and Cohorts Are Contributing to Address Public Health Concerns' 27th – 28th November 2017, Lyon, France.
- Participated in the B3Africa training workshop, 29th November 2017 – 1st December 2017, Lyon, France.
- A lecture in biobanking was delivered to MSc Surgery students.
- Lectures on the role of Research Ethics Committees were delivered in the MSc Clinical Ethics and Law course, offered by the Faculty of Medicine and Surgery.

BBMRI.nl (Member)

Country

Year joining BBMRI-ERIC: 2013
GDP: €600.4 billion
Population: 17.1 million
Number of biobanks and stand-alone collections as specified in the Directory 4.0: 80 biobanks

National Node

Start date: 2013
Director: Cisca Wijmenga (UMCG), Gerrit Meijer (AVL/NKI)
Total staff (FTE/year and headcount): 20 FTE/year and approx. 70.
Total funding (period): €2–9.8 million (2000–2018). Overall BBMRI funding €32.8 million (2009–2018).
Funding body: Ministry of Education, Culture and Science (OCW)
Legal entity of/hosting institution of National Node: University Medical Center Groningen
Partners (total 19): *Academic Medical Center, Erasmus Medical Center, Leiden University Medical Center, Maastricht University Medical Center+, Radboud University Medical Center, University Medical Center Utrecht, University Medical Center Groningen, Netherlands Cancer Institute, University of Groningen, VU University Medical Center, Free University Amsterdam, Lygature, Parelsnoer Institute, PALGA, Netherlands Heart Institute, SURFsara, Dutch Techcentre for Life Sciences, Legal Pathways, The Hyve*
Web: http://www.bbmri.nl
National Catalogue: https://catalogue.bbmri.nl/

About

BBMRI.nl is building and implementing the Dutch National Biobank Infrastructure, i.e., collecting, managing and making accessible data, samples and images for personalised medicine and health research. BBMRI-NL enables the (re)-use of human samples, data and images, to advance biomedical research in compliance with ethical, legal and privacy demands and active participation of donors. A strong feature of BBMRI.nl is the contribution of population imaging. Linked to 'traditional' biobank measurements like lifestyle, clinical characteristics, biomarkers, and omics, the addition of image analysis broadens the scientific value of biobank/cohort studies. Within BBMRI.nl, both large-scale image acquisition procedures as well as images processing pipelines have been developed. BBMRI.nl coordinates the national support for ELSI aspects of biobank research. This includes national policy and legislation, often linked to European developments like the GDPR. In collaboration with other research organisations, information meetings and support sessions are organised. In 2017, BBMRI.nl started building a National ELSI service desk. The IT aspects of biobank research are well organised within BBMRI.nl, closely linked to the BBMRI-ERIC IT common service. There is a national catalogue of all biobank studies in the Netherlands, as well as sample catalogue of the larger studies. This includes the national pathology archive, which includes the pathology samples

of all Dutch hospitals. BBMRI.nl, EATRIS-NL, and DTL/ELIXIR-NL have developed a common vision and roadmap on how the Netherlands can set course for a collective Personalised Medicine and Health Research infrastructure. The goal is to bundle and connect a wide range of resources, including biobanks, IT-infrastructure, -omics facilities and data collections, into one large-scale research infrastructure named Health-RI. This will stimulate and facilitate collaboration through the sharing of data, images and biomaterials among researchers, medical practitioners, and the general population (patients and healthy citizens) at a national level.

Specific Strengths

- 4P biobanking: Personalised medicine – oriented
- Donor participation
- Central portal for request of samples and/or data
- Access to the decentralised pathological tissue bank Dutch National Tissue Portal DNTP
- Multilevel 'Omics'- integration: Genotypes/epigenomics/transcriptomics/metabolomics imaging integration
- Imaging platform: federated storage, analysis and integration with other data
- Legal expertise in synergy with BBMRI-ERIC Common Service ELSI
- National ELSI service desk
- ICT systems and application development in synergy with BBMRI-ERIC Common Service IT

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

e-Infrastructure Various systems and applications development:

- Central portal for request of samples and/or data
- Imaging platform that facilitates the running of image-analysis pipelines on medical images
- BBMRI-Omics Warehouse with available data resources

Quality

- QC/QA systems not national but biobank-specific; participation in BBMRI-ERIC QA/QS expert working groups

Clinical Biobanks

- Coordinated activities in Pearl String Institute: decentralised activities of clinical biobanks in European disease-specific projects (ERN)

Population-based Cohorts

- Close ties between major population biobanks and epidemiology, BBMRI-ERIC and international infrastructure projects (e.g., BBMRI-LPC, Bioshare, ADOPT BBMRI-ERIC, CORBEL)

ELSI

- Three Patient and Public Advisory Councils organised, data shared and two field visits carried out. Jointly-recognised informed consent templates for human biomaterial are in preparation.
- Funding (ZonMw) for development of a National ELSI Service Desk by BBMRI.nl in collaboration with COREON.
- Joint response of the Life Science field on the Dutch implementation legislation of the GDPR. Development of a data protection, registration and compliance tool (in Dutch).

- Joint response of the Biobanking field to governmental plans on Dutch legislation for secondary use of biological samples. Development of guidance for incidental findings (in Dutch).
- Jointly-recognised informed consent templates for human biomaterial are in preparation.
- National ELSI expert meeting (Task Force Societal Issues).
- Dissemination of BBMRI.nl tool development in BBMRI-ERIC Common Service ELSI and Common Service IT respectively (e.g., Wiki-Legal, My Biobank, Miabis Catalogue development).

Expert Centres

- Expert Centres in development on biomarker discovery, metabolomics, Common Service and IT technology.

Education & Training

- Organised 7 courses (2 metabolomics workshops, BIKE Biobank summer course, 3 Translational IT (TraIT) workshops, XNAT workshop)
- Development of the Biobank Game

Other

- Health-RI business plan: a collective Personalised Medicine and Health Research infrastructure to bundle and connect a wide range of resources, including biobanks, IT-technologies, facilities and data collections, into one large-scale research infrastructure.

BBMRI.no (Member)

Country

Year joining BBMRI-ERIC: 2013 (as an Observer), as of 2016 (full Member)
GDP: €376 billion
Population: 5.084 million
Number of biobanks and stand-alone collections as specified in the Directory 2.0: 1 biobanks

National Node

Start date: 2011
Director: Kristian Hveem
Total staff (FTE/year and headcount): 13 FTE/year and 27
Total funding (period): €8.3 million (80 MNOK) 2011–2013 and €8.9 million (85.3 MNOK) 2016–2018 funded by the Research Council of Norway.
Funding body: The Research Council of Norway
Legal entity of/hosting institution of National Node:
Partners (total 10): *University of Tromso, University of Bergen, University of Oslo, Norwegian University of Science and Technology (Coordinator), Norwegian Institute of Public Health, Northern Norway Regional Health Authority, Central Norway Regional Health Authority, Western Norway Regional Health Authority, Eastern Norway Regional Health Authority, Cancer Registry of Norway.*
Web: http://www.ntnu.edu/biobanknorway
National Catalogue: https://www.biobankregisteret.no/#/home

About

BBMRI.no is a large-scale national research infrastructure for health sciences, including almost all the population-based and clinical biobanks in Norway. BBMRI.no is presently leading the Nordic Biobank Network. BBMRI.no shall maximise the use of biobanks as a basis for excellent research and innovation and reinforce their ability to participate in international research projects. BBMRI.no shall provide internationally competitive biobanking services for basic, clinical, and epidemiological medical research. BBMRI.no has been funded twice through the infrastructure program initiated by the Research Council of Norway (RCN), with a total grant of ∼200 million NOKS (20 million). BBMRI.no are presently preparing a new grant proposal for the coming five years.

Specific Strengths

- BBMRI.no builds upon a strong Norwegian tradition of population-based health surveys ongoing since the early 1970s, including collection and storage of biospecimens.
- A national network of all population biobanks was already organised in 2002. When BBMRI.no/ Biobank Norway was funded as a national research infrastructure in 2010, all the clinical biobanks and the serum biobank of the Norwegian Cancer Registry were also included as

partners, promoting a rapidly growing network of biobanks offering a wide range of well described, richly annotated bio-specimens and corresponding health related data.
- In parallel, a large number of active, dedicated biobankers throughout the entire country have involved themselves in developing and implementing SOPs and an interactive Best Biobanking Practice.
- ELSI has been a strong component in the BBMRI.no network, presently with a special focus on the ethics involved in genetic studies and Next Generation Sequencing.
- In recent years, almost 200,000 samples from the largest population biobanks have been genotyped and inputted, available for researchers on a national and international level.

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

e-Infrastructure

- BBMRI.no has been involved in the development of both a National and Nordic biobank registry as well as the development of computer cloud solutions for the storage and processing of genetic data.

