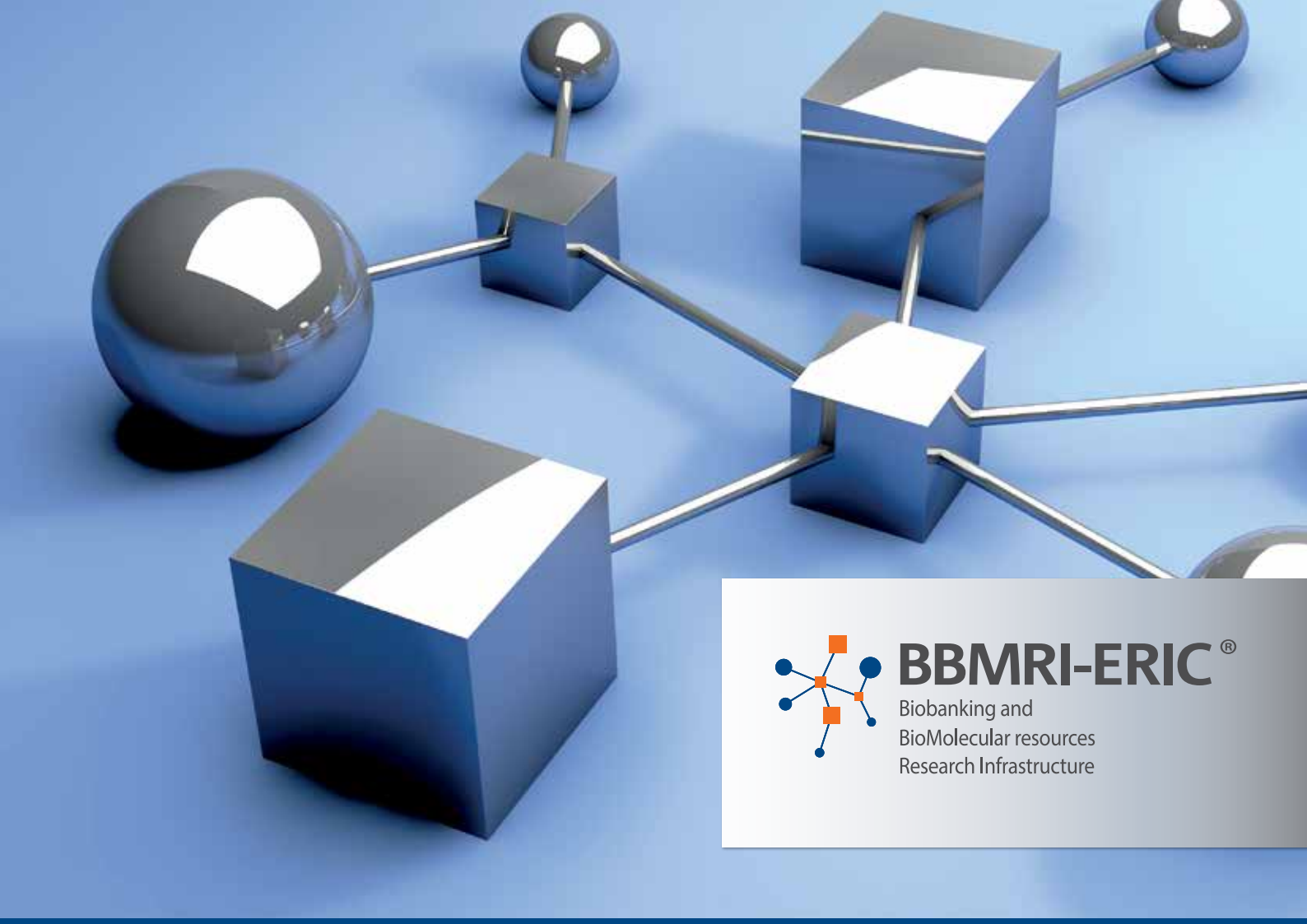


BBMRI-ERIC®
Biobanking and
BioMolecular resources
Research Infrastructure

ANNUAL AND FINANCIAL REPORT 2015 ON ACTIVITIES AND ACHIEVEMENTS OF BBMRI-ERIC

‚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)

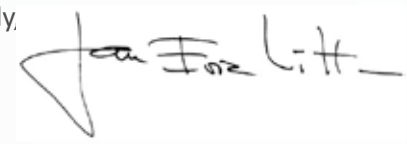
EXECUTIVE SUMMARY

I am very pleased to introduce this ‚Annual and Financial Report 2015', which describes the achievements of the distributed research infrastructure BBMRI-ERIC along the Work Streams as outlined in the ‚Work Programme 2015'. In particular, I am excited that we have managed to reduce the start-up phase of BBMRI-ERIC (which was calculated in the Business Plan for a period of 36 months) to 18 months only. This means that the ‚Work Programme 2015' paved the way for the implementation of our services in our Member States.

Of mutual benefit was certainly the decision of the **United Kingdom** (new member) and **Norway** (previously Observer) respectively to apply for full membership to BBMRI-ERIC, an application that was enthusiastically welcomed and approved by BBMRI-ERIC's Assembly of Members. With the addition of these 2 countries, BBMRI-ERIC included 17 countries and one international organisation (IARC) by the end of 2015. **Quality** above quantity is a key phrase for BBMRI-ERIC (see page 19). In this respect, BBMRI-ERIC actively contributes to the process of international standard developments as **Observer Liaison of ISO/TC 276** Biotechnology **as well as of ISO/TC 212** Clinical laboratory testing and in vitro diagnostic test systems. As Observer Liaison, BBMRI-ERIC has been asked to contribute to the drafting process by addressing comments and references as well to as share the developments of the ISO Working Groups with the BBMRI community. This allows BBMRI-ERIC to fulfill its mandate as an international organisation in the interest of the European biobanks. To date, 75 technical experts and researchers at universities, biobanks and laboratory infrastructures are contributing to this unprecedented pan-European joint harmonisation effort. This work will have a direct impact on research and healthcare to reproduce data, save a significant amount of money for our members and help sustain biobanks. According to the BBMRI-ERIC Statutes (Art. 3(4)) 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. As the first Common Service of BBMRI-ERIC, the **Common**

Service ELSI started according to these values in February 2015, and **today comprises 21 experts in the field of law, ethics and social science from across Europe** (see page 12). Just to take one example, the ELSI group has been instrumental in writing a Position Paper on the General **Data Protection Regulation** and helped to translate complex issues into a lay language for the general public and policy makers alike.
In July 2015, the first upgrade of the **BBMRI-ERIC Catalogue - the Directory 1.0** was launched. It allowed users to explore the infrastructure of BBMRI-ERIC, to put biobanks on the map, to communicate with biobanks, to identify the biobanks' samples and data of interest, and to facilitate the negotiation for access with the respective sample/data custodians. **During late 2015, the Directory 2.0 was released encompassing 60 million biobank samples from our member states' biobanks. Ultimately,** the setup of the BBMRI-ERIC **Common Service IT** has been a critical activity and was approved by the Assembly of Members in October. In the coming years, it will act as a sustainable development and operations platform for the IT services of BBMRI-ERIC (see page 21). A major part of development during these years will be funded through the HORIZON 2020 project ADOPT BBMRI-ERIC, which aims at boosting and accelerating implementation of BBMRI-ERIC and its services throughout the member states. **ADOPT BBMRI-ERIC** is of particular strategic importance as it involves all National Nodes (see page 90). However, all **project participation of BBMRI-ERIC proved rather successful:** all coordinated projects of BBMRI-ERIC were accepted and strategic partnerships could be formed. In total, BBMRI-ERIC has allocated **€6.6 million through participation in research project proposals, of which €3.68 million fall under direct income in 2015 for activities of the Headquarters, Common Services and linked third parties.** In less than two years, we were able to double the amount of the member states' contributions to the core budget of BBMRI-ERIC through successful participation in numerous grant applications **(a detailed description, see page 89).** Besides the obvious financial benefits, it enabled BBMRI-ERIC to boost and accelerate the implementation of BBMRI-ERIC (especially the Common Services) as well as to include the National Nodes (which are either linked third parties or project participants/beneficiaries represented by their National Node host institutions) in building on their respective strengths. A major reform achievement was to better convey the various **expertise, contributions and achievements** (both nationally and for the biobanking community) **of the National Nodes** in embracing the variety of their governance structures and funding streams which showcases the distributed nature of BBMRI-ERIC, and highlighting these in this year's report (see page 43).
Consequently, I would like to thank the National and Organisational Node Directors for their countries' contribution to the pan-European effort as well as the staff at Headquarters and Common Service experts for their excellent work. Once more, this Annual and Financial Report 2015 illustrates the vast productivity of the BBMRI family in 2015.

Sincerely,



Prof. Jan-Eric Litton
Director General BBMRI-ERIC

July 2016

KEY ACHIEVEMENTS IN 2015

1 **WORK PLAN**
e-INFRASTRUCTURE
Work Stream 1.1:
A New Gateway to European Biobanks

2 **WORK PLAN**
QUALITY
Work Stream 2.1: Quality Management System
Work Stream 2.2: Self-Evaluation
Work Stream 2.3: Implementation of the Bioresource Research Impact Factor (BRIF)
Work Stream 2.4: Development of a BBMRI-ERIC Approval Process

3 **WORK PLAN**
CLINICAL BIOBANKS
Work Stream 3.1: Clin Bio

4 **WORK PLAN**
POPULATION-BASED COHORTS
Work Stream 4.1: BBMRI-LPC

• **NEW MEMBERS & GOVERNANCE MEETINGS & PROJECT STARTS**

JANUARY

- 6 CS ELSI launched
- 2 BRIF/CoBRA guidelines
- 7 EXCEMET interested in becoming a BBMRI-ERIC Expert Centre/Trusted Partner
- • Accepted by EC as project participant of BioMedBridges (in effect as of October 2014)
- • Invitation to Qatar (interested in joining BBMRI)
- • MC #8, 11-12 February 2015, Munich
- • MC #9 26-27 February 2015, Milan

FEBRUARY

- • Invitation to Portugal (interested in joining BBMRI)

MARCH

- 1 CS IT tender published
- 6 BBMRI-ERIC Observer Liaison with ISO Technical Committees 276 and 212
- • United Kingdom welcomed as new Member by the AoM
- • Project Participant of RD-Connect (in effect)
- • FC #4, 23 April 2015 (teleconference)
- • AoM #4, 27 April 2015, Vienna ('Annual and Financial Report 2014' approved)
- 6 BMS RIs meet with rare disease community under BBMRI-ERIC leadership
- 6 BBMRI-ERIC and EVAg publicised MoU

APRIL

- 5 Identification of key priorities for the 'Work Programme 2016' with National Nodes/Common Service Directors
- 2 Self-assessment questionnaire provided by BBMRI.it
- • CY-Biobank project start
- • Visit to Moldova (interested in joining BBMRI)
- 6 General Data Protection Regulation Day of Action in the European Parliament
- 6 Comments to the draft WMA Declaration on ethical considerations regarding health databases and biobanks
- • EGI-Engage project start

MAY

JUNE

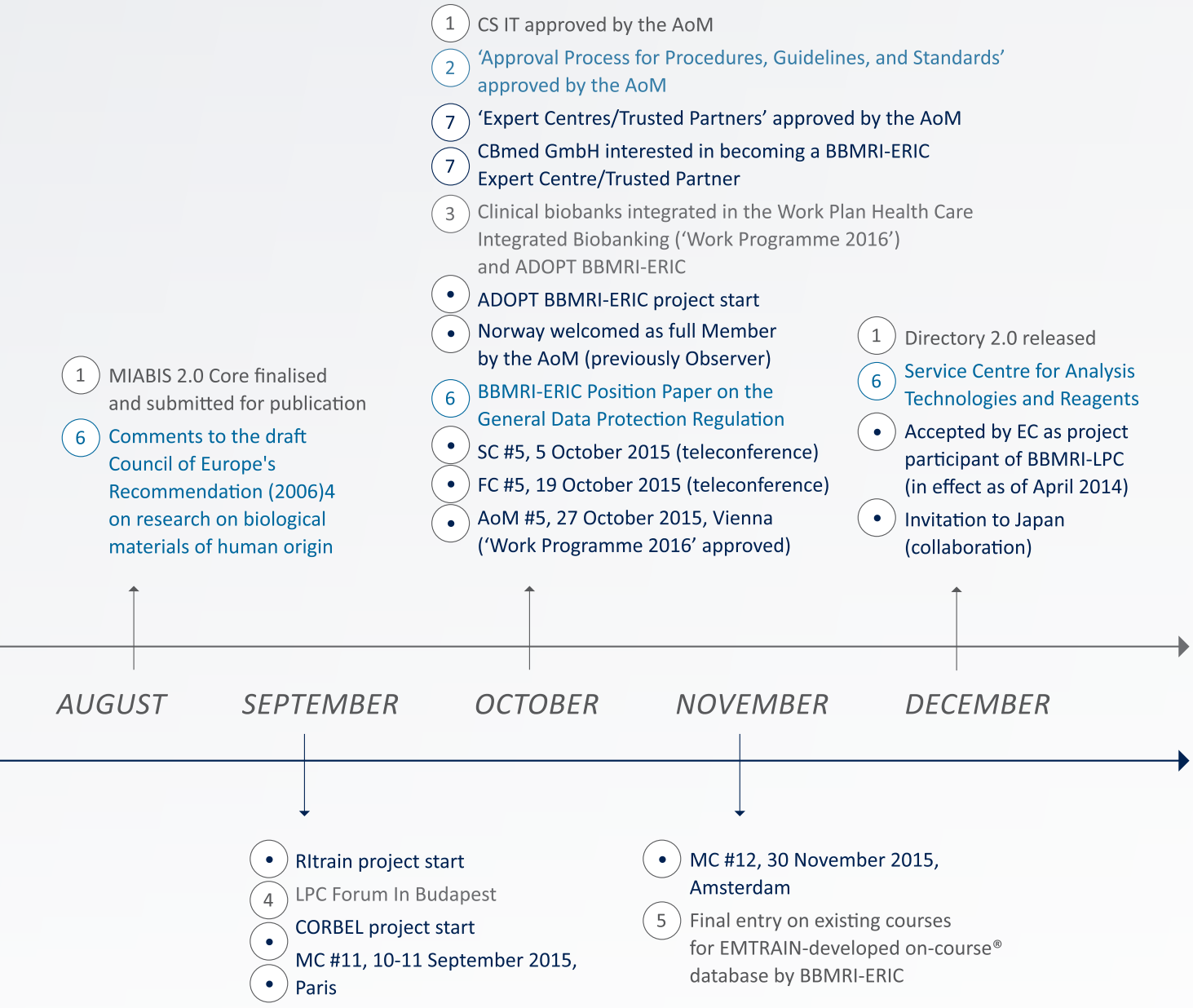
- 1 Directory 1.0 released
- 2 Quality Managers identified within National Nodes
- • B3Africa project start
- 5 HandsOn: Biobanks Conference in Milan during EXPO
- • MC #10 , 29 July 2015, Milan

JULY

5 **WORK PLAN**
BIOBANK OUTREACH
Work Stream 5.1: Scientific Retreat
Work Stream 5.2: HandsOn: Biobanks Conference
Work Stream 5.3: Education & Training Strategy

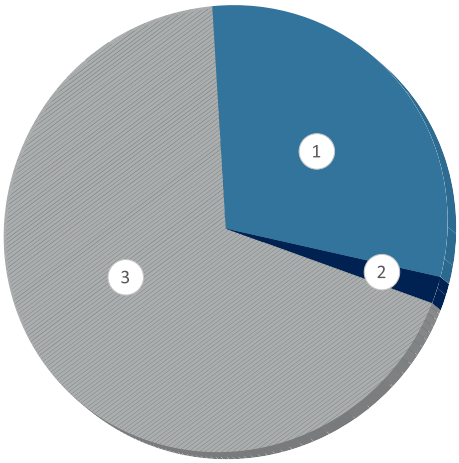
6 **WORK PLAN**
COMMON SERVICES
Work Stream 6.1: Working Group on Rare Diseases
Work Stream 6.2: Common Services for Biological Resources
Work Stream 6.3: Biobanking Infectious Materials
Work Stream 6.4: Common Service ELSI

7 **WORK PLAN**
EXPERT CENTRES
Work Stream 7.1: Planning for a Structure



FINANCE FACTS & FIGURES

Expenditures & Net Earnings Core Budget 2015 (absolute values)	€1,506,174
BBMRI-ERIC Sources of Income 2015	€5,422,886
ADOPT BBMRI-ERIC Budget Distribution	€4,949,449

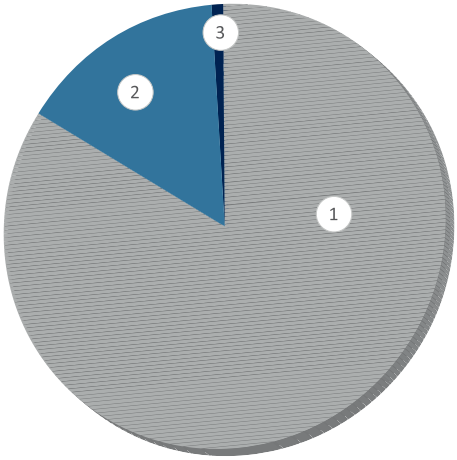


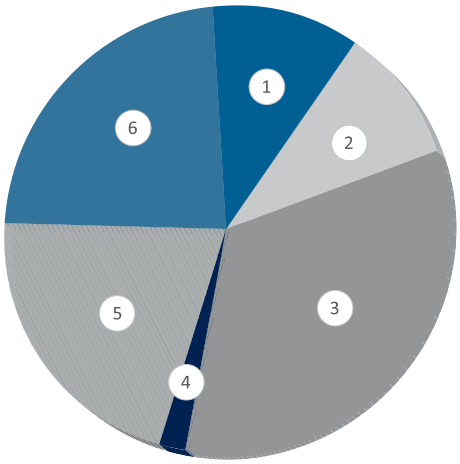
BBMRI-ERIC Sources of Income 2015

1. **Country mandatory contributions:** €1,614,998
2. **Host country contributions:** €127,590
3. **EU project contributions:** €3,680,298

EXPENDITURES & NET EARNINGS CORE BUDGET 2015

1. **Headquarters:** €1,259,903
2. **CS ELSI:** €235,820
3. **CS IT:** €10,452
4. **Stakeholder Forum Secretariat:** €0





ADOPT BBMRI-ERIC Budget Distribution

1. **Headquarters:** €551,098
2. **CS ELSI:** €524,948
3. **CS IT:** €1,499,850
4. **Stakeholder Forum Secretariat:** €125,000
5. **Linked 3rd parties:** €1,089,284
6. **Other beneficiaries:** €1,159,270

ABOUT BBMRI-ERIC

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.

Governance of BBMRI-ERIC

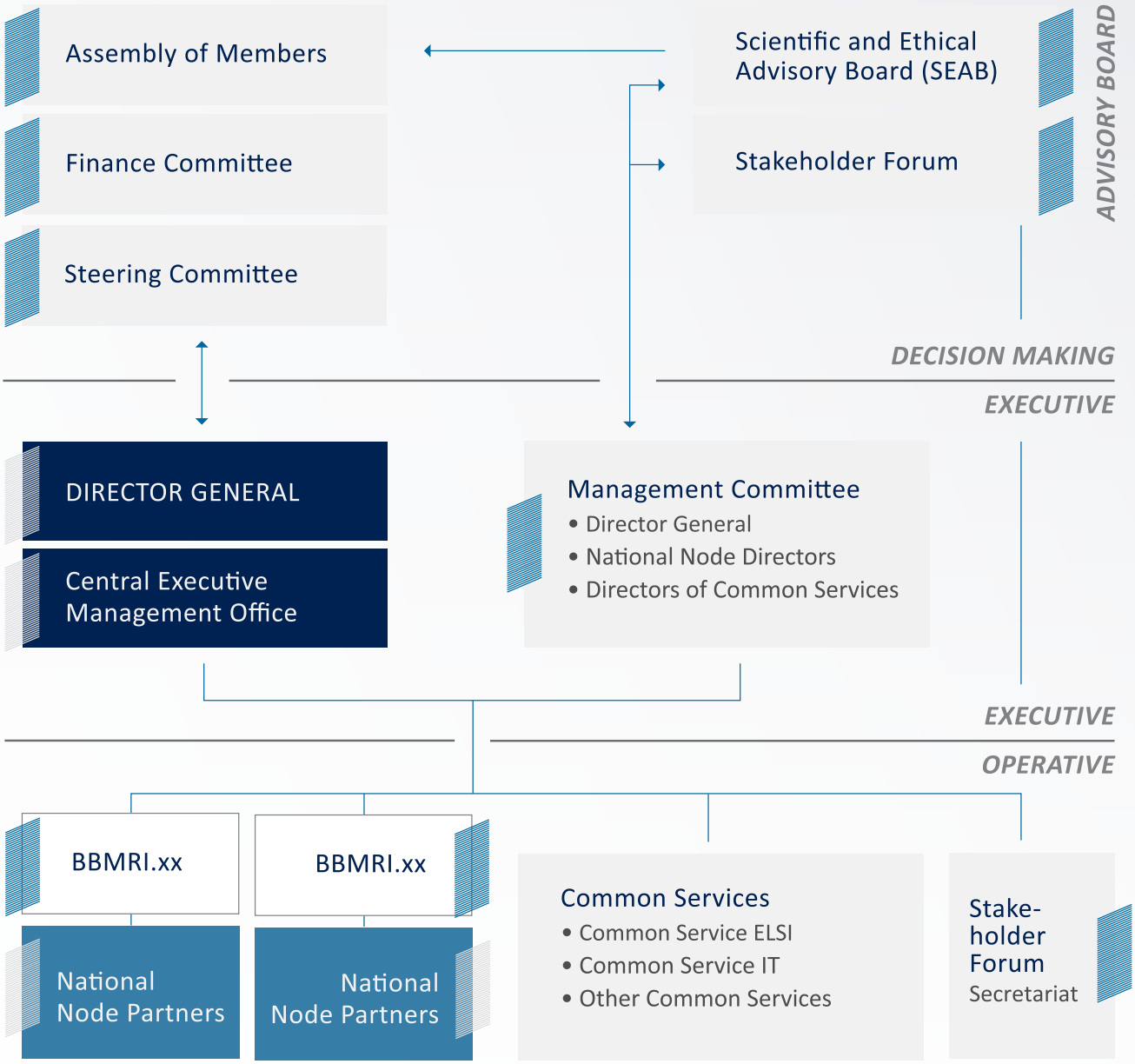


Figure 1: Governance Structure

ASSEMBLY OF MEMBERS

#4 - 27 April 2015, Vienna

MEMBER STATES

AT	Hemma Bauer (Delegate)
AT	Oliver Mayer (Delegate)
AT	Kurt Zatloukal (Advisor/Proxy)
CZ	Dalibor Valik (Delegate)
DE	Isabell Hahn (Chair of FC, Delegate)
DE	Michael Hummel (Advisor)
EE	Priit Tamm (Delegate)
FI	Anneli Törrönen (Delegate)
FI	Riina Vuorento (Delegate)
FI	Heli Salminen-Mankonen (Advisor/Proxy)
FR	Georges Dagher (Vice Chair of AoM, Delegate)
GR	Suzanne Kolyva (Delegate)
IT	Luca Sangiorgi (Vice Chair of FC, Delegate)
MT	Alex Felice (Delegate)
NL	Edvard Beem (Chair of AoM)
NL	Gert-Jan van Ommen (Delegate)
SE	Maria Anvret (Delegate)

OBSERVERS

IARC	Maimuna Mendy (Delegate)
CH	Stéphanie Wyss (Delegate)
NO	Karianne Solaas (Delegate)
PL	Anna Chroscicka (Delegate)
PL	Dominik Strapagiel (Delegate)
TR	Nese Atabey (Delegate)

GUESTS

UK	Jon Fistein (Delegate)

#5 - 27 October 2015, Vienna

MEMBER STATES

AT	Hemma Bauer (Delegate)
AT	Oliver Mayer (Delegate)
AT	Kurt Zatloukal (Advisor/Proxy)
BE	Michele Oleo (Delegate)
CZ	Dalibor Valik (Delegate)
DE	Isabell Hahn (Chair of FC, Delegate)
DE	Michael Hummel (Advisor)
EE	Priit Tamm (Delegate)
FI	Anneli Törrönen (Delegate)
FI	Riina Vuorento (Delegate)
FI	Eero Vuorio (Advisor)
FR	Georges Dagher (Vice-Chair of AoM, Delegate)
FR	Tiphaine De Jouvencel (Advisor)
GR	Suzanne Kolyva (Delegate)
IT	Luca Sangiorgi (Vice Chair of FC, Delegate)
NL	Edvard Beem (Chair of AoM)
NL	Ronald Stolk (Delegate)
SE	Maria Anvret (Delegate)
SE	Katrin Brandt (Delegate)
UK	Jon Fistein (Delegate)

OBSERVERS

IARC	Maimuna Mendy (Delegate)
NO	Karianne Solaas (Delegate)
PL	Anna Chroscicka (Delegate)

Image 1: Assembly of Members' 5th Session, Vienna

FINANCE COMMITTEE

Isabell Hahn (Chair)
Luca Sangiorgi (Vice Chair)
Alex Felice, Antti Hautaniemi, Nese Atabey, Aysim Yilmaz, Edvard Beem, Christian Bonnici, Dalibor Valik, Francois Chambelin, Hemma Bauer, Isabell Hahn, Jon Fistein, Katrin Brandt, Luca Sangiorgi, Mark Debono, Oliver Mayer, Philippe Desmeth, Priit Tamm, Roman Slaweta, Suzanne Kolyva, Toivo Raim, Tove Andersson, Karianne Solaas

CENTRAL EXECUTIVE MANAGEMENT OFFICE / HEADQUARTERS

Jan-Eric Litton (Director General)
Michaela Th. Mayrhofer (Senior Project Manager)
Andrea Wutte (Quality Manager)
Petr Holub (Senior IT/Data Protection Manager)
Outi Törnwall (EU Project Manager)
Markus Pasterk (Administrative Director)
Nadja Palko (Communication Assistant)
Ulrike Rohrer (Finance/Administration Assistant)
Luc Deltombe (Finance/Communication Assistant)
Fereniki Ioakeimidou - on leave since 12/2015 /Meghan McCarroll (Secretary/Receptionist)

STEERING COMMITTEE

Edvard Beem (Chair of AoM)
Georges Dagher (Vice Chair of AoM)
Isabell Hahn (Chair of FC)
Luca Sangiorgi (Vice Chair of FC)

MANAGEMENT COMMITTEE

Jan-Eric Litton (Chair)
Marialuisa Lavitrano (Vice Chair)

Comprised of the Director General of BBMRI-ERIC, the National/ Organisational Node Directors and the Directors of the Common Services.

NATIONAL / ORGANISATIONAL NODE DIRECTORS

BBMRI.at:	Kurt Zatloukal
BBMRI.be:	Karin Haustermans
BBMRI.ch:	Stéphanie Wyss (proxy) / Christine Currat (2016-)
BBMRI.cz:	Dalibor Valik
BBMRI.de:	Michael Hummel
BBMRI.fi:	Anu Jalanko
BBMRI.fr:	Georges Dagher
BBMRI.gr:	Dimitris Thanos
BBMRI.ee:	Andres Metspalu
BBMRI.it:	Marialuisa Lavitrano
BBMRI.mt:	Alex Felice
BBMRI-NL:	Cisca Wijmenga and Gerrit Meijer; National Node/BBMRI-ERIC coordinator: Gert-Jan van Ommen
BBMRI.no:	Kristian Hveem
BBMRI.pl:	Łukasz Kozera
BBMRI.se:	Joakim Dillner
BBMRI.tr:	Nese Atabey
BBMRI.uk:	Anne Carter (until 2015) / Philip Quinlan (since 2016)
WHO/IARC:	Maimuna Mendy

SCIENTIFIC AND ETHICAL ADVISORY BOARD (SEAB)

David Byrne
Carolyn Compton
Thomas Hudson
Mark Daly
Anders Ekblom
Alastair Kent

COMMON SERVICE ELSI

Board of Directors: Anne Cambon-Thomsen (Co-Director, Coordinator), Jasper Bovenberg (Co-Director), Mats Hansson (Co-Director), Marialuisa Lavitrano (Co-Director), Maria del Rosario Sanchez-Albor (administrative support)

Chief Policy Officer: Michaela Th. Mayrhofer

Figure 2: Governance Structure of the Common Service ELSI

COMMON SERVICE ELSI TEAM & EXECUTIVE BOARD MEMBERS

Kurt Zatloukal, Isabelle Salmon, Radek Halouzka, Tom Southerington, Emmanuelle Rial-Sebbag, Roland Jahns, Gillian Martin, Jane Kaye, Gauthier Chassang, Moa Kindström Dahlin, Heidi Howard, Olga Tzortzatou, Anna P. Durnova, Johannes Starkbaum, Liis Leitsalu, Martin Boeckhout, Irene Schlünder, Sara Casati, Araceli Diez-Fraile, Alison Parry-Jones, Vicky Chico

COMMON SERVICE IT TEAM

Director: Michael Hummel

Chief Information Officer: Petr Holub

Common Service IT team:

Diogo Alexandre, Raffael Bild, Araceli Diez-Fraile, Jean-Paul Ebejer, Niina Eklund, Kaisa Silander, Klaus Kuhn, Juha Knuuttila, Florian Kohlmayer, Lefteris Koumakis, Ines Leb, Nicolas Malservet, Kostas Marias, Sebastian Mate, Roxana Merino Martinez, Kristjan Metsalu, Timo Miettinen, Luciano Milanesi, Heimo Müller, Philip Quinlan, Hans-Ulrich Prokosch, Cornelia Rufenach, Morris A. Swertz, Frank Ückert, David van Enckevort, Ondřej Vojtíšek, Gianluigi Zanetti

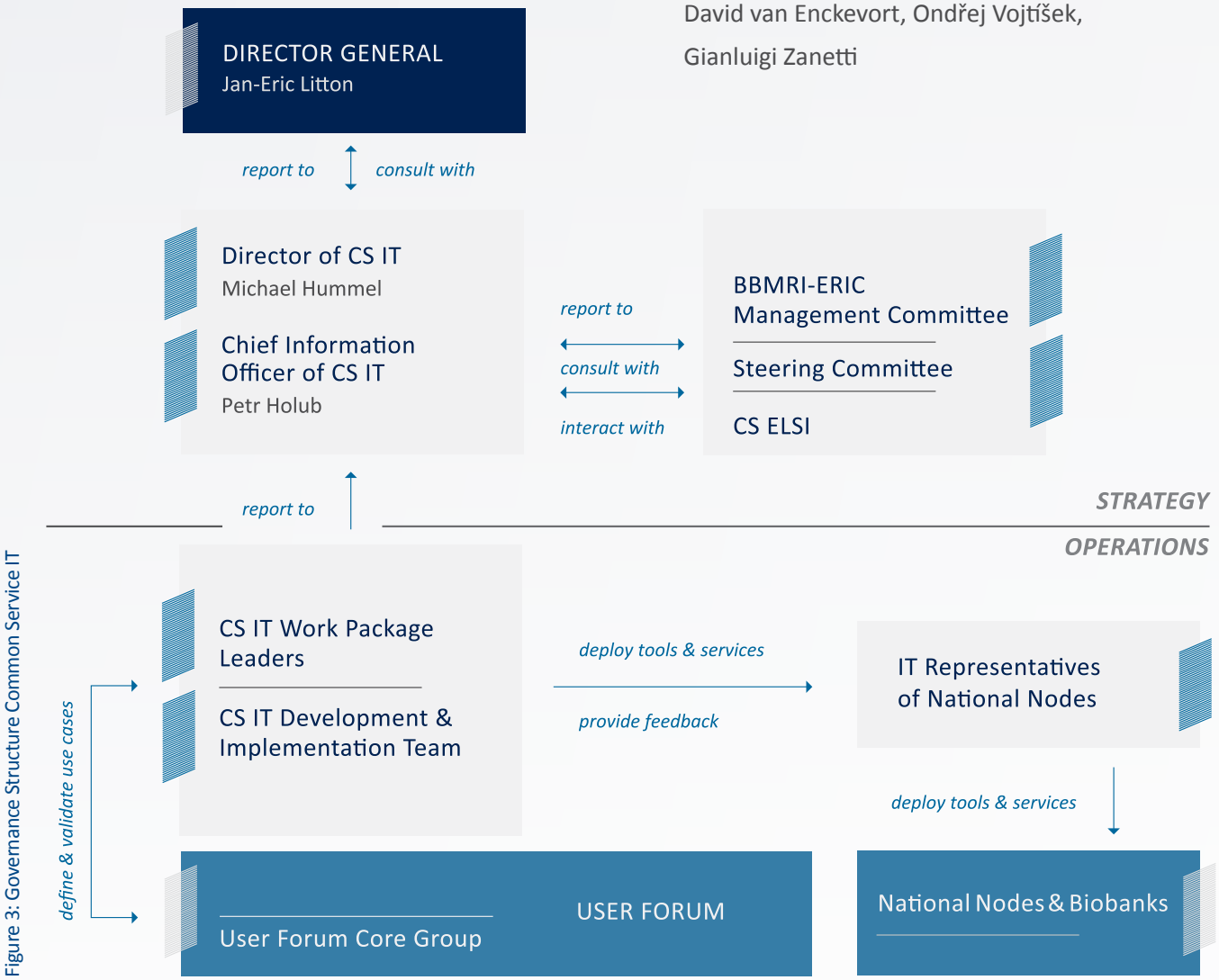


Figure 3: Governance Structure Common Service IT

ACTIVITIES AND ACHIEVEMENTS 2015

BBMRI-ERIC
CORE WORK PROGRAMME

BBMRI-ERIC®
Biobanking and
BioMolecular resources
Research Infrastructure

E-INFRASTRUCTURE

A NEW GATEWAY TO EUROPEAN BIOBANKS

- **Work Stream 1.1** ✓ **Completed.**

Biobanks are a key element for research involving human -omics in conjunction with other personal or health data. In order to move towards a European e-infrastructure for biobanks, the Directory was launched and the Common Service IT was prepared in 2015.