Quality

- NTNU (Coordinator of BBMRI.no) was the co-chair of Work Package 9 in BBMRI-LPC, where 25 European biobanks have contributed to the development of an evidence-based research platform for scientific evaluation of biobank samples and procedures, organised a Biobank BRISQ, studied quality of DNA and RNA across biobanks, and participated in a number of workshops related to biobank quality issues. BBMRI-LPC has been terminated and this activity will gradually be 'merged' with the Quality work stream for BBMRI-ERIC. Ten technical biobank experts from BBMRI.no are involved in the development of a Biobank Quality Standard for BBMRI-ERIC.

Clinical Biobanks

- In the new work programme for BBMRI.no, the development of prospective clinical biobanks is highly prioritised as well as running a national pilot study on the establishment of a fresh frozen tissue sample biobank, using prostate cancer as a use case. A samples tracing and management system has already been implemented in several clinical biobanks.

Population-based Cohorts

- The HUNT study (130,000) is running a new survey (HUNT 4), using new sensor technologies and a variety of imaging procedures in addition to clinical examinations and an extensive sampling of biological material. Both the HUNT study and the Mother and Child study (300,000) participates in BBMRI-LPC.

ELSI

- BBMRI.no has established a national Common Service ELSI operating a national Helpdesk.

Expert Centres

- BBMRI.no has a dedicated Work Package for innovation and industrial collaboration that involves all partners. Pre-competitive arrangements have been discussed with several pharma companies and potential bi-lateral agreements are under evaluation.

Education & Training

- BBMRI.no has organised PhD courses in GWAS-analyses as well as being part of an annual, national PhD course in molecular medicine. The national Common Service biobanking offers guidance and training opportunities through internships. We also arrange an introduction course to Research Biobanking (10p credits) for approx. 30 students annually.

Other BBMRI.no Performance Indicators 2017:

- National Steering Board meetings: 3
- National WP/CS-meetings: 38
- Partner in EU projects: > 10 National meetings: > 10
- International conferences/meetings: 30
- National and international seminars/conferences/WS: 4

Research/Communications

- Presentations at Norwegian and international conferences: 19
- Participation and representation in the Press: > 800/year
- Scientific publications > 100/year[36]
- Collective Nordic research project on colorectal cancer: 2–3 Norwegian Researchers
- Operating the projects web pages (bbmri.no / biobanknorway.no)
- Preparations for the survey 'Data in question' in collaboration with BBMRI-ERIC ELSI[37]

Infrastructure

- Nordic Biobank Network (Project Management 2014 onward)
- Integration of Norwegian platforms to the BARC database
- Building of a new regional biobank facility in Bergen
- Upgrade of the Janus Serum Bank at the Cancer
- Representing Norway in the Management Committee – BBMRI-ERIC
- NTNU/HUNT biobank ISO9001:2015 certified

[36] http://www.ntnu.no/biobanknorge/publikasjoner, http://www.kreftregisteret.no/no/Forskning/Janus-serumbank/Forskning/Publiserte-artikler1

[37] http://www.bbmri-eric.eu/news-events/survey-on-elsi-challenges-in-biobank-based-research/

BBMRI.pl (Member)

Country

Year joining BBMRI-ERIC: 2017
GDP: €446.69 billion
Population: 39 million
Number of biobanks and stand-alone collections as specified in the Directory 4.0: 6

National Node

Start date: 1 August 2016
Director: Lukasz Kozera
Total staff (FTE/year and headcount): 31 FTE/year and n.a.
Total funding (period): €9.4 million (2017–2021)
Funding body: Ministry of Science and Higher Education (MNiSW)
Legal entity of/hosting institution of National Node: Wroclaw Research Centre EIT+ Medical University of Gdansk; Medical University of Warsaw; Medical University of Lublin; Wroclaw Medical University, University of Lodz, Regional Science and Technology Centre Checiny
Partners (total 6): *Medical University of Gdansk*, *Medical University of Warsaw*, *Medical University of Lublin Wroclaw Medical University*, *University of Lodz*, *Regional Science and Technology Centre Checiny*
Web: In preparation
National Catalogue: In preparation

About

BBMRI.pl is a newly formed biobanking network, initially created by the WRC EIT+ Biobank and six other partners. The aim of BBMRI.pl is to show the potential of Polish biobanks to European partners. The BBMRI.pl project, funded by the Ministry of Science and Higher Education, started in January 2017 and will dedicate funding towards the creation of a national biobanking registry, common IT solutions, quality assurance tools, the National Node and ELSI aspects of research on human samples. At the end of 2017, BBMRI.pl mapped more than 40 biobanks interested in joining our network. Further recruitment is still ongoing. Our consortium actively organises trainings and conferences dedicated to newly formed and established biobanks. In addition to project activities, we are involved in several initiatives promoting the development of personalised medicine, biobanking law and a dialogue between patients and scientific community. BBMRI.pl actively promotes collaboration between biobanks and the pharmaceutical industry in order to create a platform for setting up projects and exchanging ideas.

Specific Strengths

- BBMRI.pl has a few fields of expertise relating to the backgrounds of the people involved in founding this organisation. Since most of the biobanks are specialised units, our group focuses on tissue engineering and the collection of biological material from several groups of

patients suffering from both common and rare diseases. BBMRI.pl is also actively developing population-based biobanking (i.e., biobanks from Wroclaw, Lodz, Gdansk, Bialystok). Our specific strengths are in IT solutions and aspects of quality.

e-Infrastructure

- The majority of the funding received is directed towards IT infrastructure such as common biobanking software, linkage to the national registries and storage of large-scale clinical data.

Quality

- Three national experts collaborate in different fields of quality management.

Clinical Biobanks

- The majority of Polish biobanks are located in clinical settings.

Population-based Cohorts

- BBMRI.pl has officially mapped two population-based biobanks and a few smaller population-based cohorts.

ELSI

- Nominated ELSI expert – Prof. Jakub Pawlikowski.

Expert Centres

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Education & Training

- BBMRI.pl members organise training and national conferences on a yearly basis.

BBMRI.se (Member)

Country

Year joining BBMRI-ERIC: 2009
GDP: €404.7 billion
Population: 9.8 million
Number of biobanks and stand-alone collections as specified in the Directory 2.0: 101 biobanks

National Node

Start date: 1 January 2009
Director: Tobias Sjöblom (to be appointed)
Total staff (FTE/year and headcount): 10 FTE/year and 12
Total funding (period): €3.5 million over 2 years
Funding body: Swedish Research Council (Vetenskapsrådet) and partners
Legal entity of/hosting institution of National Node: Karolinska Institutet
Partners (total 14): Uppsala University, Karolinska Institutet, Umeå University, Örebro University, Linköping University, University of Gothenburg, Lund University, Västerbotten County Council, Uppsala County Council, Region Örebro County, Region Östergötland, Region Västra Götaland, Region Skåne, Stockholm County Council
Web: http://www.biobanksverige.se/
National Catalogue:
http://bbmriregister.meb.ki.se:8080/AwareIM/logonGuest.aw?domain=BBMRIRegister

About

The new incarnation of Sweden's national biobanking infrastructure, Biobank Sweden (BIS), of which BBMRI.se is a part, was launched in January 2018. Healthcare providers and universities with medical faculties are working together towards national harmonisation at the strategic and operational levels, with input from patient organisations and industry representatives. With six regional biobank centres managing more than 450 biobanks and approximately 160 million samples, Sweden stands to benefit substantially from increased harmonisation, and a more formalised integration of university biobanks and their regional healthcare counterparts. Thanks to funding from the Swedish Research Council, a strengthened research infrastructure focusing on coordination, efficiency and sustainability in terms of biobank samples and associated healthcare and molecular analysis data, has also been initiated in integration with Biobank Sweden's activities. The core activities in the research infrastructure will be: improved information with a common website for biobank infrastructure, sample collection and withdrawal; improved sample withdrawal support; IT development for sample searchability across biobanks; support for healthcare-integrated biobanking to support collection of high quality samples; and legal and ethical coordination including adaption to GDPR and participation in ELSI.

BIS aims to:

- establish a nationally coordinated biobank infrastructure and strengthen the cooperation between health care providers, academia and the life sciences industry, both regionally and nationally.
- expand on-demand healthcare-integrated biobanking services to all university hospitals and implement standardisation for the collection and handling of tissue and blood samples.
- provide professional and internationally competitive biobank services for clinical and epidemiological medical research.
- increase the accessibility and output of existing clinical biobanks, prospective cohorts and other sample collections in academic biobanks.
- develop better biobank information technology systems for sharing samples and data and thereby promote national and international research studies based on biobanks.
- develop new tools that link biobanks to clinical data and population-based health registers.
- strengthen Swedish participation in BBMRI-ERIC and thereby promote scientific excellence in medical research, technology and quality development and in ethical and legal aspects of biobanking.