Achievements

The **BBMRI-ERIC Directory** (Image 2) was the first IT service delivered by BBMRI-ERIC. It is available both for external users and internal BBMRI-ERIC purposes. The first two versions of the Directory have been jointly developed by the BBMRI-ERIC IT community, prior to the start of the Common Service IT. The Directory 1.0 was released in July 2015 and the Directory 2.0, covering 515 biobanks with more than 60,000,000 samples, was released in December 2015 as the first milestone of the ADOPT BBMRI-ERIC project (further information see page 90).

On BBMRI-ERIC web: www.bbmri-eric.eu

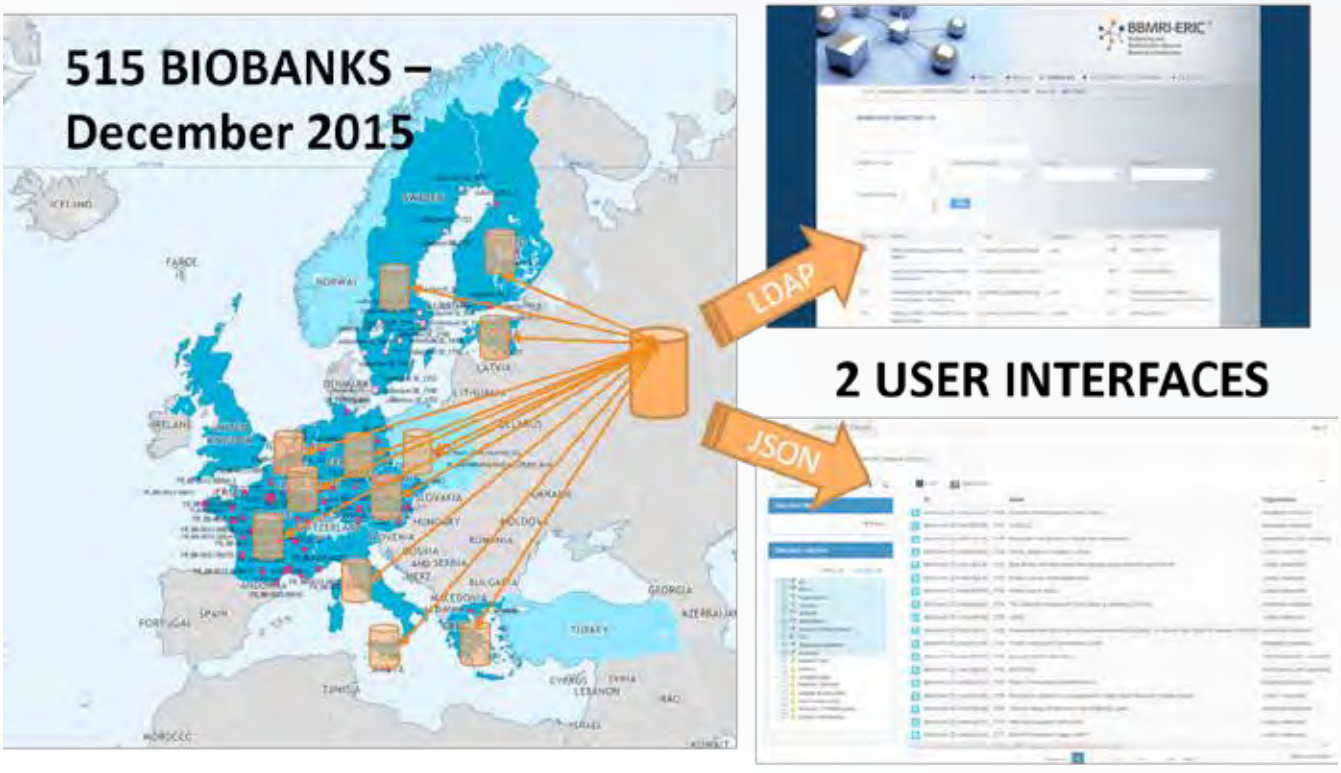


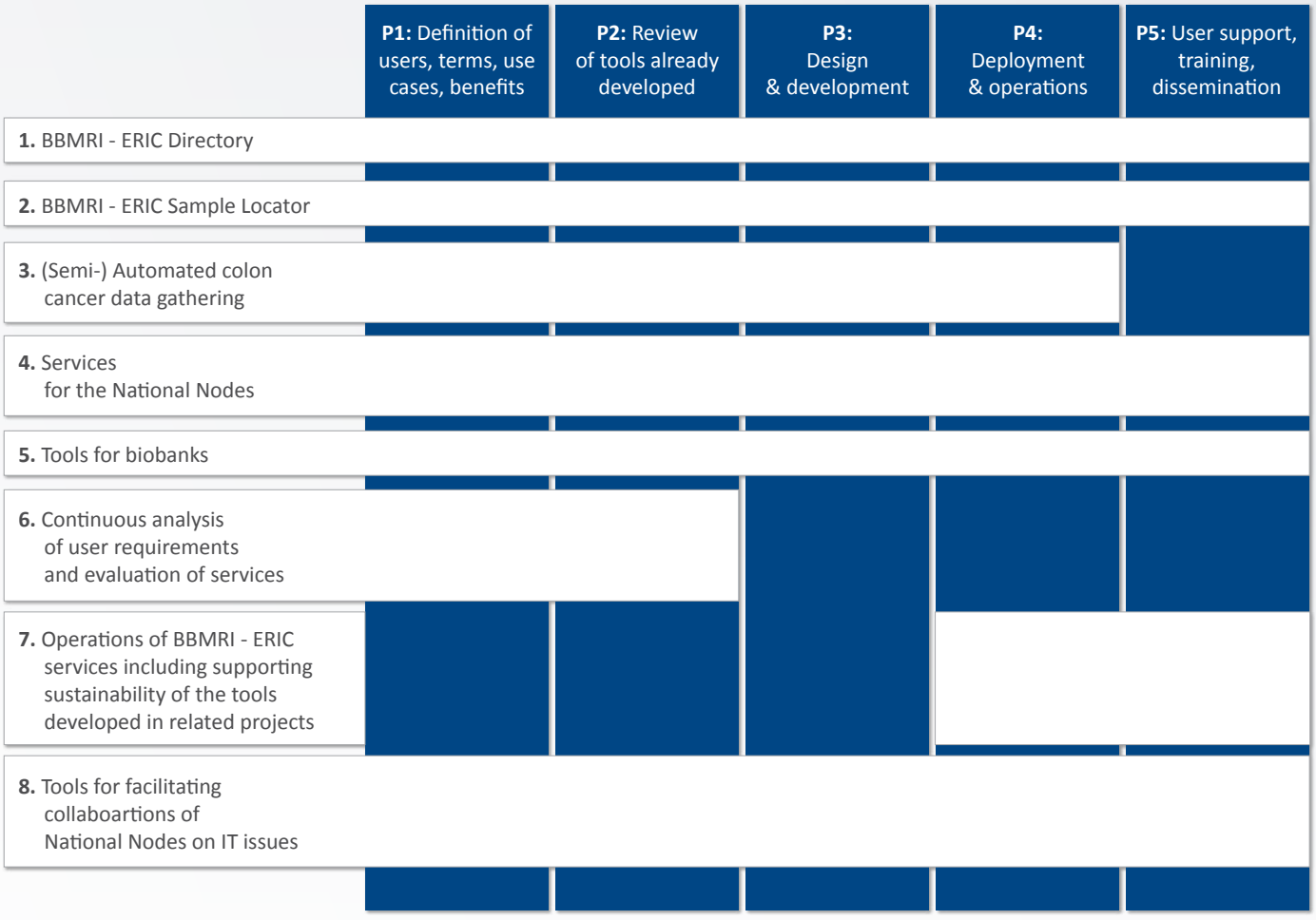
Image 2: Directory 2.0

The **MIABIS 2.0 Core** (Minimum Information About Biobank data Sharing) community standard was finalised in August 2015 and submitted to Biobanking and Biopreservation (accepted in January 2016). This core module focuses on representation of the biobanks, sample collection, and study entities. The Directory 2.0 is based on and fully compliant with the MIABIS 2.0 Core, which has also been used for implementing the MIABIS Federation querying interface as described in BioMedBridges (Building data bridges and services between biological and medical infrastructures in Europe) project (Deliverable 10.3).

The Common Service IT

On 30 April 2015, the call for tender for the **Common Service IT** (Figure 4) was published in order to provide expertise, services, and tools relevant to the pursuance of tasks and activities of BBMRI-ERIC. A consortium comprising all full members of BBMRI-ERIC responded with one application to the call. Following the evaluation of the proposal by external reviewers, the Assembly of Members approved the Common Service IT on 27 October 2015. It became fully operational in January 2016. Additionally, the ADOPT BBMRI-ERIC project complements the tasks of the Common Service IT (see page 90). The project is specifically intended to accelerate the development and deployment of the BBMRI-ERIC IT infrastructure. It also further specifies mandatory milestones and deliverables for the Common Service IT.

Figure 4: Structure of the Common Service IT (call for tender)



Goals of the Common Service IT

include implementing the following key services:

- **Directory:** a metadata and public data information service with aggregated information about biobanks, their sample and data collections, as well as additional services.
- **Sample/Data Locator and Negotiator:** services to allow for negotiating access of the requesters to samples and data sets hosted by the biobanks and to locate samples and data sets of interest for the requesters. The Negotiator focuses on making the communication between many requesters and biobanks as efficient as possible. The Locator will allow for detailed privacy-preserving, multi-criteria search of samples and data sets, while also respecting the degree of control required by the biobank infrastructure operators. This will also include the development of connectors to interface to the information systems of biobanks.
- **Data harmonisation tools:** middleware services that provide ontology registries and translation tools to be used by other BBMRI-ERIC IT services and possibly also external services in the future. These tools result from the heterogeneity of standards in medical information used across Europe as well as beyond.
- **Reference tools for biobanks:** integrated toolbox designed to accommodate basic functionality needs of the biobanks, such as biobank information management systems or connectors to BBMRI-ERIC IT services. Because of the modular component architecture, it will support both newly established biobanks as well as the integration of existing biobanks.

The Common Service IT services will rely on detailed and continuous analysis of users' requirements, as well as the evaluation of services of pilot user groups. The Common Service IT, as well as a basic set of tools, serves to operate the IT infrastructure of BBMRI-ERIC's National Nodes.

The Work Plan focuses specifically on the most urgently needed IT services of BBMRI-ERIC. Common Service IT members will also collaborate with the broader IT community of BBMRI-ERIC to design and implement other services related to data storage and processing. The Common Service IT may also reprioritize development of the services based on results of continuous analysis of users' needs.

Other Activities

- In July 2015, BBMRI-ERIC published a description of the data architecture[1] in order to communicate key architectural aspects to the Research Data Alliance (RDA) Data Fabric IG. This document has received several updates by the end of 2015 and subsequently received significant attention from European e-Infrastructures, namely European Grid Infrastructure (EGI) and pan-EUropean DATa infrastructure (EUDAT) as well as other related service providers.

[1] HOLUB, Petr – MAYRHOFER, Michaela Th. – LITTON Jan-Eric – Common Service IT Contributors. RDA Data Fabric IG (DFIG): BBMRI-ERIC IT. http://dx.doi.org/10.5281/zenodo.51593.

QUALITY

QUALITY MANAGEMENT SYSTEM (QMS)

- **Work Stream 2.1** ✓ **Completed.**

Figure 5: Overview of QM web presence at www.bbmri-eric.eu

BBMRI-ERIC aims to provide guidance on establishing and improving an appropriate Quality Management System (QMS) for biobanks. For this purpose BBMRI-ERIC focused first on ‚community building' by reaching out to appointed quality managers nominated by the National Node Directors. Community interactions started on the basis of mutual exchange of experiences and information with 18 Quality Managers in webinars and personal meetings and exchanges (e.g., during HandsOn: Biobanks 2015 in Milan). A quality management web presence (Figure 5) was established, informing about the latest quality management news, recommended standards and guidelines.

Secondly, BBMRI-ERIC established in April 2015 an official Observer Liaison to the International Organization for Standardization (ISO) technical committees ISO/TC 276 ‚Biotechnology' (contributing to five Working Groups described in the box below) and ISO 212 ‚Clinical laboratory testing and in vitro diagnostic test systems'.

ISO/TC (International Organisation for Standardization / Technical Committees)

ISO/TC 276 Working Group 1 ‚Terminology' is working on the identification of currently used national and international standards, guidelines and other relevant documents, as well as terms and definitions, related to ISO/TC 276 Biotechnology. **ISO/TC 276 Working Group 2 ‚Biobanks and Bioresources'** is elaborating a package of international standards in the Biobanking field including human, animal, plant and microorganism resources for Research & Development, but excluding therapeutic products. **ISO/TC 276 Working Group 3 ‚Analytical Methods'** is developing standards for accurate, reproducible and robust measurement and analysis in support of biotechnologies. WG 3 will develop a package of international standards for biologically relevant molecules and entities, including nucleic acids, proteins, and cells. This WG will develop horizontal standards and, when applicable, vertical/particular standards for industry sectors. The WG will also coordinate with relevant technical committees and standardisation initiatives. **ISO/TC 276 Working Group 4 ‚Bioprocessing'** is identifying standardisation needs in four major technology spaces: 1) component materials control; 2) bioreactor processes; 3) collection, separation, purification and formulation; and 4) handling, transportation & storage. Each category of materials/technology space may affect many current and future applications. **ISO/TC 276 Working Group 5 ‚Data Processing and Integration'** will develop standards in the field of processing and integration of life science data and derived models, simulations and graphical representations. This includes annotation, analysis, validation, integration and comparison of data and models from heterogeneous sources. The main focus is the definition of interfaces, formats, and metadata connecting related data and models.

By active contribution of BBMRI-ERIC to the International Organization for Standardization, the foundation was laid to support the BBMRI-ERIC community in implementing appropriate standards to build up pan-European interoperability of biobanks as well as in acting as an information hub for future developments on biobank standards also in the pipeline of ISO. These standard development processes by ISO are of major interest for the BBMRI-ERIC community, particularly because these emerging standards will directly influence the working procedure of European biobanks and Expert Centres connected to BBMRI-ERIC. BBMRI-ERIC received a very friendly welcome from all ISO technical committee members and delegates around the globe.

Achievements

- In April 2015, BBMRI-ERIC established an official Observer Liaison to ISO/TC 276 ‚Biotechnology' and ISO/TC 212 ‚Clinical laboratory testing and in vitro diagnostic test systems'. Thereafter, BBMRI-ERIC participated in two plenary meetings of ISO/TC 276 in Shenzen, China and Tokyo, Japan as well as ISO/TC 212 in Geel, Belgium.
- Appointed Quality Managers discussed and exchanged in webinars on (1) biobanking guidelines and standards, (2) a biobanking manuscript and (3) commented the technical specifications for pre-examination processes in biobanks.
- The ISO 9001, ISO 15198, and ISO 17025 standards were introduced as commonly known industry requirements to the appointed Quality Managers.
- Quality control was discussed as a QM topic at the annual HandsOn: Biobanks 2015 Conference in July 2015 in Milan, BBMRI.it organised a dedicated QM workshop with six international speakers. Additionally, a casual face-to-face-meeting called ‚QM-café' was organised by BBMRI-ERIC with ten participating Quality Managers and technical experts.
- BBMRI-ERIC audit programme will be addressed in the ‚Work Programme 2017'.

BBMRI-ERIC raised awareness of the importance of the newly published technical specifications (CEN/TS) by introducing these to the biobanking community on the occasion of lectures, talks at conferences and meetings. BBMRI-ERIC addressed CEN technical specifications for pre-examination processes: (1) snap frozen tissue for isolated RNA and isolated proteins, (2) FFPE tissues for isolated RNA, isolated proteins and isolated DNA, (3) venous whole blood for isolated genomic DNA and isolated circulating cell free DNA from plasma.

SELF - EVALUATION

- **Work Stream 2.2** ✓ **Completed** with deviations (audit programme 2017).

In order to facilitate access to pan-European quality-defined human health/disease biological resources including associated data, it is crucial to gather the pan-European community and identify quality-oriented biobanks.

Community building is key to finding acceptance and convincing the biobanks to perform self-assessments and furthermore accept audit programmes. In December 2015, BBMRI-ERIC developed and released a call for technical experts in preparation for the activities in 2016, which addresses the self-evaluation.

Achievements

- BBMRI.it provided a biobank self-assessment questionnaire.
- Development of a BBMRI-ERIC self-assessment tool was incorporated in the ‚Work Programme 2016' (call for technical experts completed).
- BBMRI-ERIC's audit programme is postponed until provisionally 2017.

IMPLEMENTATION OF THE BIORESOURCE RESEARCH IMPACT FACTOR (BRIF)

- **Work Stream 2.3** ✓ **Completed** with some deviations (see CoBRA).

The **Bioresource Research Impact Factor** (BRIF) initiative is building a framework that enables the set up of indicators for the use of bioresources and rewarding mechanisms. Bioresources are defined as collections of biological samples with associated data (medical/epidemiological, social), databases independent of physical samples or other collections of biomolecular and bioinformatics research tools. Generated as part of the BRIF initiative, the ‚Citing Of Bioresources in Research Articles' (CoBRA) guideline provides guidance for citing bioresources in academic literature: it specifies where and how to cite bioresources in each section of a research article.

Achievements

- The CoBRA guideline, developed to standardise citation of bioresources in academic literature and part of BRIF, was published in February 2015 in BMC Medicine as a result of the BRIF and Journal Editors Subgroup's work[2]. Its checklist has been included in the reporting guidelines of the EQUATOR network (Enhancing the QUAlity and Transparency Of health Research)[3] and was disseminated via the BBMRI-ERIC e-Newsflash and other channels. On 9 October 2015, a workshop with journal editors and key stakeholders followed suit. It explored possibilities of introducing the CoBRA requirements in the journals' manuscript submission guidelines. The workshop took place on 9 October 2015 in Toulouse and was co-organised with EASE (European Association of Science Editors)[4]. The dialogue with journal editors is promising though gradual and will yield results only in the long term. Therefore, the referencing of biobanks according to CoBRA guidelines is proposed to be included as a mandatory paragraph in MTAs/DTAs. This strategy is expectantly leading to a wider usage of BRIF in the mid term.
- A second step was the introduction of BRIF elements, especially the use of persistent unique identifiers, in working groups of the RDA (Research Data Alliance) on the occasion of a workshop in Paris in September; contact was taken up with DataCite regarding DOI as persistent identifiers and a workshop on 4 December was held in Toulouse entitled.

[2] http://www.biomedcentral.com/content/pdf/s12916-015-0266-y.pdf
[3] http://www.equator-network.org/reporting-guidelines/cobra/
[4] Napolitani et al. (in press) Biobankers: Treat the poison of invisibility with CoBRA, a systematic way of citing bioresources in journal articles in Biobanking and Biopreservation.

BRIF: From identifiers, parameters and sharing policies, towards metrics to measure bioresources impact‘.

- The collective adoption of an identification scheme for bioresources and the creation of a necessary bioresource ID database/registry will become an integral part of the Directory.
- The involvement of the IT service to create a tool for calculating the research impact of bioresources is part of the ADOPT BBMRI-ERIC project.

DEVELOPMENT OF A BBMRI-ERIC APPROVAL PROCESS

- **Work Stream 2.4** ✓ **Completed.**

The main objective of this Work Stream was to describe the process for approval of the BBMRI-ERIC procedures, guidelines and standards. The Director General and the Management Committee prepared and proposed the descriptive document ‚Approval Process for BBMRI-ERIC Procedures, Guidelines, and Standards‘ and presented it for approval and authorisation to the Assembly of Members in October 2015.

Achievements

- Document ‚Approval Process for BBMRI-ERIC Procedures, Guidelines and Standards‘ prepared.
- Presentation of the document on 29 July 2015 at the Management Committee meeting #10 in Milan.
- Presentation and approval of the document at the Assembly of Members meeting #5 in Vienna on 27 October 2015.

BIOBANK LEXICON

- **Work Stream 2.5** ✓ **Forthcoming,** aligned with the development of ISO/TC 276 ‚Biotechnology‘.

Definitions used for biobank terminologies are an important part in our Work Programmes having already been a challenge for a common understanding since the BBMRI Preparatory Phase: Without precise ontologies it will remain very difficult to develop a common language and standards.

Achievements

- As stated above (see QMS), BBMRI-ERIC established an official Observer Liaison with ISO/TC 276 ‚Biotechnology‘ and ISO/TC 212 ‚Clinical laboratory testing and in vitro diagnostic test systems‘. The inclusion in the ISO/TC Working Group 1 ‚Terminology‘ allows BBMRI-ERIC to contribute to the identification of currently used national and international standards, guidelines and other relevant documents, as well as terms and definitions. For BBMRI-ERIC, this integrates the goals of the Biobank Lexicon into the ISO activities. BBMRI-ERIC has been accepted as Liaison to contribute to the drafting process by addressing comments and references as well as to share the developments of the ISO Working Groups with the BBMRI community.

CLINICAL BIOBANKS

CLIN BIO

- **Work Stream 3.1** ✓ **Completed** with revision (ADOPT BBMRI-ERIC/Work Programme 2016).

The mission of this Work Stream was to identify the needs of clinical biobanking on the European scale.

Achievements

- Initially, Working Group 4 ‚Clinical Biobanking' identified breast cancer as a good starting point for a use case and several preparatory steps along these lines took place. In the context of the ADOPT BBMRI-ERIC grant proposal, however, a shift using colon cancer as the first fully implemented disease entity, for which validated data and samples should be made available in the BBMRI-ERIC IT gateway to European biobanks (ADOPT BBMRI-ERIC Work Packages 2 and 3) was made. Ultimately, the activities of Working Group 4 were integrated into the activities of ADOPT BBMRI-ERIC and into the Work Plan Health Care Integrated Biobanking (‚Work Programme 2016').

POPULATION-BASED COHORTS

BBMRI-LPC

- **Work Stream 4.1** ✓ **Completed.**

Large prospective cohorts to which study participants have been recruited prior to the onset of disease(s) and followed through life, are instrumental in understanding the risk factors in disease aetiology. The BBMRI-LPC (BBMRI-Large Prospective Cohorts) project was launched in 2013 to bring together a network of BBMRI-LPCs across Europe in order to: (1) facilitate access to large prospective cohorts, (2) evaluate and improve the harmonisation of existing health data and endpoints, (3) to improve the research technologies that facilitate high-quality and fair access to samples and data, and (4) to establish a networking and training platform for the exchange of expertise between established biobanks and the emerging ones (LPC-Forum). BBMRI-ERIC became member of the BBMRI-LPC project in 2014 to maximise the synergies with BBMRI-LPC, and to assure that the results of BBMRI-LPC will be integrated into BBMRI-ERIC (further information on BBMRI-LPC, see page 92). BBMRI-LPC has provided extensive insights into how the collaboration for transnational projects in

biobanking science and access to European cohorts can be performed in the most efficient way. Transnational access procedure has been examined in detail within the BBMRI-LPC to pinpoint the hurdles and offer guidance on how to smoothen the procedure in the future within BBMRI-ERIC. BBMRI-ERIC has been part of this monitoring activity and documentation. It has become clear that one major hurdle is the preparation and approving of access during which cohort contacts are established and local scientific and ethical approvals are attained together with relevant registry linkages. Another problematic area is organising the access itself, which entails tardy, usually case-by-case negotiations to establish Material Transfer Agreements (MTA) between the parties (access provider and requester) before the realisation of sample/data transfers. Recommendations on to how to improve the efficiency of providing access to samples/data highlight the importance of catalogued resources, streamlined approval pipelines for administrative matters (e.g., ethical clearance) and the need for standardised pre-approved MTA templates for the cohorts in Europe.

To facilitate and support the cross-border exchanges of human biological resources and data, the BBMRI-ERIC Common Service ELSI (Ethical, legal and social issues) and BBMRI-LPC have searched for synergies in the form of working towards one common Material Transfer Agreement (MTA) for large prospective cohorts. In parallel to the access activities, BBMRI-LPC has worked in collaboration with BBMRI-ERIC to offer a forum for the emerging biobanks and prospective members of BBMRI-ERIC (LPC-Forum), serving as a community for information and expertise exchanging activities relevant to biobanking. In September 2015 the third LPC-Forum was organised in Budapest on 24-25 September with 70 registered participants (Image 3).

Achievements

LPC-Forum: communication with the community:

- Thirteen participants from emerging biobank countries (Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, Georgia, Hungary, Kazakhstan, Kuwait, Latvia, Lithuania, Romania, Uzbekistan, Vietnam) have confirmed the success of the dissemination strategy of BBMRI to attract the active participation of Eastern European countries, among others.
- Gradual build-up of the emerging biobank community supported by LPC-Forum. Feedback from the LPC-Forum participants suggest that there is an outspoken desire for the forum to promote, enable and stimulate dialogue and information exchange between emerging and established biobanks even more.

- Participation of ministerial representatives in the LPC-Forum. In Budapest, professor Jozsef Pálinkás (President of the National Research, Development and Innovation Office of Hungary) participated in the Forum and gave an update on Hungarian infrastructure policy. A ministerial representative from Latvia was also present.

Synergies and collaboration, overlapping activities:

- BBMRI-ERIC has participated in the access procedure monitoring steered by the BBMRI-LPC project. Roadmap to access is a deliverable of the BBMRI-LPC project materialising in 2016 that will significantly help BBMRI-ERIC in gaining specific information on access to prospective cohorts in Europe.
- Efforts in working towards achieving one common Material Transfer Agreement (MTA) for large prospective cohorts have taken place within the BBMRI-LPC-project. The results of these efforts have been communicated to BBMRI-ERIC.

Image 3: BBMRI-LPC Meeting in Budapest (c) BBMRI-LPC

BIOBANK OUTREACH

SCIENTIFIC RETREAT

- **Work Stream 5.1** ✓ **Completed.**

BBMRI-ERIC's Scientific Retreat is a yearly event with the National Nodes, the headquarters and individual guests to encourage the exchange of new ideas and discuss burning issues in an environment that allows undivided attention. The second Scientific Retreat took place on 1-3 June 2015 at Castle Obermayerhofen close to Graz, Austria (Image 4). It began with scientific lectures on BBMRI-LPC (Markus Perola), BioSHaRE (Ronald Stolk) and Biobank Graz (Berthold Huppertz) and continued with break out sessions on discussing Key Performance Indicators, agreeing on the governance structure of the Common Service IT, and brainstorming about public engagement activities.

Achievements

Identification of **key priorities for the ‚Work Programme 2016' and ‚Work Programme 2017':**

- e-Infrastructure
- Quality management systems

HANDSON: BIOBANKS CONFERENCE

- **Work Stream 5.2** ✓ **Completed.**

BBMRI.it/University Milano-Bicocca organised the HandsOn: Biobanks 2015 Conference on 29-31 July in Italy in the context of the EXPO in Milan. The local organising committee included Marialuisa Lavitrano, Ida Biunno, Elena Bravo, Maria Grazia Daidone, Rita Lawlor, Luciano Milanesi, Barbara Parodi, Daniela Pistillo, and Giorgio Stanta. Co-Organisers: Anu Jalanko, Outi Törnwall, Jan-Eric Litton, Michaela Th. Mayrhofer, Markus Pasterk, Kurt Zatloukal, and Georges Dagher.

The HandsOn: Biobanks 2015 discussed the growing relevance of clinical biobanks, and the essential infrastructure for the development of personalised medicine. The programme included sessions on quality in all aspects of the biobanking process, pre-analytical conditions, international outreach, and the partnership between academia and industry. The scientific programme covered the major topics Common Service with plenary and parallel sessions, keynote lectures, posters, ethics café discussions and interactive

Image 4: Outlining the ‚Work Programme 2016' (c) BBMRI-ERIC

idea labs. Also, with the help of sponsors, the participants followed ‚The Route', the interactive exhibition where practical aspects of collection, storage and use of liquid biopsies and archive tissues were presented.

The HandsOn: Biobanks 2015 strove to strengthen the national community in an inclusive way and to highlight the organic relationship between the National Nodes, and the BBMRI-ERIC headquarters. The congress was opened with a participatory workshop with patients as well as biobanks, both involved as partners and as panelists. Many experts, representatives of institutions actively involved during the HandsOn: Biobanks, are now in the list of BBMRI ERIC ELSI experts.

Achievements

Table 1: Overview of Highlights

EDUCATION & TRAINING STRATEGY

- **Work Stream 5.3** ✓ **Completed.**

The mission of this Work Stream was to jointly develop a policy framework for Europe and beyond in the field of Education & Training for biobank employees and the user community, deliver a European curriculum, sustainability, access and training. This mission can only be achieved once a full landscape of existing activities is available, and the needs for Education & Training activities are collected and skill sets are defined. This Work Stream is linked to the EU project Research Infrastructures Training Programme (RItrain) and Coordinated Research Infrastructures Building Enduring Life-sciences, HORIZON 2020 project (CORBEL) (therein Work Package 8).

Achievements

During 2015, two telephone conferences and a mapping exercise to collect information about all biobanking related training activities in BBMRI-ERIC member countries were completed. Information was received from Austria, Belgium, Estonia, Finland, International Agency for Research on Cancer (IARC), Norway, Sweden, and Italy; all existing courses were inserted into the European Medicines Research Training Network (EMTRAIN) -developed on-course® database. In the course of 2016, BBMRI-ERIC will discuss alignment or potential cooperation with universities that are either providing or planning a Masters programme on biobanking.

ADDITIONAL ACHIEVEMENTS ON INTERNATIONAL OUTREACH

On 5-10 December 2015, the Director General of BBMRI-ERIC was invited by the Ministry of Economy, Trade and Industry (METI) to present the research infrastructure to Japanese governmental and industry representatives as well as researchers and biobankers (e.g., Japan Human Biospecimen Science Society, Tohoku Medical Mega Biobank, National Cancer Center and the Biobank Japan). Of major interest for Japan was international standardisation. Other outreach activities included visits to Moldova, Quatar, South Africa and China.

Image 5: B3Africa Project Kick-off Meeting Bridging Biobanking and Biomedical Research across Europe and Africa in Cape Town, South Africa (August 2015)

COMMON SERVICES

WORKING GROUP ON RARE DISEASES

- **Work Stream 6.1** ✓ **Completed.**

In 2014, it became evident that rare diseases require specific solutions in relation to data management, quality criteria, access rules and ethical issues. More importantly, BBMRI-ERIC emphasised the relationship with the rare disease community, especially the EuroBioBank network and the RD-Connect project (see page 100) of which BBMRI-ERIC is an official partner.

Achievements

The RD-Connect Catalogue on rare disease samples and data in Europe and beyond is prepared to be moved to the BBMRI-ERIC Directory 2.0 and should guarantee sustainability for the databases & registries beyond the time span of an EU project. This is even more important as the submitted INNORARE proposal failed. Additionally, the activities within the ADOPT BBMRI-ERIC project (Work Package 7: Rare Diseases) support the Working Group activities.

For the purpose of further integration of rare disease biobanks into BBMRI-ERIC, three meetings took place in 2015: (a) on 18 March initiated by BBMRI-ERIC in Bologna - bringing together all key actors in the rare diseases community as well as all Biological and Medical Sciences (BMS) Research Infrastructures; (b) on 28 May in the context of the European Advanced Translational Research Infrastructure in Medicine (EATRIS) Conference Amsterdam; (c) on 18 September in Luxembourg and (d) on 19 November in the context of the CORBEL kick-off meeting in Hinxton - kick-starting the collaboration in a structured manner (esp. agreeing to participate in joint calls). This series of meetings was imperative to overcome the fragmentation of the rare disease community, identify the fields of expertise of the individual research infrastructures and collaborate in combined actions with a number of stakeholders and their projects to achieve the next level in connecting rare disease resources based on linkable data at the source. Under the leadership of BBMRI-ERIC, the collaboration on joint calls is ongoing and a key activity.