Specific Strengths

Sweden's national infrastructure is characterised by clear contact points at all levels; national (Biobank Sweden), regional health care (6 regional biobank centres), local (21 county councils and 1 university biobank). Roles and responsibilities are well-established, as well as communication routes. There is now national collaboration between healthcare providers, universities with medical faculties, and the pharmaceutical and medical technology industry, creating a joint national infrastructure for healthcare, academia and industry.

e-Infrastructure

- All sample collections stored in Swedish biobanks are included in the Directory 2.0.

Quality

- BIS has appointed representatives to most BBMRI-ERIC Expert Working Groups. They participate actively in WG meetings and report back to Biobank Sweden. Several BIS partners have worked on the ISO standard for biobanking, ISO 20387. Sweden was represented at the two international meetings in Seoul and Rome held during 2017. The Gothenburg node is currently leading biobank quality research projects with the goal of investigating sample quality using metabolomics, single cell parallel sequencing, cell free DNA/RNA and other advanced techniques applied to different biobank samples. In this endeavor, the Sahlgrenska University Hospital, the University of Gothenburg and Chalmers work closely together with the national network within BBMRI.se.

Clinical Biobanks

- Healthcare biobank samples are a prerequisite for research on causes for disease, clinical trials and pharmaceutical studies for better and more individualised treatment, quality assurance and the development of better diagnostic instruments. Samples from healthcare biobanks can be found, used and linked to other clinical data through Sweden's unique personal identification numbers for each citizen, which are used in all health care and registers. A standardised process for collecting, handling and storing samples for research has been implemented

across Sweden. The process is integrated in a well-functioning routine healthcare system including a functional IT infrastructure, and uses a standardised aliquoting process. This enables collection of samples with high and known quality with an arm-to-freezer time. Currently 19 hospitals can provide healthcare-integrated biobanking for blood- and other liquid samples for research purposes, and 60 studies collect samples using the process. Support for long-term maintenance of the program is now provided by BIS. The main sample collections consist of samples collected in a healthcare context, with the purpose of diagnostics, treatment and care (approximately 95% of all collected samples). The largest healthcare sample collections are found mainly in clinical pathology and cytology (approximately 90%), followed by clinical microbiology and the PKU biobank (approximately 5%).

Population-based Cohorts

- All cohorts are listed in the national catalogue.

ELSI

- In terms of ELSI issues, ethical and legal advice is offered to researchers and consortia. Sweden also plays an active part as a national ELSI node in several Task Forces of the Common Service ELSI of BBMRI-ERIC.

Expert Centres

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Education & Training

- Education and training opportunities are available in the context of legal training, mainly aimed at coordinators and other staff at regional biobank centres. In addition, there are courses on sample collection for researchers and students (Karolinska Institutet, Uppsala University, Gotheburg University).

BBMRI.tr (Observer)

Country

Year joining BBMRI-ERIC: 2014 (Observer)
GDP: €595.1 billion
Population: 595.1 billion
Number of biobanks and stand-alone collections as specified in the Directory 2.0: 0 biobanks

National Node

Start date: 1 January 2014
Director: Safiye Nese Atabey (since 2015), Kemal Baysal (until 2015)
Total staff (FTE/year and headcount): 1.5 FTE/year and 3
Total funding (period): €200,000 (2014–2017)
Funding body: Ministry of Development, Dokuz Eylul University, Istanbul Development Agency (ISTKA)
Legal entity of/hosting institution of National Node: Dokuz Eylul University, Izmir International Biomedicine and Genome Institute (IBG-izmir)
Partners (total 3): *Hacettepe University Center for Biobanking and Genomics (HUBIGEM)*, *Istanbul University, Institute of Experimental Medicine (DETAE) H. Behcet Life Science Center Biobank Facility*.
Web: http://biobank.gen.tr/
National Catalogue: not yet Status: 2017

About

BBMRI.tr focuses on the establishment of a national biobanking infrastructure in Turkey to create a national registry and to increase harmonisation between biobanks. This is very important in order to facilitate access to biobanks for researchers, to improve research and innovation in life sciences. Training activities to ensure the quality of biobanks and registries, as well as educational activities to enhance awareness of biobanking, have also been organised, involving the general public, policy-makers and health-care providers.

Specific Strengths

- Hacettepe University Center for Biobanking and Genomics (HUBIGEM) is one of the largest rare disease biobanks in Europe and a member of the EuroBioBank network.
- Strong support from Turkish Health Institutions (TUSEB) to build a national biobank infrastructure.
- Support from TUSEB for the establishment of population-based biobanks and for increasing the sustainability of disease-based biobanks in Turkey.
- Clinical expertise on rare diseases and a repository of large consangious families.

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

e-Infrastructure

- BBMRI.tr actively participates in the creation of a national biobank registry and IT infrastructure for the storage and processing of samples and related genomic data in Turkey, within the scope of the Turkish Genome Project.

Quality

- BBMRI.tr actively participates in BBMRI-ERIC quality meetings with five experts, while BBMRI.tr quality management experts organised a quality workshop and prepared a guide for quality assurance.[38]

Clinical Biobanks

- To increase awareness and contributions to the development of a dataset on colon cancer collections (ADOPT BBMRI-ERIC), BBMRI.tr's Clinical Biobanking Group and the Turkish Pathology Societies Federation, Gastroenterology Working Group organised a workshop in November 2016.
- BBMRI.tr has been involved in the development of a national network infrastructure for rare disease, common disease and tumour biobanks.

Population-based Cohorts

- No biobank within BBMRI.tr is specialised in population-based cohorts.

ELSI

- The Turkish Law on the Protection of Personal Data, which is based on Directive 95/46/EC, was published on April 2016. In addition, secondary legislation regarding the protection of personal health data was adopted in October 2016. This new law and the regulation are a major step in aligning Turkey's legislative framework with the EU's and largely reflects the requirements under the current EU Directive.[39]
- A guide for 'Ethical and Legal Regulations on Biobanks' was published.[40]

[38] Erbilgin, Y, Ugur Iseri, S, Khodzhaev, K & Haryanyan, G: *Protocols and Quality in Biobanks* 2016.
[39] Ibid.
[40] Tuncel, F, Oztezel, A & Kulahci, S: *Ethical and Legal Regulations In Biobanks* 2016.

Expert Centres

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Education & Training

- A one-day workshop was organised to harmonise SOPs and train biobankers on Quality Management Systems in biobanks: Protocols and Quality in Biobanks Workshop, 6th April 2016.
- A workshop titled 'Ethics and Legal Framework of Biobanks' was held in Istanbul, 7th April 2016. During the workshop, ethical and legal issues in biobanks were discussed with interdisciplinary participation from, among others, lawyers, researchers and ethics committee members.
- The Turkish Pathology Societies Federation, Gastroenterology Working Group organised a workshop during the 26th National Pathology Congress, held in Antalya from 2nd – 6th November 2016, to increase contribution to dataset development on colon cancer collections (ADOPT BBMRI-ERIC Work Package 2).
- Workshop 1 titled 'Pre-Analytical Sample Processing in Biobanking: A Practical Laboratory Course' in Istanbul on 27th – 28th May 2016.
- Workshop 2 titled 'Data Analysis Approaches and Processing Tools in Biobanks' course in Istanbul on 30th – 31st May 2016.

BBMRI.uk (Member)

Country

Year joining BBMRI-ERIC: 2015
GDP: €1.86 trillion
Population: 65.1 million
Number of biobanks and stand-alone collections as specified in the Directory 4.0: 44 biobanks

National Node

Start date: 1 December 2014
Director: Philip Quinlan
Total staff (FTE/year and headcount): 3.5 FTE, 10
Total funding (period): €1,062,901 (£900,000) (2014–2017)
Funding body: Administered by the Medical Research Council
Legal entity of/hosting institution of National Node: University of Nottingham and UCL
Partners (total 0): –
Web: http://www.biobankinguk.org
National Catalogues: https://directory.biobankinguk.org

About

The UKCRC Tissue Directory and Coordination Centre facilitates the discovery and use of the UK's human samples and data to enable biomedical research. The work of the UKCRC TDCC is guided by the belief that the biomedical research ecosystem should be based on open standards, open-science, and pre-competitive collaboration.

Our work in enabling biomedical research is central to the success of our work. Our work focuses on four main areas:

- helping researchers find samples and data,
- helping sample resources improve their data systems,
- harmonising policy on the discovery and use of samples and data, and
- connecting the UK to Europe via BBMRI-ERIC.

We host a range of events across the UK, including workshops, focus groups and an annual event, to inform our work through an open dialogue with various groups.