COMMON SERVICE FOR BIOLOGICAL RESOURCES

- **Work Stream 6.2** ✓ **Completed.**

Scientists engaged in biobank-based research need access to up to date information concerning amongst other things relevant techniques and state-of-the-art reagents. As one of its activities, BBMRI-ERIC has committed to develop a ‚Service Centre' that will support European scientists in academia and industry with questions concerning technologies for collecting and using biobank samples. The aims are to assist preparation for, and early adoption of, emerging technologies of relevance for collecting and analysing biobank samples, and to identify best practices and support harmonisation of methods with proper documentation to promote international collaboration. Procedures for collecting and using biobank samples are set to undergo dramatic changes in coming years, necessitating efficient provision of support for users of the corresponding techniques. The costs of some analyses are decreasing by orders of magnitude making entirely new approaches realistic, while new classes of biomarkers that depend on new analytic technologies are continually appearing, and the

types of molecules that are being targeted are steadily increasing. At the same time, growing numbers of individuals are being recruited as donors of blood and other samples for biobanks. Importantly, the shift of emphasis from genetic to phenotypic markers such as transcripts, proteins and metabolites, requires frequently collected, and consecutive samples to monitor trends over time, and to provide samples suitable for identifying markers for early diagnosis, preferably before symptoms appear. All these developments are consistent with the rapidly increasing interest in precision medicine and in well-being studies for monitoring individual health.

Achievements

Image 6: Countries participating in the Biobanking Analysis Resource Catalogue (BARC)

On 10 September 2015, Ulf Landegren gave a presentation on biomolecular resources during the Management Committee #10 in Paris, which subsequently led to several idea exchanges on a dedicated ‚Service Centre'. It will build on the ‚biomolecular resources' aspect of the BBMRI Preparatory Phase that was devoted to surveying technologies and reagents for biobank analysis (Image 6), in order to inform and assist both providers and users of biobanks. An important role will be to help the industry to access resources coordinated by BBMRI-ERIC and support industrial development of new technologies and biomarkers for applications in clinical care using retrospective sample material.

BIOBANKING OF INFECTIOUS MATERIALS

- **Work Stream 6.3** ✓ **Completed.**

The mission of this Work Stream was to develop a common strategy on how biobanks with infectious materials could be best integrated in BBMRI-ERIC Common Service infrastructure to ensure the optimal use and promotion of such resources for the research community.

Achievements

For this purpose, the European Research Infrastructure on Highly Pathogenic Agents (ERINHA) and the HORIZON 2020 project European Virus Archive Global (EVAg) , represented by the Aix-Marseille University signed a Memorandum of Understanding and a Collaboration Agreement respectively to work towards a future integration in BBMRI-ERIC in relation to biological resources.

COMMON SERVICE ELSI

- **Work Stream 6.4** ✓ **Completed.**

According to the BBMRI-ERIC Statutes (Art. 3(4)) 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. As the first Common Service of BBMRI-ERIC, the Common Service ELSI started according to these values in February 2015.

In order to fulfill its mission, the 2015 priorities were to set up the governance and operational management, to prepare the ethics check procedure, to establish a process on how to screen public circulation of documents of relevance, with focus on the European level, and, in particular, to follow up and influence the EU Data Protection Reform (General Data Protection Regulation, GDPR). A further priority was to start exchanging good practices through a first annual workshop on a key domain for BBMRI-ERIC, namely data and sample sharing, with the aim of providing the basis for an infrastructure access policy. Finally, the Common Service ELSI started harmonising the tools regarding legal and regulatory matters.

Achievements

A **governance** structure was put in place (Figure 2, see page 12) that ensures the linkage for ELSI matters with the National Nodes. Its core is based on a distributed team of ELSI experts, which is comprised of 1-2 individuals per member country to address the given tasks, when feasible through specific task forces. Setting up the entirety of this system took several months as each National Node had to nominate its Common Service ELSI members. A process, which differed from country to country: whereas, for example, some National Nodes could draw on the expertise of a well established national ELSI service, others typically rely on a case-by-case liaison with ELSI experts, typically on a consultancy basis. These experiences in recruitment were greatly valuable for the set up of the second Common Service, namely the Common Service IT.

A Common Service ELSI section of the BBMRI-ERIC website is functional and a regular flow of information is assured; in addition to the activities of the Common Service ELSI itself, public information of relevance, relevant meetings and activities in the various countries are shared and disseminated through the e-Newsflash, the magazine Biobanks Europe, and new media as well as several mailing lists.

The **ethics check procedure** was a matter of numerous discussions within the Common Service ELSI in order to assure users, biobanks and BBMRI-ERIC that all projects respect the relevant ethical principles in use in the European Union while also fully respecting their national legislation. The challenge was to set up a system that would not duplicate other ethical procedures already passed. The reference system for setting up the ethics check was the procedure used at the level of the European Commission RTD for HORIZON 2020 projects. An expedited procedure based on a documented self-assessment of ten items was set up for projects that had already been through relevant checks for ethics and regulation, such as HORI-

ZON 2020 ethics checks and review panels; a standard ethics check using the same self-assessment grid and a set of criteria for this check for other projects, with intervention of ELSI experts according to the specificities of each project. In order to facilitate this check and other tasks of the Common Service ELSI where experts are needed, a database of ELSI experts has been prepared and is being populated in 2016. The ethics check will be operational in 2016.

The **advice and help desk** functions were mainly used for clarification of matters regarding informed consent, exchange of samples across countries and data protection, as well as in providing support for the ethical aspects of three HORIZON 2020 projects where the Common Service ELSI is involved: CORBEL, ADOPT BBMRI-ERIC and "Biobanking and the Cyprus Human Genome Project" (CY-Biobank). For the first two, the answers to comments and requirements of the HORIZON 2020 ethics reviews were provided and for the latter, advice on how to properly address ELSI issues when establishing a new national biobank was given.

In relation to **public consultations,** it prepared comments to the draft WMA Declaration on *ethical considerations regarding health databases and biobanks* [5] as well as the draft Council of Europe's *Recommendation (2006)4 on research on biological materials of human origin* [6].

Perhaps most importantly, it prepared and disseminated the BBMRI-ERIC *Position Paper on the General Data Protection Regulation (GDPR)* [7], which, building on the Day of Action organised by BBMRI-ERIC on 16 June 2015, led to a set of concise recommendations with the inclusion of practical examples from across BBMRI-ERIC member states on the expected impact of the regulation if it would have been accepted in the Council or European Parliament's version. Therein, BBMRI-ERIC acknowledged and embraced the dynamic potential of the **General Data Protection Regulation** for the ERA. At the same time, we stressed that wrongly aimed provisions could seriously hamper pan-European research. For this purpose, various Common Service ELSI team members also personally engaged with about 50 policy makers, members of the European Parliament, Council and Commission in the course of 2015. Especially this pro-active attitude aiming at sensitising and exemplifying cases of biobank and health registry uses for research, for regulators and members of the European Parliament or proposing common positions and adequate texts for amendments or re-formulation has certainly been a highlight and a major achievement of 2015. In particular due to these activities, BBMRI-ERIC has been established as a serious partner for EU policy makers.

Moreover, quickly analysing and disseminating practical information for biobanks on possible consequences of the cancellation of the ‚Safe Harbor' framework by the European institutions proved useful to the community [8].

In 2015, the Common Service ELSI held additionally two important meetings: **(1)** The Common Service

ELSI Executive Board Meeting in Milan (discussing the first draft outline for the ethics check with a wider audience) in the context of the HandsOn: Biobanks on 29-31 July. In the course of 2015, the ethics check was further specified. **(2)** On 8-9 September, *the ELSI Workshop on Sharing and access to data and human biospecimens for the benefit of patients – Towards a BBMRI-ERIC Policy* [9], which took place in Paris together with the first ELSI team meeting. The main aim of this meeting was to discuss the ethical, legal and social issues surrounding increased access and sharing of biomedical samples and data, including the barriers and potential solutions. In doing so, we also achieved two other important goals necessary for the functioning of the BBMRI-ERIC ELSI group: i) members of different National Nodes were able to meet, often for the first time; and ii) members were presented with the basic information surrounding the ethical, legal and social implications of sharing data and samples, thus bringing everyone to the same informational level. Both of these sub-goals will facilitate future work in the BBMRI-ERIC ELSI group.

A day prior to this workshop, the ELSI team met with representatives of the other Biological and Medical Sciences (BMS) RIs in order to discuss the expectations and needs of research infrastructure users in relation to ELSI tools and advice. It concluded that (a) access procedures and (b) the existing tools for legal advice are key for all RIs. An intranet webspace (‚playground') was set up, following a dedicated meeting to re-organise the three **tools for legal matters** (BiomedBridges tool (Building data bridges and services between biological and medical infrastructures in Europe), the legal wiki platform and hSERN) into a single user-friendly tool. The development of the tool is further supported by the CORBEL project (Work Package 7), which ultimately aims to provide a solution for legal advice for all RIs.

Finally the **dissemination** activity was intense in 2015 with presentation of the Common Service ELSI service to numerous audiences from international congresses to national events, European consortia, local and **training** events.

[5] www.bbmri-eric.eu | [6 - 9] Ibid

EXPERT CENTRES

PLANNING FOR A STRUCTURE FOR BBMRI-ERIC EXPERT CENTRES

- **Work Stream 7.1** ✓ **Completed.**

During the BBMRI Preparatory Phase (2008-2011), the rationale of Expert Centres was discussed and observed as an important cornerstone in the development of BBMRI. BBMRI-ERIC Expert Centres represent a novel public-private partnership model. They are responsible for the analysis of samples in the country of origin under internationally standardised conditions and for the generation of primary data. BBMRI-ERIC Expert Centres integrate pre-competitive public and private research and development activities by providing access not only to biological samples and medical data but also to the broad spectrum of medical and scientific expertise related to the samples, data, and their analysis. It is becoming important to take into account the whole spectrum of medical, scientific and technological issues related to a certain disease. Important issues not only include the quality of biomolecules extracted from a sample and which features of a disease are actually represented in a biological sample – but also the whole medical context [10].

In 2015, BBRMI-ERIC was developing an approval process for BBMRI-ERIC Expert Centres/Trusted Partners, as referred to in the ‚Business Plan' (version 21.1 of 3 December 2012) and the ‚Work Programme 2015'. The approval process is described in the specification document **‚BBMRI-ERIC Expert Centres/ Trusted Partners'** (V1.0).

For evaluation purposes, it is necessary to define certain criteria in a transparent manner and to ensure that all candidates for the status of Expert Centre/ Trusted Partner are only approved if they meet these criteria. The applicant will have to provide a summary of statements and documentation in an official application document on seven key objectives: (1) In general the Expert Centre has to demonstrate its purpose in the appropriate field of expertise, (2) terms and definitions, (3) management, (4) resource management, (5) technical requirements, (6) customer property, IPR, non-disclosure of information and (7) quality management.

[10] Van Ommen G-JB, Törnwall O, Bréchot C, Dagher G, Galli J, Hveem K, et al. BBMRI-ERIC as a resource for pharmaceutical and life science industries: the development of biobank-based Expert Centres. Eur J Hum Genet-. 2015;23(7):893–900. Available from: http://www.nature.com/doifinder/10.1038/ejhg.2014.235

The Assessment Process

The Director General ensures a transparent assessment of the application document. An agreed audit procedure with the Expert Centre will assure that the Expert Centre fulfils the criteria for being a high-quality Expert Centre and Trusted Partner. The Director General will, if applicable, invite an ad hoc expert review committee, with technical capabilities to evaluate the validity of the criteria.

The Director General will bring forward a recommendation for a simple majority consensus-based approval of the Expert Centre to the Management Committee.

Vote: The approval or rejection of the submitted recommendation is the decision of the Director General and the Management Committee.

The Director General and the Management Committee may ask the applicants to amend their submission documents to enable a positive vote, such that failure to make the changes requested will result in rejection of the application.

The Director General will take action to publish and disseminate the new brand of ‚BBMRI-ERIC Expert Centre/Trusted Partner' within the BBMRI-ERIC family and to appropriate stakeholders.

Achievements

- Criteria list for certificate of BBMRI-ERIC Expert Centre defined and documented.
- Document ‚BBMRI-ERIC Expert Centres/Trusted Partners' (V1.0) finalised.
- Presentation of the document on 29 July 2015 at Management Committee #10 in Milan.
- Presentation and approval of the document on 27 October 2015 at Assembly of Members #5 in Vienna.

In 2015, two potential applicants expressed general interest in becoming a BBMRI-ERIC Expert Centre/ Trusted Partner; (1) EXCEMET, an Expert Centre for metabolomics, Director: Claudio Lucinat [11] and (2) CBmed GmbH, a Biomarker Research Center, Director: Thomas Pieber [12].

[11] http://www.excemet.org | [12] http://www.cbmed.org

COMMUNICATION AND DISSEMINATION ACTIVITIES

BY BBMRI-ERIC & NATIONAL NODES

BBMRI-ERIC®
Biobanking and
BioMolecular resources
Research Infrastructure

COMMUNICATION AND DISSEMINATION ACTIVITIES

Figure 6: Communication & Dissemination Activities

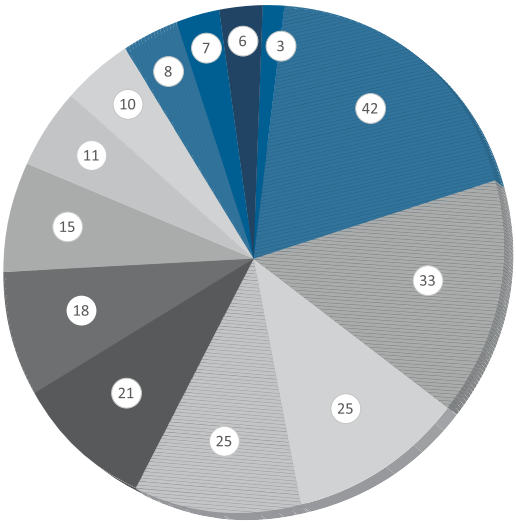
Upon its establishment, BBMRI-ERIC invested in communication through various channels for diverse audiences. Dissemination activities (Figure 6) proved crucial especially in the context of scientific conferences and networking meetings - many biobankers and researchers are still unaware about BBMRI's existence as a research infrastructure and ERIC (see page 39). Especially the new media (to other Research Infrastructures and European policy makers) and the e-Newsflash (to the National Nodes and biobanks, European and international) showed that our tailored dissemination strategy promoted the achievements, meetings and scientific results to the desired audience. In the year to come, we aim at intensifying the promotion of practical services and tools for biobanking as well as best practice examples from the National Nodes.

CONFERENCES AND MEETINGS

by BBMRI-ERIC

Since its beginning in 2014 until April 2016, BBMRI-ERIC headquarters representatives attended more than 200 events in order to promote BBMRI-ERIC, for and to, the biobanking community (Figure 7). 42 meetings fall under ‚Conferences & Workshops' constituting the largest category, comprised of talks during conferences, as well as BBMRI-ERIC or National Node workshop participations and posters. Exemplarily, there was the HandsOn: Biobanks Conference in Milan in 2015, the ESBB Annual Conference in Leibzig 2014, the 3rd Annual Biobank China 2013 & China Biobanking Summit in Shanghai 2014, the Seminar ‚EU Science: Global Challenges, Global Collaboration Conference' in Brussels in 2015 or the EuroMediterranean Meeting in Valetta in 2016. The second largest category is ‚Proposals' with 33 meetings, which are linked to the preparatory work in the context of consortia building and proposal writing. Next, the categories ‚Governance' and ‚Projects' equally comprise 25 meetings.

In relation to ‚Governance' the number of meetings is comprised of those of the governing bodies, namely the Assembly of Members, the Management Committee, the Steering Committee, the Finance Committee and the Scientific Retreats. The category ‚Projects' relates to the currently active project participation and the respective meetings and workshops. 21 and 18 meetings are linked to the activities of the Common Service IT and ELSI respectively. 15 meetings were concerned with exchange on the EU level including exchange with other research infrastructures. 11 meetings are linked to National Node activities, where at least one representative of BBMRI-ERIC Headquarters was present. 10 meetings relate to the activities of engaging with countries that are interested in joining BBMRI-ERIC. A total number of 8 meetings took place in relation to education & training, management/administrative purposes as well as Expert Centre and biomolecular resources and were summed up under the category ‚Other'. 7, 6 and 3 encounters were concerned with ‚Societies, Associations & Agencies', ‚Quality' and the ‚Stakeholder Forum' respectively.



42 **Conferences & Workshops** (talks & posters)
33 **Proposals**
25 **Governance** (AoM, MC, SC, FC, Scientific Retreat)
25 **Projects**
21 **IT**
18 **ELSI**
15 **EU & ESFRI** (networking & info days)
11 **National Nodes**
10 **New Members**
8 **Other** (Education & Training, Management & Admin, Expert Centres, Biomol. Res)
7 **Societies, Associations & Agencies** (e.g. ESF, EFPIA, EMA)
6 **Quality**
3 **Stakeholder Forum**

Figure 7: Primary Scope of Meetings attended by the Headquarters 01/2014 - 04/2016

SCIENTIFIC ARTICLES

by the BBMRI community

(BBMRI-ERIC and the National Nodes)

- **Asberg** et al. (2015), Lower hemoglobin with lower ferritin - results from the HUNT 2 Study. Scand J Clin Lab Invest.;75(2):152-5. doi: 10.3109/00365513.2014.993335. Epub.
- **Bouchal** et al. (2015), Combined Proteomics and Transcriptomics Identifies Carboxypeptidase B1 and Nuclear Factor κB (NF-κB) Associated Proteins as Putative Biomarkers of Metastasis in Low Grade Breast Cancer. Mol Cell Proteomics; 14(7):1814-1830. (IF2014: 6,564)
- **Bravo** et al. (2015), Developing a guideline to standardize the citation of bioresources in journal articles (CoBRA), in: BMC Medicine, 13:33
- **Budin** et al. (2015), Ask Not What Personalized Medicine Can Do for You - Ask What You Can Do for Personalized Medicine. Public Health Genomics. . [Epub ahead of print]
- **Ciglic**, et al. (2015), Anonymization of Data Sets with NULL Values, TLDKS (in print)
- **Croce** et al. (2015), Uterine smooth muscle tumor analysis by comparative genomic hybridization: a useful diagnostic tool in challenging lesions. Mod Pathol;28(7):1001-10. (IF 6.187)
- **Dillner** (2015), A basis for translational cancer research on aetiology, pathogenesis and prognosis: Guideline for standardized and population-based linkages of biobanks to cancer registries.. Eur J Cancer.;51(9):1018-27
- **Feng** et al. (2015), Methods for association analysis and meta-analysis of rare variants in families. Genet Epidemiol.;39(4):227-38. doi: 10.1002/gepi.21892. Epub
- **Fransson** et al. (2015), Toward a common language for biobanking', in: European Journal of Human Genetics, 23: 22-28.
- **Guerrero** et al. (2015, published online 2013), Key tumor suppressor genes inactivated by ‚greater promoter' methylation and somatic mutations in head and neck cancer. Epigenetics., 9(7), 1031-1046. ISSN 1559-2294. IF: 5.108
- **Guidry** et al. (2015), Measurement of Total and Free Urinary Phenol and Paraben Concentrations over the Course of Pregnancy: Assessing Reliability and Contamination of Specimens in the Norwegian Mother and Child Cohort Study. Environ Health Perspect. [Epub ahead of print]
- **Hummel**, Rufenach (2015) Biomaterialbanken als Grundlage für die Entwicklung genetisch basierter Präventionskonzepte. Bundesgesundheitsblatt – Gesundheitsforschung – Gesundheitsschutz Volume 58(2):127-130.
- **Jorde** et al. (2015), The DBP Phenotype Gc-1f/Gc-1f Is Associated with Reduced Risk of Cancer. The Tromsø Study. PLoS One.;10(5):e0126359. doi: 10.1371/journal.pone.0126359. eCollection
- **Köpke** et al. (2015), Efficient Projection of Ontologies. Journal on Data Semantics 4(2): 103-116.
- **Koutros** et al. (2015), Prediagnostic Serum Organochlorine Concentrations and Metastatic Prostate Cancer: A Nested Case-Control Study in the Norwegian Janus Serum Bank Cohort. Environ Health Perspect.
- **Larose** et al. (2015, published online 2014), Serum 25-hydroxyvitamin D levels and lung function in adults with asthma: the HUNT Study. Eur Respir J.;45(4):1019-26. doi: 10.1183/09031936.00069714.
- **Lerstad** et al. (2015), Thyroid function, assessed by thyroid stimulating hormone, and future risk of venous thromboembolism -The Tromsø study.

Eur J Endocrinol.. pii: EJE-15-0185. [Epub ahead of print]

- **Locke** AE, et al. (2015), Genetic studies of body mass index yield new insights for obesity biology. Nature.;518(7538):197-206. doi: 10.1038/nature14177.
- **Mitchell** et al. (2015) Biobanking from the patient perspective, in: Research Involvement and Engagement, 1: 4.
- **Mora** et al. (2015), The EuroBioBank Network: 10 years of hands-on experience of collaborative, transnational biobanking for rare diseases. Eur J Hum Genet.; 23(9):1116-1123.
- **Mueller** et al. (2015), State-of-the-Art and Future Challenges in the Integration of Biobank Catalogues; in Smart Health, vol. 8700, pp. 261-273.
- **Omland** et al. (2015), Impact of Sex on the Prognostic Value of High-Sensitivity Cardiac Troponin I in the General Population: The HUNT Study. Clin Chem.;61(4):646-56. doi: 10.1373/clinchem.2014.234369. Epub.
- **Ozguc** (published online 2015), Biobank Governance; http://www.unesco.org.tr/dokumanlar/biyoetik_komitesi/biyobanka_rapor.pdf
- **Papdopoulou** et al. (2015), Reliability of perfluoroalkyl substances in plasma of 100 women in two consecutive pregnancies. Environ Res.;140:421-429. doi: 10.1016/j.envres.2015.04.022. [Epub ahead of print.
- **Perskvist** et al (2015), The process of moving from a regionally based cervical cytology biobank to a national infrastructure. Biopreserv Biobank.;13(2):94-7.
- **Reichl** et al. (2015), Multicenter analysis of soluble Axl reveals diagnostic value for very early stage hepatocellular carcinoma. Int J Cancer; 137(2):385-394. (IF2014: 5,085)
- **Sariyar** et al. (2015), Sharing and Reuse of Sensitive Data and Samples: Supporting Researchers in Identifying Ethical and Legal Requirements, in: Biopreservation and Biobanking, 13, 4: 263-270.
- **Shungin** D, et al. (2015), New genetic loci link adipose and insulin biology to body fat distribution. Nature.;518(7538):187-96. doi: 10.1038/nature14132.
- **Skarpengland** et al. (2015), Genetic variants in the DNA repair gene NEIL3 and the risk of myocardial infarction in a nested case-control study. The HUNT Study. DNA Repair (Amst).;28:21-7. doi: 10.1016/j.dnarep.2015.01.013. Epub.
- **Surinova** et al. (2015, published online 2014), Non-invasive prognostic protein biomarker signatures associated with colorectal cancer EMBO Molecular Medicine.,7(9), 1153-1165. ISSN 1757-4676. IF: 8.665.
- **Surinova** et al. (2015, published online 2014), Prediction of colorectal cancer diagnosis based on circulating plasma proteins EMBO Molecular Medicine. 7(9), 1166-1178. ISSN 1757-4676 . IF: 8.665.
- **Tiwari** et al. (2015), Association between diastolic dysfunction and future atrial fibrillation in the Tromsø Study from 1994 to 2010. Heart. pii: heartjnl-2015-307438. doi: 10.1136/heartjnl-2015-307438. [Epub ahead of print]
- **van Ommen** et al. (2015), BBMRI-ERIC as a resource for pharmaceutical and life science industries: the development of biobank-based Expert Centres. Eur J Hum Genet. 23(7):893-900.
- **Wilbom** et al. (2015), Investigation of established

genetic risk variants for glioma in pre-diagnostic samples from a population-based nested case control study. Cancer Epidemiol Biomarkers Prev.. pii: cebp.1106.2014.

- **Wilsgaard** et al. (2015), Cardiovascular health and the modifiable burden of incident myocardial infarction: the Tromsø Study. BMC Public Health.;15:221. doi: 10.1186/s12889-015-1573-0.
- **Wilsgaard** et al. (2015), Clinically significant novel biomarkers for prediction of first ever myocardial infarction: the Tromsø study. Circ Cardiovasc Genet. (2):363-71. doi: 10.1161/CIRCGENETICS.113.000630. Epub
- **Zayats** et al. (2015), Genome-wide analysis of attention deficit hyperactivity disorder in Norway. PLoS One.;10(4):e0122501. doi: 10.1371/journal.pone.0122501. eCollection.

PRESS REPORTS

selection

- **Nature Magazine: European medical research escapes stifling privacy laws (December 2015)**
- **Netzwert Magazine: Graz ist ‚City of Biobanking' (October 2015)**
- **CORDIS, UK joins the EU's biobanking research infrastructure (15 July 2015)**
- **H2020 Project Magazine: Adopting a Gateway for Health (July 2015)**
- **The Irish Times: New data protection rules threaten vital health research. (20 July 2015)**
- **Nature Magazine: Data overprotection. Draft European rules governing privacy threaten to hamper medical research. (23 June 2015)**
- **Biomedcentral.com: Developing a guideline to standardize the citation of bioresources in journal articles (CoBRA). (17 February 2015)**

COLLABORATION AGREEMENTS

To date, BBMRI-ERIC has signed agreements and Memoranda of Undertandings with

PRESENTATION OF NATIONAL/ORGANISATIONAL NODES

www.bbmri.at

www.bbmri.be

www.swissbiobanking.ch

www.ucy.ac.cy

www.recamo.cz/en/bbmri

www.bbmri.de

www.biobank.ee

www.bbmri.fi

www.biobanques.eu

biobank.bioacademy.gr

www.bbmri.it

www.um.edu.mt/biobank

www.bbmri.nl

www.ntnu.edu/biobanknorway

forthcoming

www.bbmri.se

www.biobank.gen.tr

www.biobankinguk.org

www.iarc.fr

BBMRI.at

National Node Director: Kurt Zatloukal
Web: www.bbmri.at
Staff: 7.5 FTE/year
Funding: €3.5 million over a five-year period
Joined BBMRI-ERIC: 2013
Number of biobanks and stand-alone collections as specified in Directory 2.0: 4

BBMRI.at
Biobanking and BioMolecular resources Research Infrastructure Austria

About: BBMRI.at is comprised of Austrian biobanks, biomolecular resources, biocomputing and sample storage infrastructure complemented by scientific, technical, ethical and legal expertise. With its partner universities and biobanks, BBMRI.at establishes and further develops the Austrian biobanking research infrastructure and integrates it into BBMRI-ERIC. BBMRI.at is funded by the Federal Minstry of Science, Research and Economy, BMWFW (GZ 10.470/0016-II/3/2013).

Partners: Medical University of Graz (lead) with the Biobank Graz, Medical University of Vienna with the MedUniWien Biobank, Medical University of Innsbruck (MUI) with the MUI Biobanks, University of Veterinary Medicine with the VetCore and VetBiobank (Vienna), Paracelsus Medical Private University, with its biobank (Salzburg), Life Science Governance Institute (Vienna), and Alpen-Adria-University Klagenfurt.

National Roadmap: BBMRI-ERIC is, among other European Strategy Forum on Research Infrastructure (ESFRI) infrastructures, part of the Austrian Research Infrastructure Action Plan 2014-2020 (published in 2014) with committed funding of €3.5 million over a five-year period (2013-2018).

Specific strength: Sample, data and quality management, public engagement, impact on academia, industry and translational science. Special expertise with respect to CEN/TC Technical Specifications (CEN/TS) and related standards (e.g., board member of CEN/TC 140, consortium partner in SPIDIA [13]) (development of a self-assessment tool for conformity with CEN/TC, courses on CEN/TS implementation [14]), and Citizen Expert Panels. BBMRI.at has one of the largest biobanks in Europe in its infrastructure (Biobank Graz [15]) and is among the few National Nodes to have non-human/animal biospecimens and data (VetBiobank [16]). BBMRI.at is the local host for the Europe Biobank Week in 2016, which is jointly organised by BBMRI-ERIC together with ESBB (European, Middle Eastern & Africa Society for Biopreservation & Biobanking) (replacing the HandsOn: Biobanks Conferences). In data management, BBMRI.at currently elaborated a concept for ‚Infrastructure for the Management of Medical and Patient-related Research Data: Upgrade of BBMRI-ERIC' (consider ‚Juncker Package') [17].

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure: BBMRI.at has already designed

and implemented a BBMRI.at Catalogue of Austrian Biobanks in 2014. It contains data of all four BBMRI.at-associated biobanks and some of their collections. When the BBMRI-ERIC Directory 1.0 went public in mid-2015, BBMRI.at's catalogue was among the first ones to be included.

Quality: BBMRI.at biobank partners have nominated Quality Management (QM) coordinators, whose tasks are to support the local biobank management in developing a QM system (wherever not yet in place) and/or maintain and improve the system, as well as facilitate the harmonisation with systems of other consortium partners. QM coordinators attended trainings for internal QM auditors. They were trained on the structure of QM systems exemplified by the international QM standard ISO EN OENORM 9001:2008 and on its biobank-specific interpretation. QM coordinators recorded their local quality-related activities (organisational structures, process landscapes, documented procedures required according to ISO 9001:2008) and made them available to other BBMRI.at partners as well as in the BBMRI.at online knowledge base. This collection constitutes a basis for future harmonisation strategies. Moreover, BBMRI.at aims to establish a vivid culture of mutual quality assessments in the framework of cross-locational internal audits within the consortium. With respect to sample quality and harmonisation within BBMRI-associated biobanks, BBMRI.at started the process of harmonising preanalytical procedures. An evaluation of the current analytical procedures in all biobanks was performed and the conformity with international guidelines was analysed. BBMRI.at decided to use the CEN/TC technical specifications as a ‚guideline', as they are currently being integrated into the new ISO standards by ISO212 and ISO276 and will become the main reference for assessing sample quality. In order to structure and facilitate the evaluation process BBMRI.at developed a digital ‚Self-Assessment Tool for Conformity with the Standards'. This tool will be provided to the BBMRI-ERIC community in 2016 and will be evaluated and further developed within the BBMRI-ERIC QM Expert Group.

Clinical Biobanks: All BBMRI.at-associated biobanks with human samples are clinical biobanks located in medical universities in a hospital environment. In 2015, BBMRI.at contributed to the Work Stream ‚Clinical Biobanks': Biobank Graz confirmed its willingness to join the pilot project on breast cancer samples which, at a later stage, changed to colon cancer samples. BBMRI.at also became an integral part of ADOPT BBMRI-ERIC.

[13] http://www.spidia.eu

[14] http://bbmri.at/news/-/asset_publisher/xLKisOx4tBQH/content/successful-pre-analytical-sample-processing-in-biobanking-course-held-by-bbmri-at-in-grazhttp://bbmri.at/news/-/asset_publisher/xLKisOx4tBQH/content/2-bbmri-at-pre-analytics-course-held

[15] http://www.medunigraz.at/strategische-projekte/biobank/

[16] https://www.vetmeduni.ac.at/de/vetcore/research-units/research-units/vetbiobank/

[17] http://bbmri.at/documents/10194/13518/Brochure_InvestingInEurope+%28BBMRI+%26+Juncker%29.pdf/4b39b-d5c-fb35-46bd-a65b-07ffbf2a23cc

Population-based Cohorts: BBMRI.at-associated biobanks are clinical biobanks in hospital setting that are mainly disease-orientated.
There is no classical population-based biobank within BBMRI.at. However, the MedUniWien Biobank and the Biobank Graz have some smaller population-based cohorts.

ELSI: In 2015, BBMRI.at continued its reflection of governance processes of European biobanks, as well as its empirical work in the field of public engagement in Austria via Citizen Expert Panels [18]. Data from the Citizen Expert Panels will also be of relevance for the Common Service ELSI. Furthermore, BBMRI.at has generated informed consent templates for human and animal biomaterial respectively in a joint effort between the legal departments of all BBMRI.at medical university partners, the Intellectual Property Agreement Guide (IPAG), the Wissenstransferzentrum WTZ-Ost and the ncp-ip (expected 2016).