Specific Strengths

- IT/Data/discovery
- Stakeholder Engagement

National Expertise and Contributions to the Joint Efforts in BBMRI-ERIC

e-Infrastructure

- National Expertise: Dr Phil Quinlan and the University of Nottingham's Advanced Data Analysis Centre.
- Contributions: various contributions to the work of the Common Service IT.

Quality

- None specifically in BBMRI.uk.

Clinical Biobanks

- None specifically in BBMRI.uk.

Population-based Cohorts

- None specifically in BBMRI.uk.

ELSI

- Expertise: Dr Alison Parry-Jones and Dr Victoria Chico.
- Contributions: GDPR and ELSI advice

Expert Centres

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Education & Training

- Expertise: Ms Jessica Sims and Dr Emma Lawrence.
- Contributions: Webinars and events hosted by BBMRI.uk have been open to the BBMRI-ERIC community, including 'registering int he UKCRC Tissue Directory' and 'Biobanklink' webinars and the UK Biobanking Showcase 2016 and 2017.

Other

- Recruitment of two biobanks to the BBMRI-ERIC ADOPT project.

WHO/IARC (Observer)

Organisational Node

Year joining BBMRI-ERIC: 2013
Number of biobanks and stand-alone collections as specified in the Directory 4.0
none yet
Organisational Node Director: Maimuna Mendy (2013-Sept 2017)
Total staff 11
Legal entity of/hosting institution of National Node: World Health Organisation
Funding: €1.0 million (2013–2018)
Web: http://bcnet.iarc.fr and http://www.b3africa.org

About

For more than 50 years, since its creation by the World Health Assembly of the WHO, IARC has been making important contributions to the global fight against cancer, notably through its capacity to bring together people and organisations from across the world that share common values and objectives. IARC is first and foremost a research organisation, providing new knowledge to reduce the global burden of cancer. In addition, its place within WHO and the wider United Nations family provides unparalleled opportunities to encourage cooperation and provide leadership within the international cancer research community. IARC has a global mandate, permitting a focus on developing countries where resources are most needed and cancer remains an often-neglected disease. Furthermore, IARC's independence enables it to provide reliable and authoritative assessments of many facets of cancer information valued by scientists, governments, nongovernmental organizations and the public the world over. At any one time, about 300 people from some 50 countries are working for IARC at its Lyon headquarters. However, the number of people working with IARC worldwide stretches into the thousands through its wide network of collaborations and partnerships. With the excellent quality of its scientists and support staff, their integrity and their collective motivation to relieve cancer-related suffering, the Agency provides a rallying point for people everywhere. The IARC biobank stores over 6 million biological samples from close to one million individuals for studies conducted world-wide. The main collections in the biobank are from the European Study of Nutrition and Cancer (EPIC) and from 60+ studies conducted in over 30 countries world-wide.

Specific Strengths

- Coordination of low- and middle-income countries biobanks through the Biobank and Cohort Building Network (BCNet), international collaboration, ethics, legal and social issues (ELSI). BCNet members are from 21 countries, from Africa, Asia South America and Europe. Partners are from 10 international organisations (including BBMRI-ERIC) who are working together with IARC to increase biobanking activities and research in LMIC;
- Education and training for biobanks in LMIC countries;
- Provision of best practice guidelines in biobanking: the Common Minimum Technical Standards and Protocols for Biobanks Dedicated to Cancer Research[41]

[41] http://publications.iarc.fr

- Provision of scientific and technical support to LMIC biobanks wishing to upgrade their facilities or establish new facilities.

e-Infrastructure

- IARC is a member of the BBMRI-ERIC IT Working Group. IARC is a member of the MIABIS working groups: WG on Sample/donor metadata and WG on SOP metadata
- The working groups have worked on the definition of attributes for sample and donor metadata and for Common Data elements for SOP.

Quality

- IARC is a member of the BBMRI-ERIC quality expert working groups 1 to 5
- The quality expert working groups have worked on the development of self-assessment surveys based on published CEN technical specifications for molecular in vitro diagnostic examinations, specifications for pre-examination processes and general QMS requirements for biobanks.

Clinical Biobanks

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Population-based Cohorts

- IARC is custodian of the EPIC biobank. The European Prospective Investigation into Cancer and Nutrition (EPIC) study is one of the largest cohort studies in the world, with more than half a million (521,000) participants recruited across 10 European countries and followed for almost 15 years. EPIC was designed to investigate the relationships between diet, nutritional status, lifestyle and environmental factors, and the incidence of cancer and other chronic diseases.

ELSI

- IARC is a partner in the B3Africa project, which aims to develop an ELSI regulatory framework to bridge European and African Biobanking and Biomolecular research.

Expert Centres

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Education & Training

- IARC is a member of the BBMRI-ERIC E&T committee. The agency is Coordinator of the BCNet which is actively involved in training in LMIC regions. Some of the training has been conducted in collaboration with BBMRI-ERIC. For example, training in biobanking for pathologists and pathology/histology technicians was organised in Cairo, Egypt in May 2017. 32 participants from 13 countries attended the training.
- IARC led the organisation of a B3Africa-BCNet joint event from 27th November 2017 – 1st December 2017. The BCNet symposium 'From Biobank Infrastructure to Research' was organised to showcase the efforts of its members and institutions in developing biobank-based collaborative research projects to address public health issues. The event was attended by 58 participants from 29 research institutions, including: BCNet members, guest speakers/representatives from relevant/complementary projects/institutions; B3Africa partners and representatives from B3Africa use case institutes (IT and users).

- As part of the B3Africa project (H2020-funded project, 2015–2018), IARC coordinates the Education and Training (E&T) and Dissemination Work Packages. The E&T Work Package aims to develop and implement resources for education and training on the use of the B3Africa platform (the eB3kit), including best practices in biobanking, bioinformatics data-analysis, and data-sharing with respect to the relevant ethics and regulations. Six webinars and two in-person training workshops have been organised so far, reaching out to around 128 professionals from 26 countries, up- and down-stream of biobanking (biobank and laboratory technicians and managers; researchers and scientists; bioinformaticians; IT specialists, ethicists, etc.) The Dissemination WP disseminates the results and outcome of the project to a wider community and encourages the wider adoption of the different open source platforms.

Other

- IARC provides support and expertise to BCNet members through on-site visits or visits to the IARC biobank.

Part IV.

Externally Funded Projects

10. Active Projects

10.1. AARC2 (H2020)

Authentication and Authorisation For Research and Collaboration
Topic: H2020-EINFRA-2016 **Type of Action:** RIA **Duration:** 24
Start date: 1st May 2017 **Grant agreement:** 730941
Web: https://aarc-project.eu
Total request Grant by Consortium: €2,999,893.75
Total request Grant by BBMRI-ERIC: €39,590.00
Assigned 3rd parties/BBMRI-ERIC Framework Agreement:
none
Benefit/tasks for BBMRI-ERIC: Development of Levels of Assurance for authentication suitable for biomedical research applications.
Status: score 12 (threshold 10)

Coordinator: Licia Florio

Abstract: *Lead by GÉANT*: The goal of AARC2 is to design an AAI framework to develop interoperable AAI, to enable researchers to access the whole research and infrastructure service portfolio with one login. AARC2's objectives are: (1) enable federated access in research communities participating in AARC2, (2) assist research communities to map their requirements to concrete service offerings, (3) support research (e-)infrastructures to implement the integrated architecture and policies frameworks developed by AARC project (4) offer different trainings to adopt AARC/AARC2 results, (5) enhance the integrated architecture. AARC2 objectives will be achieved by: Piloting selected research community use-cases (SA1); Showcasing ready-to-use AAI solutions and pilot results to infrastructures (SA1-NA2); Developing a virtual Competence Centre where infrastructure representatives and AARC2 team discuss AARC2 results deployment and approaches to use-cases (all WPs); Promoting federated access and adoption of AARC2 results via training and outreach (NA2); Expand support for new technologies and policies (JRA1 and NA3); Follow a user-driven approach: development driven by use-cases and continuous community feedback on AARC2 work.