Expert Centres: BBMRI.at supported the application of CBmed GmbH [19] for becoming a BBMRI-ERIC Associated Expert Centre/Trusted Partner. CBmed GmbH is an Austrian competence centre for biomarker research in medicine located at the Medical University Graz. It has special emphasis on identifying new biomarkers, validating potential biomarkers and conducting translational biomarker research for products to be used in the clinical practice. The BBMRI.at-associated Biobank Graz, one of the largest biobanks in Europe, is one of the partners of CBmed.

Education & Training: BBMRI.at partners offered several education and training courses at local, national and international levels in 2015: a Pre-Analytical Sample Processing Laboratory Course (Med Uni Graz, Pathology, February 2015), How to build a biobank – learning by doing (Med Uni Graz, Biobank Graz, September 2015) - list not exhaustive.

[18] These are discussion events with experts, citizens and patients about topics arising in the context of biobanking and research using patient samples and data. In comparison to 2014, the panels have shifted their focus to questions on informed consent and public engagement.
[19] http://www.cbmed.org/en/about-cbmed.php

BBMRI.be

National Node Director: Karin Hausterman

Web: www.bbmri.be

Staff: 3.5 FTE

National Node Director: 1 FTE/year

ELSI Expert: 0.125 FTE/year (secondment BBMRI-ERIC)

IT expert: 0.1 FTE/year (funded by ADOPT BBMRI-ERIC)

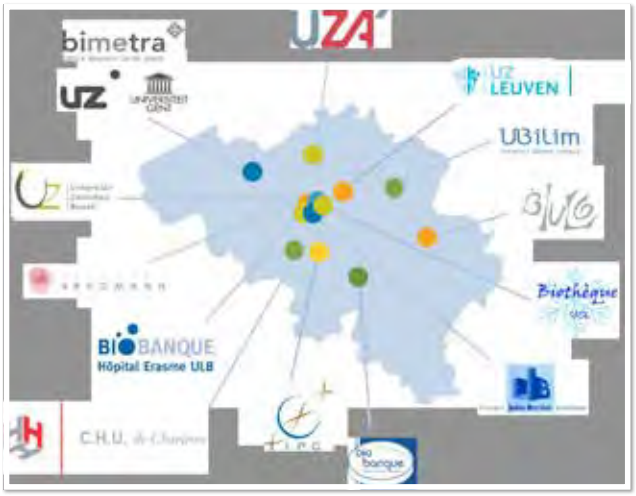
Tasks distributed among other BBMRI.be members (n= 26): +/- 2 FTE/year

Funding: BVT-BCR & 11 local partner biobanks receive funding from the Belgian Ministry of Public Health from 2009 on for an indefinite period. BWB is supported by DG06 (Walloon region) & Innoviris (Brussels capital region). The Flemish Biobank Initiative is financed by IWT: Agentschap Innoveren en Ondernemen (Flanders Innovation and Enterpreneurship) & by the Flemish Government.

Joined BBMRI-ERIC: 2013

Number of biobanks and stand-alone collections as specified in Directory 2.0: 13

About: The scientific participation of Belgium 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 i.e. Belgian Virtual Tumourbank project assigned to the Belgian Cancer Registry (BVT-BCR; Federal Initiative), Bibliothèque de la Fédération Wallonie-Bruxelles (BWB; Walloon Initiative) and the Flemish Biobank Network (Flemish Initiative). Together, this network connects 13 biobanks that are linked to public institutions such as hospitals, universities and research centres.



Partners: University Hospital of Ghent, University Hospital of Antwerp, St-Luc University Hospital, University Hospital Brussels, University Hospital Leuven, University Hospital of Liège, University Hospital of Mont-Godinne, St-Pierre University Hospital, Erasme Hospital, Brugmann University Hospital, Jules Bordet Institute, University of Hasselt, University Hospital Charleroi. Belgian Ministry for Social Affairs and Public Health, Belgian Science Policy Office (BELSPO), DG06-SPW: Fédération Wallonie-Bruxelles, Service public de Wallonie - Direction générale opérationnelle de l'Economie, de l'Emploi & de la Recherche (DG06) (General Operational Directorate for Economy, Employment and Research of the Walloon Government), EWI: Economie, Wetenschap & Innovatie (Department of Economy, Science and Innovation of the Flemish Government), INNOVIRIS: Instituut ter bevordering van het wetenschappelijk onderzoek en innovatie van het Brussels Hoofdstedelijk Gewest. (Brussels Institute for Research and Innovation), BWB, Belgian Cancer Registry, Flemish Biobank Network, RIZIV/INAMI: Rijksinstituut voor ziekte- en invaliditeitsverzekering / l'institut national d'assurance maladie invalidité (National Institute for Health and Disability Insurance), Agentschap Ondernemen, FWO+: Fonds Wetenschappelijk Onderzoek (The Research Foundation – Flanders), FNRS: Fonds de la Recherche Scientificque (Funds for Scientific Research).

National Roadmap: The 2014-2016 Belgian Roadmap for Research Infrastructures follows the Belgian political structure. It includes research institutions that are organised and funded on a regional and language community basis and Federal Research Institutions funded at the federal level. The participation of all these research institutes and the Belgian financial contribution to the ESFRI (European Strategy Forum on Research Infrastructure) infrastructures is coordinated by the Commission for International Cooperation (CIS-INFRA) workgroup managed by the Belgian Science Policy Office. This commission groups together representatives of the federated entities (regions and communities) and the federal level of Belgium. The CIS-INFRA workgroup has approved the participation in 11 ESFRI infrastructures including BBMRI; the participation in five other ESFRI infrastructures depends on the progress of these projects at EU level.

Specific strength: BBMRI.be has a high number of clinical biobanks with high quality samples and associated data available. At the moment, two of the three networks from BBMRI.be have an operational sample locator with sample-level data available; one with oncological samples (BVT) and one with biobanks focussing on different diseases e.g., sudden cardiac death, hepatotropic viruses, diabetes, inflammatory bowel disease, rheumatoid arthritis (Flemish Biobank Network). The third network (BWB) is currently developing such a sample locator. Due to the experience with sample locators, BBMRI.be can give valuable input on the development of the e-infrastructure of BBMRI-ERIC. The broad expertise among the BBMRI.be members, the sample and data availability in different disease areas and the central location in Europe greatly facilitate collaborations with other European partners.

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure: Directory 1.0 & Directory 2.0: BBMRI.be representatives collected the information from the different Belgian biobanks for the Directory 1.0 and set up the LDAP system in BBMRI.be that connects to the BBMRI-ERIC platform. After the launch of the Directory 1.0, a data curation was undertaken by BBMRI.be followed by the collection of additional data for the Directory 2.0 (launched in November 2015).

Quality: BBMRI.be representatives have reviewed several of the ISO/TC 276 Biotechnology documents distributed by BBMRI-ERIC. At the end of 2015, BBMRI.be has nominated ten quality experts to participate in the joint evaluation by BBMRI-ERIC of the recently published CEN/Technical Specifications for pre-examination processes and existing Guidelines/ Best Practices and Standards for biobanks.

Clinical Biobanks: BBMRI.be representatives have been involved in the Working Group Clinical Biobanks from the beginning (September 2014). At the TMF workshop in Berlin (February 2015), the national biobank registries available in Belgium were presented. Eight Belgian biobanks have confirmed their interest in participation in the colon cancer pilot project that is part of ADOPT BBMRI-ERIC (Work Package 2).

Population-based Cohorts: -

ELSI: Belgium participates in the Common Service ELSI with an appointed Executive Board member (Isabelle Salmon) and a seconded ELSI expert (Araceli Diez-Fraile). Additional BBMRI.be members are contributing to the assigned tasks and attending ELSI meetings.

Expert Centres: -

Education & Training: During 2015, representatives of BBMRI.be attended two teleconferences and information on all available biobank-related courses in Belgium were collected.

BBMRI.ch

National Node Director: Christine Currat
(from November 2015)
Web: www.swissbiobanking.ch/
Staff: 2.3 FTE/year in 2015, then it will be increased during 2016 to 4.4 FTE in the central office and 3.0 FTE in University Hospitals
Funding: CHF 3.2 million for 4 years
Joined BBMRI-ERIC: 2013
Number of biobanks and stand-alone collections as specified in Directory 2.0: not yet

About: The Swiss Biobanking Platform (SBP) is the newly created national coordination platform for human and non-human biobanks. It was initiated by the Swiss National Science Foundation (SNSF) in response to increasing requests from biomedical researchers regarding quality and interconnectedness of biobanks for research purposes. SBP's vision is to help Switzerland consolidate its position at the forefront of biomedical research by facilitating access and optimal usage of its existing and future biobanked specimens. SBP mission is to develop a reliable customer-oriented network of biobanks in Switzerland with harmonised processes.

BBMRI.ch
Biobanking and
BioMolecular resources
Research Infrastructure
Switzerland

Partners: The five University Hospitals from Basel, Bern, Geneva, Lausanne and Zürich, Swiss Tropical and Public Health Institute, Vetsuisse, as well as many other Swiss organisations related to research activities (SCTO, SAMW, FOPH, …).

National Roadmap: To that end, SBP shall attain the following objectives in the next 3 years:

- Setup of a professional organisation in close collaboration with the 5 University Hospitals.
- Creation of a central web-based catalogue of biobanks with data and samples' access policies.
- Integration of non-human biobanks.
- Coordination and harmonisation of biobanking activities.
- Support in terms of legal, ethical and societal issues (ELSI).
- Implementation of a proof of concept study for the credibility of the platform.
- Representation and evolution as the Swiss node in the BBMRI network.
- Development of a SBP business model for its sustainable funding.

Specific strength: General consent, human genetic biobanks, population-based cohorts, hospital based cohorts, quality management and biobank sustainability.

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure: The creation of a biobank register, then the development of a dynamic catalogue of biobanks is one of the priorities of the SBP to promote access and usage of existing biobanks. In parallel, access and benefit sharing guidelines shall be proposed. Then, a major challenge is also interconnection of existing biobank management systems as well as promoting a dedicated Laboratory Information Management System (LIMS) integrating not only the collection of samples and data, but also the returns of research results.

Quality: The development of the Swiss Biobanking Platform will be done based on the fact that sample quality is the cornerstone of a biobank's reputation. Thus, providing access to multiple Swiss biobanks could only occur when the quality of samples as well as a quality management strategy will be well documented to respond to the researcher's needs and to become a reliable platform.

Clinical Biobanks:

Population-based Cohorts: The construction of the Swiss Biobanking Platform will not only aim at promoting the existing biobanks, but also at promoting a reference cohort with both volunteers and patients' samples and data for research and for human biomonitoring purposes.

ELSI: The development of a Swiss general consent and biobank consent template will be established as well as the harmonisation of general consent implementation with best practices. These should not only include the process, but need to come with guidance on the right to know about potential returns of results in society, on supporting practitioners, and on a facilitated process for a research project's submission to ethics committees.

Expert Centres: -

Education & Training: In Switzerland, training and education on biobanks is insufficient and needs to be improved not only with regard to ELSI issues, but also to issues of quality and biobank management.

BBMRI.cz

National Node Director: Dalibor Valik
Web: www.bbmri.cz
Staff: 3.75 FTE/119 workers per the network plus hospital-affiliated specialist staff
Funding: -
Joined BBMRI-ERIC: 2013
Number of biobanks and stand-alone collections as specified in Directory 2.0: 5

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 Regional Centre for Applied Molecular Oncology (RECAMO).

Partners: First Faculty of Medicine of Charles University in Prague, Faculty of Medicine of Charles University in Hradec Králové, Faculty of Medicine of Charles University in Plzeň, Faculty of Medicine of Palacký University in Olomouc

National Roadmap: Using standardised procedures, BBMRI.cz collects, processes and stores human-derived biospecimens (such as primary tumour tissues and other relevant specimens) that would be otherwise irreversibly lost. Such biospecimens are of critical importance for either existing or future research projects and for patient benefit as well. In the Czech Republic, BBMRI.cz not only organises a dedicated set of cancer-oriented biorepositories, but also operates a unique set of technologies and knowledge to perform clinical applications of translational research including clinical trials. The user community may take advantage of the expertise of the BBMRI.cz qualified staff as well as resources archived in biorepositories. BBMRI.cz represents a Czech National Node of BBMRI and has been a member of the BBMRI-ERIC since 2013.

Specific strength: BBMRI.cz's development plan comprises taking 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. At the academia-industry interface, BBMRI.cz will increase its role as a leading

partner for innovative industrial activities to enhance introduction of new potential medicinal products to better serve the patient community in the country. Direct socio-economic impact of BBMRI.cz pertains to activities defining key documents of national health policies 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. Search for relevant biomarkers specific for certain disease using archived human tissues is a critical component in the design of innovative medicinal products and diagnostic procedures in human diseases.

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure: Activities focused on three basic areas in 2015: (1) connection of 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 (similar to the sample/data negotiator of BBMRI-ERIC), in particular based on feedback of biobank operativeness; (3) involvement of the infrastructure into BBMRI-ERIC IT infrastructure.
Beside the connection to national partners the integration efforts towards the established BBMRI-ERIC infrastructure was carried out. The information about Czech biobanks was migrated to the Directory service.

Quality: The source laboratories for BBMRI.cz (i.e. the labs where a part of patient biological material for biobanking storage is sampled) are currently accredited either by CAI according to the ISO 15189 standard or accredited by NASKL according to the ISO standard 15189. Qualified medical staff supervise the biobanking and sampling processes.

Clinical Biobanks: The overall research infrastructure is realised through the organisational structures of partner institutions as described [20].

Population-based Cohorts: At present, BBMRI.cz primarily focuses on cancer research.

ELSI: BBMRI.cz has nominated an expert to the Common Service ELSI.

Expert Centres: The institution utilises the infrastructure either for a) staff training (i.e. how to process human material for biobanking purposes) or b) the source of stored material for collaborative projects. The National Node and partner institutions participate in addition to BBMRI.cz activities also in a number of international cooperations aiming at the development of biological and medical research, which may apply to the BBMRI-ERIC Expert Centre / Trusted Partners.

ELSI: -

Education & Training: Students take advantage of expertise of staff linked to LI (pathologists, molecular biologists, and experts in laboratory medicine (1), of subject of choice or other special educational activities focused on biobanking (2). We support the education of IT students – they represent pilot students at the interface of IT services and medical activities – we intend this expertise to evolve to the ‚school of interdisciplinary medical collaboration'.

[20] The overall organisational concept and BBMRI_CZ system implementation was described and published in ‚The biobanking research infrastructure BBMRI_CZ: a critical tool to enhance translational cancer research.' Holub P, Greplova K, Knoflickova D, Nenutil R, Valik D. Klin Onkol. 2012;25 Suppl 2:2S78-81.

BBMRI.de

National Node Director: Michael Hummel
Web: www.bbmri.de
Staff: 2.5 FTE/year
Funding: -
Joined BBMRI-ERIC: 2013
Number of biobanks and stand-alone collections as specified in Directory 2.0: 10

About: The German Biobank Node (GBN/BBMRI.de) is the central contact and exchange point for the German biobank community - not only for researchers, but also for politics, media, and representatives of patients, industry and funding institutions. In addition, GBN represents Germany within BBMRI-ERIC. The GBN started at the end of 2013 as a project funded by the Federal Ministry for Education and Research (BMBF). According to the idea of this project, GBN represents the German national biobank community in the Management Committee of BBMRI-ERIC and functions as the national hub for BBMRI-ERIC. The GBN project consists of four work packages with the central office at Charité in Berlin and contributions to IT infrastructure, Quality Management and ELSI or engagement activities by various national experts. In the first funding period of three years, the primary goal for GBN is the establishment of the central office and the representation of Germany within BBMRI-ERIC. In addition, concepts for the tasks of the work packages are being developed. These concepts for IT networking, for quality assurance and for public relations will lay the basis for implementing a GBN that enables an efficient and broad interaction at the national and international level.

Partners: The establishment of central biomaterial banks was realised in the last five years at five university hospitals based on the funding of the German Federal Ministry for Education and Research (BMBF). In parallel, many university hospitals started to build up very comparable centralised biobank structure with internal resources. This important structural installation goes along with the set-up of local IT infrastructures to handle and to link these biomaterials to associated medical information. In parallel, six German Centres for Health Research have been established, all of which are involved in biobanking. Moreover population-based biobanking was boosted by a huge initiative (‚National Cohort') to collect many biomaterials and metadata from 200,000 German citizens. Since 2013 a platform for the German biobank community under the umbrella of the TMF was established for continuous exchange. A biobank registry was launched in 2012, which provides an overview over many national activities of more than 100 biobanks. Also since 2012 an annual national biobanking symposium takes place in Berlin where all stakeholders discuss over two days relevant biobanking issues.