List of Participants: INFRAFRONTIER GmbH, Stichting EGI, Akademia Gorniczo-Hutnicza im. Stanisława Staszica w Krakowie, Istituto Nazionale di Astrofisica, Universidad de Cantabria, ETHNIKO DIKTYO EREVNAS TECHNOLOGIAS AE, European Molecular Biology Laboratory, Karlsruher Institut für Technologie, CESNET zájmové sdružení právnických osob, European Organization for Nuclear Research, Biobanks and BioMolecular resources Research Infrastructure Consortium, INSTRUCT Academic Services Limited, SURFnet bv, DAASI International GmbH, Forschungszentrum Jülich GmbH, Stichting voor Fundamenteel Onderzoek der Materie – FOM, Moravská zemská knihovna v Brně, Instytut Chemii Bioorganicznej Polskiej Akademii Nauk, Cardiff University, GÉANT Vereniging, Stichting LIBER, RETI SPA, Science and Technology Facilities Council, Consortium GARR, EISCAT Scientific Association

10.2. ADOPT BBMRI-ERIC (H2020)

implementAtion anD OPeration of the gateway for healTh into BBMRI-ERIC
Topic: H2020-INFRADEV-3-2015 **Type of Action:** RIA **Duration:** 36 months
Start date: 1st October 2015 **Grant agreement:** 676550
Web: http://bbmri-eric.eu/adopt-bbmri-eric
Total request Grant by Consortium: €4,950,860.00
Total request Grant by BBMRI-ERIC: €3,786,840.00 (Common Service IT, Common Service ELSI)
Assigned 3rd parties/BBMRI-ERIC Framework Agreement:
(1) BBMRI.at/MUG; (2) BBMRI.fi/THL; (3) BBMRI.mt/UoM; (4) BBMRI.it/UNIMIB
Benefit/tasks for BBMRI-ERIC: Coordinated by BBMRI-ERIC, funding for key activities.
Status: score 12 (threshold 10)/accepted

Coordinator: (until August 2017), Erik Steinfelder (since August 2017)

Abstract: *Lead by BBMRI-ERIC*: The ADOPT BBMRI-ERIC proposal aims at boosting and accelerating implementation of BBMRI-ERIC and its services. Its main deliverables are designed to complete or launch the construction of key Common Services as required for ESFRI-projects 'under implementation', reflecting the targets of the European Research Area (ERA). Revealing complex diseases (e.g., cancer) diseases will depend critically on the study of human biological samples and data from large numbers of patients and healthy individuals. The EU's ageing population is will result in an increase in many of those diseases and consequently an increased healthcare expenditure for senior citizens. BBMRI-ERIC is a specific European asset having become a fundamental component in addressing the ongoing and future requirements particularly of Europe's health service frameworks, including competitiveness and innovativeness of health-related industries. Its implementation is essential for the understanding of the diversity of human diseases, biological samples and corresponding data, which are required for the development of any new drug or diagnostic assay and are, therefore, critical for the advancement in health research, ultimately leading to personalised medicine. BBMRI-ERIC will provide a gateway access to the collections of the European research community, expertise and services building on the outcome of ADOPT BBMRI-ERIC.

List of Participants: BBMRI-ERIC incl. 3rd parties (namely MUG on behalf of BBMRI.at, THL on behalf of BBMRI.fi, UoM on behalf of BBMRI.mt, UNIMIB on behalf of BBMRI.it), BELSPO on behalf of BBMRI.be, Belgium; SNF on behalf of BBMRI.ch, Switzerland; MMCI on behalf of BBMRI.cz, Czech Republic; Charité on behalf of BBMRI.de, Germany; UT on behalf of BBMRI.ee, Estonia; INSERM on behalf of BBMRI.fr, France; AA on behalf of BBMRI.gr, Greece; LUMC and UMCG on behalf of BBMRI.nl, The Netherlands; NTNU on behalf of BBMRI.no, Norway; Kierujący Biobankiem Wrocławskiego Centrum; Badań EIT on behalf of BBMRI.pl, Poland; KI on behalf of BBMRI.se, Sweden; Dokuz Eylul University on behalf of BBMRI.tr, Turkey; IARC, France; TUM, Germany; IOR, Italy, University College London, United Kingdom

10.3. B3Africa (H2020)

Bridging Biobanking and Biomedical Research across Europe and Africa
Topic: INFRASUPP-6-2014 **Type of Action:** CSA **Duration:** 36 months
Start date: 1st July 2015 **Grant agreement:** 654404
Web: http://www.b3africa.org/
Total request Grant by Consortium: €201,250.00
Total request Grant by BBMRI-ERIC: €70,000.00
Assigned 3rd parties/BBMRI-ERIC Framework Agreement:
none
Benefit/tasks for BBMRI-ERIC: contacts to Africa, ELSI activities will be informative for the work of the Common Service ELSI
Status: score 13 (threshold 10)/accepted

Coordinator: Erik Bongcam-Rudloff

Abstract: *Lead by Sverige Lantbruksuniversitet:* B3Africa - Bridging Biobanking and Biomedical Research across Europe and Africa will dramatically improve and facilitate the development of better predictive, preventive and personalised healthcare worldwide. The rapidly evolving African biobanks are an invaluable resource: The African population has the greatest genomic diversity on the planet and represents an incredible resource of information to advance biomedical research. B3Africa aims to implement a cooperation platform and technical informatics framework for biobank integration between Africa and Europe. The collaboration harmonises the ethical and legal framework, biobank data representation and bioinformatics pipelines for sharing data and knowledge among biobanks and allowing access for researchers from both continents. Main actors from the relevant initiatives including Human Heredity and Health in Africa project (H3Africa), European Biobanking and Biomolecular Resources research infrastructure (BBMRI-ERIC) and LMIC Biobank and Cohort Network (BCNet) collaborate in B3Africa to address the following objectives: a. Defining an ethical and regulatory framework for biobank data sharing between Europe and Africa. b. Defining data models for representing biobank and research data based on existing best practices, standards and ontologies. c. Designing an informatics platform using existing open-source software (with eBioKit and BiBBox as essential modules) integrating workflows for biobank applications. d. Implementation of an education and training system for information and capacity building. e. Validating the B3Africa concept with existing biobanks from both continents. B3Africa will provide the critical mass to maximise efficiency in biomedical research, supports defragmentation through integration and allows efficient leverage of existing biobanks and e-infrastructures in Europe and Africa. The technical informatics framework will be designed for easy upscaling and integration with other research infrastructures.

List of Participants: Swedish University of Agricultural Sciences; BBMRI-ERIC; Karolinska Institutet; Centre for Research Ethics and Bioethics; University of the Western Cape; Makerere University; University of Stellenbosch; IARC; International Livestock Research Institute; Medical University of Graz; Institute of Human Virology, Nigeria

10.4. BBMRI-LPC (FP7)

Biobanking and Biomolecular Resources Research Infrastructure – Large Prospective Cohorts
Topic: INFRA-2012-1.1.9 **Type of Action:** CP&CSA **Duration:** 48 months + extension
Start date: 1st February 2013 **Grant agreement:** 313010
BBMRI-ERIC as a full partner: 1st April 2014
Web: http://www.bbmri-lpc.org/
Total request Grant by Consortium: €8,000,000
Total request Grant by BBMRI-ERIC: €14,552 (Common Service IT, Common Service ELSI)
Assigned 3rd parties/BBMRI-ERIC Framework Agreement:
none
Benefit/tasks for BBMRI-ERIC: BBMRI LPC Forum
Status: score 13.5 (threshold 10)/accepted. A no-cost-extention has been allowed for BBMRI-LPC until October 2017, when the project closed successfully.

Coordinator: Markus Perola
Co-coordinator: Gert-Jan van Ommen

Abstract: *Lead by THL:* Large prospective cohort (LPC) studies following up initially healthy participants for years or decades are considered more reliable and different diseases can be studied. LPC studies require large numbers of subjects, which are costly but particularly benefited from the advent of high throughput techniques providing opportunities for powerful study designs. This proposal unites the large study sets of the European Biobanking and Biomolecular Research Infrastructure (BBMRI) and the International Agency for Research on Cancer (IARC), thus achieving a worldwide unique scale of integration. Specifically, we aim to: 1) Evaluate/improve the harmonisation of individual data on health, lifestyle and other exposures; 2) Develop/implement harmonised definitions of diseases; 3) Improve biobanking and research technologies and develop innovative solutions facilitating high-quality, fair transnational access to samples and data; 4) Provide free transnational access by users, through study proposals selected by an open, pan-European call; 5) In the framework of these studies, generate and provide access to whole genome sequences, transcriptome, proteome, metabolome and methylome data; 6) Build new public-private partnerships involving large-scale prospective cohorts, and strengthening existing ones, allowing transparent industrial access to academic expertise; 7) Build a network transferring the expertise of established European large-scale biobanks to new biobank initiatives under development in other countries (BBMRI-LPC Forum).

List of Participants: UH-FIMM; LUMC; IARC-WHO; ICL; MUG; KI; WTSI; UMCG; HMGU; NTNU; UTARTU; UU; CNAG-CRG; UP; RI MUHC; LEGAL PATHWAYS; EHF (DECODE); THL; IPRI; LLBMC; CCGH; EIT+; TUM-MED; INSERM; MEDLAW; MU; NIPH; SSI; UBRIS; BBMRI-ERIC; UNIMIB.

10.5. CETOCOEN Excellence (H2020)

CETOCOEN Excellence
Topic: H2020-WIDESPREAD-2016-2017 **Type of Action:** CSA **Duration:** 12 months
Start date: 1st September 2017 **Grant agreement:** 763677
Web: https://cordis.europa.eu/project/rcn/211429_en.htm
Total request Grant by Consortium: €384,867.00
Total request Grant by BBMRI-ERIC: €43,005.00
Assigned 3rd parties/BBMRI-ERIC Framework Agreement:
none
Benefit/tasks for BBMRI-ERIC: Developing methods for integrating biobanks with exposome data
Status: score 14.5 (threshold 10)/accepted

Coordinator: Jana Klánová

Abstract: The aim of this project is to exploit research capacities built in Central Europe with support from the European Structural and Investment Funds and develop a cutting-edge research platform capable of addressing major scientific and societal challenges of contemporary Europe in the area of Environment and Health. It will enhance a scientific value of existing regional population studies and turn them into the accessible source of valuable information by developing sustainable biobanking platform and harmonizing their protocols, questionnaires, and standard operating procedures to allow for their joint assessment and interpretation of results. Existing research programmes will be expanded to address questions related to a wider range of factors (generically called exposome) impacting human health and wellbeing. To identify new biomarkers of exposures, effects, and susceptibility to pathologies, innovative approaches to the assessment of multiple exposures have to be developed including omics technologies, novel methods for integrative analysis, software tools and computational models, chemical sensors and triggers allowing for tracing such processes in biological systems. This innovative research is well aligned with the European and national strategic priorities and documents (including the National Innovation Strategy), and will generate substantial new knowledge needed for prioritization of future research and policy actions in the area of chemical management as well as practical tools applicable in health protection, prevention, diagnostics, and intervention with the aim of minimising the burden of disease, improve the health and well-being of citizens and lower health costs.

List of Participants: MASARYKOVA UNIVERZITA, FAKULTNI NEMOCNICE U SV. ANNY V BRNE, UNIVERSITY COLLEGE LONDON, EIDGENOESSISCHE TECHNISCHE HOCHSCHULE ZUERICH

10.6. cliniMARK (COST)

Good biomarker practice to increase the number of clinically validated biomarkers
Topic: H2020 OC-2016-1-20724 **Type of Action:** COST **Duration:** 48 months
Start date: 14th March 2017 **Grant agreement:** CA16113
Web: http://www.cost.eu/COST_Actions/ca/CA16113
Total request Grant by Consortium: –
Total request Grant by BBMRI-ERIC: –
Assigned 3rd parties/BBMRI-ERIC Framework Agreement:
none
Benefit/tasks for BBMRI-ERIC: Experts contributing to the establishment of best biomarker practices, networking
Status: approval date 24th October 2016

Chair: Theo M. Luider
Vice Chair: Antonia Vlahou

Abstract: *Lead by ERASMUS MC (main proposer of network):* Thousands of circulating proteins have been shown to be hallmarks of emerging disease, response to treatment, or a patients' prognosis. The identification of these small molecule biomarkers holds a great promise for significant improvement of personalized medicine based on simple blood tests. For instance, diagnosis and prognosis with biomarkers (e.g. carcinoembryonic antigen (CEA)) has significantly improved patient survival and decreased healthcare costs in colorectal cancer patients. Unfortunately, despite significant investments to increase the number of biomarker studies, only 150 out of thousands of identified biomarkers have currently been implemented in clinical practice. This is mainly caused by the time-consuming process of reliably detecting biomarkers, the irreproducibility of studies that determine a biomarkers' clinical value, and by a mismatch in studies that are performed by academia and what is required for regulatory and market approval. To increase the number of clinically validated biomarkers, rather than further increasing the number of biomarker discovery studies, CliniMARK will improve the quality and reproducibility of studies and establish a coherent biomarker development pipeline from discovery to market introduction.

CliniMARK aims to achieve said goal by creating a Best Biomarker Practice (BBP) community, which will provide guidance to:

- Classify biomarkers according to their characteristics, anticipated clinical use, and their phase of development,
- Select and validate appropriate research-grade biomarker detection tests,
- Select appropriately designed studies and biological samples to reliably and reproducibly validate biomarkers clinically, and
- Select and report on appropriate clinical data storage, biomarker data storage, data analysis protocols, privacy concerns, ethical issues, and statistical analysis methods.

List of Participants: Austria, Bosnia and Herzegovina, Croatia, Cyprus, Czech Republic, Denmark, Estonia, France, Germany, Greece, Iceland, Ireland, Israel, Lithuania, Malta, The Netherlands, Norway, Poland, Portugal, Romania, Serbia, Slovakia, Spain, Switzerland, United Kingdom

10.7. CORBEL (H2020)

Coordinated Research Infrastructures Building Enduring Life-science services
Topic: H2020 INFRADEV-4 **Type of Action:** RIA **Duration:** 48 months
Start date: 1st September 2015 **Grant agreement:** 654248
Web: http://www.corbel-project.eu/
Total request Grant by Consortium: €14,000,000.00
Total request Grant by BBMRI-ERIC: €1,900,093.00 (including 3rd parties)
Assigned 3rd parties/BBMRI-ERIC Framework Agreement:
(1) bbmri.nl /LUMC €454,340.08, (2) bbmri.fi/THL €80,500.00, (3) bbmri.no/NIPH,NTNU €80,500.00, (4) bbmri.ee/UTARTU €80,500.00, (5) bbmri.at/MUG €177,850.00
Benefit/tasks for BBMRI-ERIC: Co-Coordinated by BBMRI-ERIC; WP3: case studies (National Nodes); WP5: Access; WP7: Common Service ELSI; WP9: Training
Status: score 11 (threshold 10)

Coordinator: Niklas Blomberg
Co-coordinator: Jan-Eric Litton (until August 2017), Erik Steinfelder (since August 2017)

Abstract: *Lead by European Molecular Biology Laboratory, co-lead by BBMRI-ERIC:* CORBEL will establish a collaborative framework of shared services between the ESFRI Biological and Medical Research Infrastructures that transform the European research community from discovery of basic biological mechanisms to applied medical translation – through the provision of a unified interface, aligned services and coordinated user access to a range of advanced technology platforms.

List of Participants: EMBL, Universitair Medisch Centrum Utrecht, Fundacio Institut de Ciencies Fotoniques, Fundacio Centre de Regulacio Genomica, University of Dundee, BBMRI-ERIC, Foundation of Biomedical Research of the Academy of Athens, Erasmus University Medical Centre Rotterdam, EATRIS-ERIC, ECRIN-ERIC, University of Liverpool, Istituto di Ricerche Farmacologiche Mario Negri (IRCCS-IRFMN), Heinrich-Heine-Universitaet Duesseldorf, Infrafrontier GmbH, Helmholtz Zentrum Muenchen Deutsches Forschungszentrum fuer Gesundheit und Umwelt GmbH, INSTRUCT, Consorzio Interuniversitario Risonanze Magnetiche di Metallo Proteine, Agencia Estatal Consejo Superior de Investigaciones Cientificas, CNRS, Stazione Zoologica Anton Dohrn, The University Court of the University of St Andrews, Forschungsverbund Berlin e.V., Imperial College of Science, Technology and Medicine, Max Delbrueck Centrum fuer Molekulare Medizin, The University of Manchester, Stichting VU-VUMC, Deutsches Krebsforschungszentrum, Leibniz-Institut DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH, Jacobs University Bremen GGmbH, Koninklijke Nederlandse Akademie van Wetenschappen, Tieteen Tietotekniikan Keskus Oy, CAB International, Medical University of Vienna, Academisch Ziekenhuis Groningen, Universita Degli Studi di Torino, Erasmus MC, Univ Groningen

10.8. EGI-Engage (H2020)

Engaging the EGI Community towards an Open Science Commons
Topic: H2020 EGI-EINFRA-1-6 **Type of Action:** RIA **Duration:** 30 months
Start date: 1st May 2015 **Grant agreement:** 654142
Web: https://www.egi.eu/about/egi-engage/
Total request Grant by Consortium: €8,000,000.00
Total request Grant by BBMRI-ERIC: €128,550.00
Assigned 3rd parties/BBMRI-ERIC Framework Agreement:
BBMRI.cz, BBMRI.se, BBMRI.nl
Benefit/tasks for BBMRI-ERIC: BBMRI Competence Centre in WP6 (SA2) Knowledge Commons; cross-border procurement in WP2
Status: score 15 (threshold 10)/accepted

Coordinator: Yannick Legré

Abstract: *Lead by Stichting European Grid Initiative:* High-throughput technologies are more accessible to research-biobanking and the number of biobanks providing services that require large storage capability and parallel data analysis is increasing dramatically. Moreover, data from multiple biobanks must now be pooled to reach statistical power to elucidate meaningful associations, while complying with legal and regulatory issues. This BBMRI-ERIC EGI Competence Centre thus focuses on helping BBMRI-ERIC to bridge this gap with the implementation of big data storage in combination with data analysis and data federation using EGI federated cloud infrastructure.

List of Participants: Stichting European Grid Initiative, ÖAW, Vlaams Instituut voor de Zee VZW, Institute of Information and Communication Technologies, – Bulgarian Academy of Sciences, Swiss National Grid Association, CESNET, Zajmove Sdruzeni Pravnickych OSOB, GWDG, Agnecia Estatal Consejo Superior de Investigaciones Cientificas, CSC-Tieteen Tietotekniikan Keskus Oy, Centre Nationale de la Recherche Scientifique, Institut National de la Recherche Agronomique, The Greek Research and Technology Network S.A., Sveuciliste u Zagrebu Sveučilišni Računski Centar, Magyar Tudomanyos Akademia Szamitastechnikai es Automatizalasi Kutatointezet, Istituto Nazionale di Fisica Nucleare, CIRMMP, Provincia Lombardo Veneta Ordine Ospedaliero di San Giovanni di Dio – Fatebenefratelli, CNR, Engineering – Ingegneria Informatica SpA, SURFsara B.V, Akademia Górniczo-Hutnicza im. Stanisława Staszica – Academic Computer Centre CYFRONET AGH, Laboratorio de Instrumentacao e Fisica Experimental de Particulas, ICETA, Institut za Fiziku, Beograd, Uppsala Universitet – Swedish National Infrastructure for Computing, Ustav Informatiky, Slovenska Akademia Vied, Turkiye Bilimsel ve Teknolojik Arastirma Kurumu, Science and Technology Facilities Council, BBMRI-ERIC, EMBL, CERN, EISCAT Scientific Association, Food and Agriculture Organisation of the UN, Agro-Know I.K.E, Maat France SARL, The Trustees of Indiana University, Academia Sinica, Advance Science and Technology Institute, ITB-BHMN, Korea Institute of Science and Technology Information, Universiti Putra Malaysia, National Science & Technology Development Agency

10.9. EOSCpilot (H2020)

The European Open Science Cloud for Research Pilot Project
Topic: INFRADEV-04-2016 **Type of Action:** RIA **Duration:** 24
Start date: 1st February 2017 **Grant agreement:** 739563
Web: https://eoscpilot.eu/
Total request Grant by Consortium: €9,953,067.50
Total request Grant by BBMRI-ERIC: €78,405.00
Assigned 3rd parties/BBMRI-ERIC Framework Agreement:
none
Benefit/tasks for BBMRI-ERIC: Development and piloting of policies of medical data sharing as a part of European Open Science Cloud.
Status: score 11.5 (threshold 9)

Coordinator: Juan Bicarregui

Abstract: *Lead by Science and Technology Facilities Council*: The EOSCpilot project will support the first phase in the development of the European Open Science Cloud (EOSC) as described in the EC Communication on European Cloud Initiatives [2016].

- It will establish the governance framework for the EOSC and contribute to the development of European open science policy and best practice;
- It will develop a number of pilots that integrate services and infrastructures to demonstrate interoperability in a number of scientific domains; and
- It will engage with a broad range of stakeholders, crossing borders and communities, to build the trust and skills required for adoption of an open approach to scientific research.

These actions will build on and leverage already available resources and capabilities from research infrastructure and einfrastructure organisations to maximise their use across the research community. The EOSCpilot project will address some of the key reasons why European research is not yet fully tapping into the potential of data. In particular, it will:

- reduce fragmentation between data infrastructures by working across scientific and economic domains, countries and governance models, and
- improve interoperability between data infrastructures by demonstrating how data and resources can be shared even when they are large and complex and in varied formats.

In this way, the EOSC pilot project will improve the ability to reuse data resources and provide an important step towards building a dependable open-data research environment where data from publicly funded research is always open and there are clear incentives and rewards for the sharing of data and resources.

List of Participants: CSC; MPG; EMBL, SURFSARA BV; EGI.eu; CNRS; KIT; UEDIN; LIBER; TRUST-IT; ATHENA RC; JISC; PRACE; CNR; INFN; DESY; INGV; BSC; UGOE; KNAW; ICOS ERIC; GEANT Assn; INAF; BBMRI-ERIC; ESS ERIC; NERC; GmBH; ECRIN ERIC, UNIMAN; PIN SCRL; CEA; CINECA

10.10. PhenoMeNal (H2020)

PhenoMeNal: A comprehensive and standardised e-infrastructure for analyzing medical metabolic phenotype data
Topic: H2020-EINFRA-1-2014 **Type of Action:** RIA **Duration:** 36 months
Start date: 1st September 2015 **Grant agreement:** 654241
Web: http://phenomenal-h2020.eu/
Total request Grant by Consortium: €8,810,922.00
Total request Grant by BBMRI-ERIC: €145,076.00
Assigned 3rd parties/BBMRI-ERIC Framework Agreement:
none
Benefit/tasks for BBMRI-ERIC: proposal trying to organise the metabolomics community at the European level, and we are keen to do it in full synergy with BBMRI.
Status: score 13 (threshold 10)/accepted

Coordinator: Christoph Steinbeck

Abstract: *Lead by: European Molecular Biology Laboratory:* During the next 10 years, a significant number of the a significant number of the 742,000,000 European citizens will have their genome determined routinely. This will be complemented with much cheaper measurement of the metabolome of biofluids which will link the genotype with data on the exposome of patients, which for the first time enables the development of a truly personalised and hand tailored medicine based on hard scientific measurement.

List of Participants: EMBL-EBI, Imperial College of Science, Technology and Medicine, Leibniz-Instiitut für Pflanzenbiochemie, Universitat de Barcelona, University of Birmingham, Consorzio Interuniversitatio Risonanze Magnetiche di Metallo Proteine, Universiteit Leiden, The Chancellor, Masters and Scholars of the University of Oxford, Swiss Institute of Bioinformatics, Uppsala Universitet, BBMRI-ERIC, Commissariat a l'entegie atomique et aux energies alternatives, Institut national de la recherche agronomique, SRI International, The Governors of the University of Alberta/University of Alberta

10.11. RD-CONNECT (FP7)

RD-Connect: An integrated platform connecting registries, biobanks and clinical bioinformatics for rare disease research
Topic: FP7-HEALTH-2012-INNOVATION **Type of Action:** SP1 Collaboration **Duration:** 72
Start date: 1st November 2012 **Grant agreement:** 305444
BBMRI-ERIC as a full partner: 1st April 2015
Web: http://rd-connect.eu/
Total request Grant by Consortium: €11,997,111.00
Total request Grant by BBMRI-ERIC: €100,000.00
Assigned 3rd parties/BBMRI-ERIC Framework Agreement:
none
Benefit/tasks for BBMRI-ERIC: Set and implement quality standards for rare disease biobanks, contribution to the biomaterial sharing work, incorporate new biobanks, develop synergies among BBMRI-ERIC and RD-Connect training activities, investigate sustainability options.
Status: score 13.5 (threshold 10)/accepted

Coordinator: Hanns Lochmüller

Abstract: *Lead by University Newcastle upon Tyne*: By developing robust mechanisms and standards for linking and exploiting these data, RD-Connect develops a critical mass for harmonisation and provide a strong impetus for a global 'trial-ready' infrastructure for rare diseases. Among other things, the integrated, user-friendly RD-Connect platform, built on efficient informatics concepts already implemented in international research infrastructures for large-scale data management, provides access to federated databases/registries, biobank catalogues, harmonised -omics profiles, and cutting-edge bioinformatics tools for data analysis. All patient data types will be linked via the generation of a unique identifier ('RD-ID') developed jointly with the US NIH. The RD-Connect platform will be one of the primary enablers of progress in IRDiRC-funded research and will facilitate gene discovery, diagnosis and therapy development.

List of Participants: University of Newcastle upon Thyne, Fundacio Parc Cientific de Barcelona, Université d'Aix Marseille, Instituto Superiore di Sanita, Uppsala Universitet, Academisch Ziekenhuis Leiden, Fundacion Centro Nacional de Investigaciones Oncologicas Carlos III, Fondazione Telethon, Universidade de Aveiro, Karolinska Institutet, University of Patras, EURORDIS, Interactive Biosoftware SARL, FINOVATIS, Institute de Salud Carlos III, INNOLYST Inc. Corporation Patientcrossroads, Medizinische Universität Graz, Université Paris Diderot – Paris 7, Universita ta Malta, Fondation maladies rares, Universität Ulm, Universität Zurich, Uiverzita Karlova V Praze, United States Department of Health and Human Services, Murdoch University, Department of Health Government of Western Australia, European Molecular Biology Laboratory, BBMRI-ERIC, Academisch Ziekenhuis Groningen, Fundacio Centre de Regulacio Genomica

10.12. RItrain (H2020)

Research Infrastructures Training Programme
Topic: H2020 INFRASUPP-3 **Type of Action:** RIA **Duration:** 48 months
Start date: 1st September 2015 **Grant agreement:** 654156
Web: http://ritrain.eu/
Total request Grant by Consortium: €1,999,075.95
Total request Grant by BBMRI-ERIC: €514,423.20
Assigned 3rd parties/BBMRI-ERIC Framework Agreement:
none
Benefit/tasks for BBMRI-ERIC: Coordinated by BBMRI-ERIC. Definition of required competences in distributed RIs throughout the lifecycle of an RI, from the initiation preparatory phase through to operational maturity.
Status: score 11.5 (threshold 10)/accepted

Coordinator: Markus Pasterk

Abstract: *Lead by BBMRI-ERIC*: The overarching goal of RItrain is to identify the competency requirements for the leadership of European research infrastructures and design a training programme to fulfil these requirements. Our highest priority is reaching those professionals who are already working in research infrastructures, including directors, coordinators, senior project managers, legal representatives, heads of finance, human resources and communication. However, by designing a flexible, modular programme, we will also be able to provide a new qualification aimed at future leaders of research infrastructure – the Master in Research Infrastructure leadership. Another important consideration is that many research infrastructures, have a distributed operations structure, building on existing structures or networks. These therefore require a different set of unique competences to deal with issues such as multinational operations, transnational access and data flow; different social security systems, different administrative cultures, different legal systems etc. For a truly European Research Area it requires: (i) increased effectiveness of national research systems, (ii) improved transnational cooperation and competition including establishing and effectively operating key research infrastructures, (iii) a more open labour market for researchers, (iv) gender equality and main-streaming in organisations carrying out and selecting research projects and (v) optimal circulation and transfer of scientific information, including via digital means and broader and more rapid access to scientific publications and data.

List of Participants: Biobanking and BioMolecular resources Research Infrastructure –European Research Infrastructure Consortium (BBMRI-ERIC), European Molecular Biology Laboratory – European Bioinformatics Institute (EMBL-EBI), Medical University of Vienna (MUW), Infrafrontier GmbH, EATRIS-ERIC, ECRIN-ERIC, University of Minho (UMinho) on behalf of MIRRI, Institute of Molecular Genetics of the ASCR, v. v. i. on behalf of Euro-BioImaging (IMG), Imperial College London on behalf of ISBE (IMPERIAL), University of Milano-Bicocca (UNIMIB), Centre National de la Recherche Scientifique (CNRS) on behalf of DARIAH, SHARE-ERIC

10.13. SPIDIA4P (H2020)

SPIDIA for Personalized Medicine – Standardisation of generic Pre-analytical procedures for Invitro DIAgnostics for Personalized Medicine
Topic: SC1-HCO-02-2016 **Type of Action:** CSA **Duration:** 48 months
Start date: 1st January 2017 **Grant agreement:** 733112
Web: http://www.spidia.eu/
Total request Grant by Consortium: €1,999,972.50
Total request Grant by BBMRI-ERIC: €100,673.75 (Headquarters Quality Service)
Assigned 3rd parties/BBMRI-ERIC Framework Agreement:
none
Benefit/tasks for BBMRI-ERIC: standards to biobanks and reference centres, education and training programmes, industry-academia stakeholder workshop
Status: score 14.5 (threshold 10)/accepted

Coordinator: Uwe Oelmüller

Abstract: *Lead by Quiagen:* Molecular in vitro diagnostics and biomedical research have allowed great progress in personalised medicine but further progress is limited by insufficient guidelines for pre-analytical workflow steps (sample collection, preservation, etc.) as well as by insufficient quality assurance of diagnostic practice. This allows using compromised patients' samples with post collection changes in cellular and extra-cellular biomolecules' profiles thus often making diagnostic test results unreliable or even impossible. Thus, SPIDA4P aims to generate and implement a comprehensive portfolio of 22 pan-European pre-analytical CEN/TS and ISO/IS, addressing the important pre-analytical workflows applied to personalized medicine. These will be applicable to biomarker discovery, development and validation as well as to biobanks. Corresponding External Quality Assurance Schemes will be developed and implemented (survey the resulting quality of samples and diagnostic practice). Additionally, SPIDIA4P will ensure stakeholder involvement as well as training, education, and counselling. We will closely coordinate with large European public research consortia to obtain access to research and validation studies data serving as evidence for the new standards developments and achieved improvements of diagnosis, patient stratification and prognosis of disease outcome.

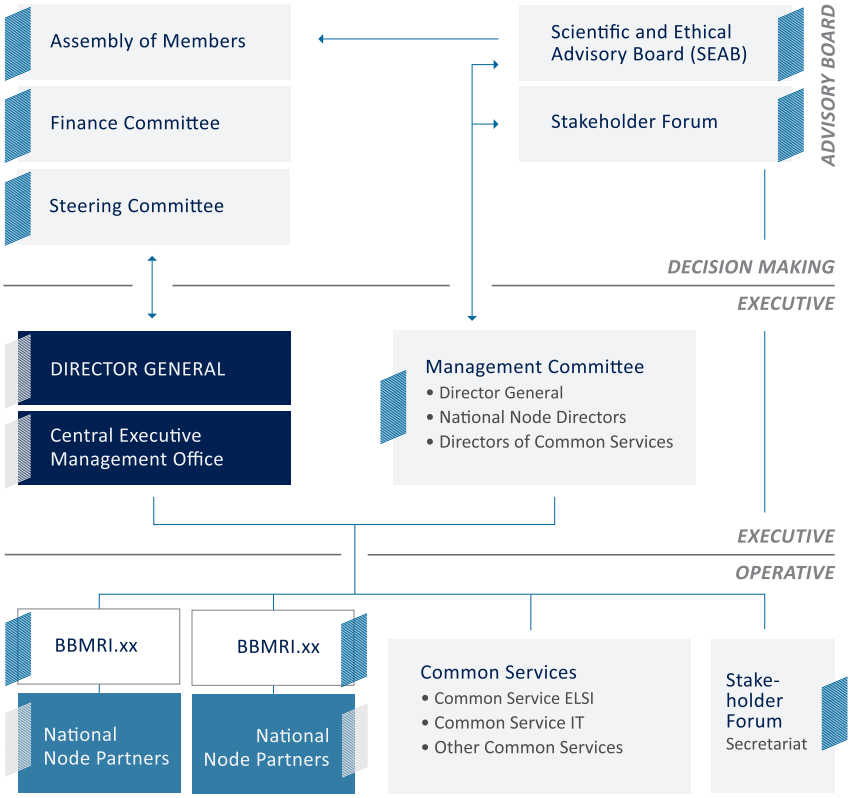
List of Participants: Qiagen Gmbh (QIA), Lgc Limited (LGC), Technische Universität München (TUM), DIN Deutsches Institut Fuer Normung E.V. (On Behalf Of CEN) (DIN), Preanalytix Gmbh (PAX), Inivata Ltd (INIVATA), Cambridge Protein Arrays Ltd (CPA), Tataa Biocenter Ab (TATAA), Universita Degli Studi di Firenze (UNIFI), Consorzio Interuniversitario Risonanze Magnetiche di Metallo Proteine (CIRMMP), Universita Degli Studi di Trieste (UNITIS), Universita Degli Studi di Torino (UNITO), Biobanks And Biomolecular Resources Research Infrastructure Consortium (BBMRI-ERIC), Luxembourg Institute Of Health (IBBL), Medizinische Universitaet Graz (MUG), Institut National De La Sante Et De La Recherche Medicale (INSERM), Erasmus Universitair Medisch Centrum Rotterdam (EMC), Fundacio Centre De Regulacio Genomica (CNAG-CRG), Fondazione Irccs Istituto Nazionale Dei Tumori (INT).

Part V.

About BBMRI-ERIC

Governance, Framework and Values

Governance Structure



Framework On 3 December 2013, BBMRI was officially awarded the Community legal framework for a European Research Infrastructure Consortium (ERIC). This specific legal form is designed to facilitate the joint establishment and operation of research infrastructures of European interest.

Values The activities of BBMRI-ERIC shall be politically neutral and guided by the following values: pan-European in scope, combined with scientific excellence, transparency, openness, responsiveness, ethical awareness, legal compliance and human values.

Contents

Photo: eliasfreiberger.at

PUBLISHING INFORMATION

PUBLISHER: BBMRI-ERIC

LEGAL ADDRESS:
BBMRI-ERIC
Neue Stiftingtalstrasse 2/B/6
8010 Graz
AUSTRIA
Phone: +43 316 34 99 17-0
Email: contact@bbmri-eric.eu
Website: http://www.bbmri-eric.eu/

FOLLOW US ON TWITTER: @BBMRIERIC

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