National Roadmap: the BMBF has decided to prioritise the cooperation with BBMRI and consequently to become a member of BBMRI-ERIC. To this end, GBN was established as a National Node for BBMRI and provided with funding since 2013. In order to reinforce the position of the German biobanks within the European research infrastructure BBMRI-ERIC and to facilitate the exchange of samples and data across

Europe, the German government launched a call for tender in late 2015 for a German Biobank Alliance, which is currently undergoing the review process. The intention of this new call is to implement the concepts created in the first funding period of GBN together with a number of selected national biobanks.

Specific Strength: -

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure: The coordinator of bbmri.de, Michael Hummel, is also the Director of the Common Service IT and therefore intensely involved in all ongoing IT activities of BBMRI-ERIC. Two research groups are involved: Frank Ückert and his team at the Deutsches Krebsforschungszentrum (DKFZ) in Heidelberg are responsible for the sample locator and negotiator; Hans-Ulrich Prokosch and his team form the University of Erlangen work on ontology mapping.

Quality: A close cooperation with the BBMRI-ERIC activities (QM-manager Andrea Wutte) and the international standardisation activities (ISO and CEN) is already established. Several German experts are involved in the working groups of the QM-CEN standardisation process; Bettina Meinung from the University of Jena is co-chair of BBMRI-ERIC Expert Working Group 5 QMS. Michael Kiehntopf from Jena is very active in relation to ISO standards as well as Karl-Friedrich Becker from Munich.

Clinical Biobanks: Michael Hummel is chair of the Working Group Clinical Biobanking. In September 2014 bbmri.de hosted a workshop on clinical biobanking with more than 30 participants to prepare the ‚Work Programme 2015'.

Population-based Cohorts: Major population-based cohorts are the German National Cohort [21], KORA-Cooperative Health Research in the Region of Augsburg [22] and POPGEN in Kiel. The first two are also part of BBMRI-LPC: Erich Wichmann (IMSE, Munich) is principal investigator of the Work Package 4 ‚transnational access'. Work Package 4 provides the financial support to provide access to biospecimen and associated data of participating cohorts ‚free of charge' for selected scientific projects. Cohorts are reimbursed for their efforts, to this end a tool is developed to calculate costs in population-based cohorts aiming at reimbursement of cohorts for access to their sample and data. An extension of the existing BBMRI catalogue for population-based cohorts is also part of Work Package 4. In addition, the Helmholtz Institute in

Munich (Melanie Waldenberger at AME/HMGU) participates in Work Package 8 ‚access to upgraded data' by generating expanded data sets from genotyping and metabolome analysis of samples from participating cohorts.

ELSI: For the Common Service ELSI, GBN is playing a very active role in the development and setting-up the services. Two persons are involved for GBN: Irene Schlünder (Berlin) as a lawyer and Roland Jahns (Würzburg) for ethical aspects. Irene Schlünder as part of the Common Service ELSI team is active in several tasks: She is member of the task force GDPR dealing with the impact of the new data protection regulation on biobanking; she co-chairs the task force to monitor international organisations (e.g., WMA, OECD) preparing new laws, recommendations, and guidelines; she chairs the task force ‚tool integration' which aims to integrate ELSI tools (such as hSERN, LAT, Legal Wiki) already being developed in previous projects and which will be used in the context of the Common Service ELSI help desk; and she works in several working groups of Coordinated Research Infrastructures Building Enduring Life-science services (CORBEL) e.g., to develop a consent template.

Expert Centres: -

Education & Training: -

[21] http://nako.de | [22] http://www.helmholtz-muenchen.de/kora

BBMRI.ee

National Node Director: Andres Metspalu
Web: www.biobank.ee
Staff: 0,3 FTE/year
Funding: Estonian Roadmap grant no 3.2.0304.11-0312
Joined BBMRI-ERIC: 2013
Number of biobanks and stand-alone collections as specified in Directory 2.0: 7

About: 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 National Node. The Estonian Genome Center is a research institute of the University of Tartu with a population-based, prospective and longitudinal biobank the Estonian 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, close to 52,000, represents a large proportion, 5%, of the Estonian adult population, making it ideally suited to population-based studies. General practitioners (GPs) and medical personnel in the special recruitment offices have recruited participants throughout the country [23]. There is a significant amount of molecular phenotyping data, but also the possibility to recontact gene donors is a very valuable option. The data are continuously updated through periodical linking to national electronic databases and registries. A part of the cohort has been recontacted for follow-up purposes and resampling, and targeted invitations are possible for specific purposes, for example people with a specific diagnosis. The Estonian Genome Center of the University of Tartu is actively collaborating with many universities, research institutes and consortia and encourages fellow scientists worldwide to co-initiate new academic or industrial joint projects with us [24]. 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. An aim of the EGCUT is to facilitate the development of personalised medicine in Estonia by implementing the genomic data among all other medically relevant information of the patient in medical care. The biobank is actively used by researchers worldwide with hundreds of projects underway. Data sharing is flexible and all legal and societal issues of biobanking are well covered by the special law: The Human Genes Research Act of Estonia. The funding for the Estonian Biobank is provided from the Estonian Government through the budgets of the Ministry of Social Affairs and the Ministry of Education and

[23] http://www.geenivaramu.ee/for-scientists/data-release/
[24] Leitsalu et al.Int J Epidemiol 2015

Research, and various international grants from the European Commission and elsewhere.

Partners: Estonian Ministry of Education and Research, Estonian Genome Center, University of Tartu

National Roadmap: In Estonia, the national node activities were funded by a grant of the Estonian Center for Genomics (Estonian Roadmap grant no 3.2.0304.11-0312) between 2011-2015. The funding for the second period is also confirmed, but the Node activities are not supported any more from the roadmap grant. The three key activities of the grant Estonian Centre for Genomics (ECG) in the first period were: a) Upgrade the existing genotyping and sequencing core facilities to the level of European expert centres in the context of ERIC and ensure their sustainable development in future. In doing so, we are building comprehensive technological platform for life sciences in general which shall be matched with the respective investment in computational capabilities. b) Ensuring the constant development of the EGC Biobank as one of the cornerstones of the ECG by regular follow-up of gene donors' health status by linking national registers and assembling high-density SNP maps and full genome sequences. c) Coordination and participation in scientific endeavours on Estonian, European and world-wide levels, contributing to the training of young scientists and participation in projects together with entrepreneurs.

Specific strength: Estonian Genome Center is not just a population-based biobank, but also a leading research institution in the field of genomics consisting of three workgroups: biostatistics (head is Krista Fischer), bioinformatics (head is Reedik Mägi) and genomics (head is Tõnu Esko). There is a team of 51 people (40 FTE) working at the research unit, at the biobank and at the sequencing and genotyping core lab (head is Lili Milani) and support staff. One of the strengths is the transparent and simple access rule to biobank samples and data, but also the national law (Human Genes Research Act [25]) that regulates management of sample collections and biobanks in Estonia.

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure: Estonia has provided the data about local biobanks and sample collections to BBMRI-ERIC databases. According to the tasks in the ADOPT BBMRI-ERIC grant we will help with validating the new algorithms for performing fine search in new databases.

Quality: EGCUT is using ISO 9001-2008 and the sequencing and genotyping core lab is Illumina CSPro (Certified Service Provider). All biological samples have been collected and processed while following standardised Lab Information Management System (LIMS) -assisted protocols with various checkpoints, and are stored in LN2 within 72 hours of blood drawing. Furthermore: it is a training centre for Eastern European biobanks, and a model biobank, sharing its standard operating procedures (SOPs) widely.

Clinical Biobanks: We have had a number of translational medicine projects for studying cancer-related somatic mutations, gene expression and epigenetic changes in lung cancer, in cooperation with surgeons, oncologists and pathologists from Tartu University Hospital and North Estonia Regional Hospital.

[25] https://www.riigiteataja.ee/en/eli/531102013003/consolide

The traditional tumour tissue analysis has been lately complemented with the circulating tumour DNA analysis. Our lung cancer clinical cohorts currently consist of >200 surgery and >60 oncology patients. In addition, the EGCUT storage facility holds blood plasma, buffy coat and genomic DNA samples from over 100 individuals who have been later diagnosed with lung cancer, hence interesting for analysis of early cancer-related changes in the collected samples.

Population-based Cohorts: In order to map the institutions with a possible interest in biobanking, we have collected information from 117 different contacts, mostly from Eastern Europe. Among them, we have an overview of twelve cohorts in Estonia.

ELSI: The ELSI representative from the EGCUT has shared experiences regarding the consent and biobank legislation. The EGCUT has applied a broad consent form since the recruitment of biobank participants started in 2002. The Estonian Human Genes Research Act is a legislation that regulates maintenance and use of the biobank, as well as the recontacting of participants, permits retrieval of additional information from national registries, and gives participants the right to receive individual research results.

Expert Centres: -

Education & Training: As the Estonian node of BBMRI-ERIC, EGC is responsible for the training of emerging biobanks in the framework of the BBMRI-LPC project, it has become a learning centre for several Eastern European and Asian biobanks. There has been huge interest towards biobanking in Eastern Europe (Moldova, Georgia, Russia, Ukraine, Balkan countries, etc.), but also outside Europe and in quite prominent countries such as South Korea, Qatar, Vietnam, Japan, USA, India, etc. The Estonian node has mapped the training courses and lectures in MD and biotech curricula in Estonia that are connected with biobanking issues. As a result of the tasks in the BBMRI-LPC grant, the Estonian node has organised several educational events during the last 4 years.

BBMRI.fi

National Node Director: Anu Jalanko
Web: www.bbmri.fi
Staff: 2.5 FTE/year for network coordination
Funding: €3.4 million (2010-2013)
Joined BBMRI-ERIC: 2013
Number of biobanks and stand-alone collections as specified in Directory 2.0: 9

About: BBMRI.fi is a National Node of BBMRI and operates under collaboration between all of the nine national biobanks. It is an interface with the national Network of Biobanks and Biological resources and coordinates their activities with those of BBMRI-ERIC. Overall, BBMRI.fi aims to create an internationally leading biobank infrastructure providing strategic support to biomedical research, healthcare and the biomedical industry. The following working groups operate BBMRI.fi with participation from all the national biobanks:

- BBMRI.fi network coordination.
- Coordination of biobank IT infrastructure development.
- Harmonisation of activities within BBMRI.fi.
- Biobank quality issues.
- Ethical and legal issues.

Partners: Host Institute of National Node: National Institue for Health and Welfare (THL), Auria Biobank (University of Turku and hospital districts of Southwest Finland, Satakunta and Vaasa), THL Biobank (National Institute for Health and Welfare THL), FHRB Biobank (Finnish Hematology Registry, Finnish Red Cross Blood Service and FIMM), Helsinki (AMCH), Biobank (Hospital districts HUS, CAREA, Eksote and UH), Northern Finland Biobank Borealis (Oulu University Hospital, University of Oulu, NordLab and the healthcare districts of Kainuu, Lapland, Central Ostrobothnia and Länsi-Pohja), Tampere Biobank (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), Eastern Finland Biobank (Eastern Finland Biobank Initiative (Hospital District of Northern Savo, University of Eastern Finland, and Hospital Districts of Itä-Savo and Etelä-Savo and North Karelia Central Hospital and Honkalampi Centre), Central Finland Biobank (Central Finland Health Care District (KSSHP) and Univ. of Jyväskylä (UJ).

National Roadmap: The 2014-2018 Finnish Roadmap for Research Infrastructures includes 31 national research infrastructures, 18 of which are European Strategy Forum on Research Infrastructure (ESFRI) partnerships. The National Infrastructure Committee (FIRI) has nominated Finland for nine memberships within ESFRI infrastructures and BBMRI-ERIC is one of them. Academy of Finland (AoF) has funded building of BBMRI.fi with €3.4 million in 2010-2013. From 2014 onwards, AoF is committed to cover the BBMRI-ERIC membership fee and national coordination costs of €500,000/year and the AoF has also granted €800,000/year of competed funding for biobank equipment.

Specific strength: BBMRI.fi capitalises on the possibilities provided by the special strengths of Finland, having an excellent healthcare system, reliable health care registers, world-class population cohorts and clinical collections, genetically homogenous population, internationally recognised genetic research, high-quality epidemiology and clinical sciences as well as top ICT professionals. Most importantly, BBMRI.fi builds on the national network of biobank professionals and top-level scientists, representing areas like epidemiology, clinical practice, genetics, molecular biology, statistics and computer sciences. The Finnish Biobank Act provides a solid framework for efficient utilisation of samples and linked medical EHR (Electronic Health Records) and biological data for biobank research. For Hospital Districts, the biobank era will bring a variety of new operations and they are motivated to integrate the biobank to the hospital routine since it is foreseen to promote the high-quality of clinical research, novel solutions for clinical practice and public-private partnerships. The unique feature of BBMRI.fi includes the strong support of two ministries (Education and Health) and participation of all national biobanks to build the national biobank infrastructure. In addition, BBMRI.fi is one of the major players for implementing Growth strategy for research and innovation in the health sector by three ministries (the Ministry of Employment and the Economy, the Ministry of Social Affairs and Health, the Ministry of Education and Culture) with Tekes and the Academy of Finland. The Finnish approach and favorable regulatory framework for biobank-related samples and data is foreseen to serve as a model to other European BBMRI-ERIC Member States. This development would not have been possible without the joint commitment of all the major universities, hospital districts and THL. Currently, Finnish biobanks and their background organisations are planning for a strategy to unite to one organisation serving as a one-stop-shop.

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure: BBMRI.fi was actively involved in the planning phase of the Common Service IT by attending the preparatory meetings and writing the work plan. The Common Service started operations in late 2015 and the coordination is divided between Germany, Netherlands and Finland. BBMRI.fi participates actively in the Minimum Information About Biobank data Sharing (MIABIS) working group, together with other BBMRI-ERIC member countries. The goal of this working group is to further develop the Minimum Information About Biobank Data Sharing (MIABIS), to include standard attributes to describe different aspects of biobank data and samples. During 2015, the MIABIS Working Group defined the MIABIS 2.0 core version, which includes standard attributes describing biobanks, collections and studies. BBMRI.fi updated information on all Finnish biobanks into the BBMRI-ERIC Directory during 2015.

Quality: BBMRI.fi has been commenting the ISO/TC276 standard.

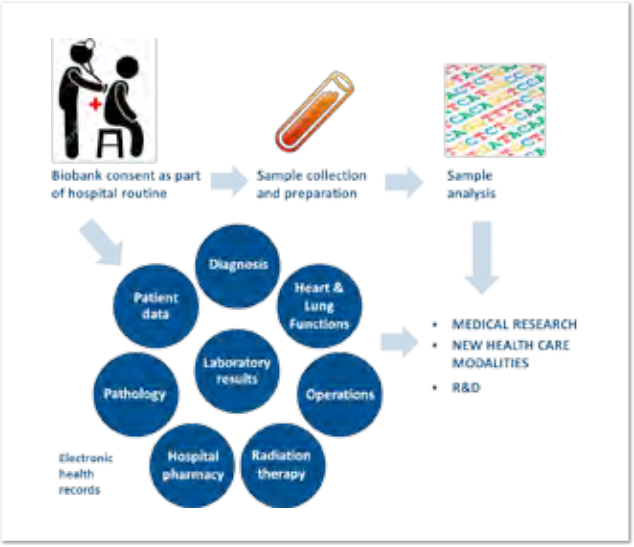
Clinical Biobanks: BBMRI.fi researchers have actively participated in planning of the BBMRI-ERIC collaboration of clinical biobanks. BBMRI.fi had a very active role in the planning phase of ADOPT-BBMRI-ERIC and BBMRI.fi researchers are actively participating in the implementation phase of the ADOPT BBMRI-ERIC proposal (Work Package 2) concerning the collection of the Colon Cancer dataset.

Population-based Cohorts: BBMRI.fi is closely linked to BBMRI-LPC [26], which is coordinated by Finland. In 2015, the BBMRI-LPC coordination team worked actively in collaboration with the BBMRI-ERIC headquarters in planning the integration of BBMRI-LPC activities into BBMRI-ERIC and this resulted in the BBMRI-ERIC work stream BBMRI-LPC.

ELSI: In 2015, the Finnish Common Service ELSI team participated in the initial meeting and the executive board meeting in connection with the HandsOn: Biobanks 2015 (to which BBMRI.fi contributed) as well as the first all-inclusive ELSI Workshop in Paris in September. A joint presentation with the French node on intellectual property rights was given. We participated in the preparation/commenting on the General Data Protection Regulation response and the BBMRI-ERIC ethics check process. We also provided example material for and commented on the LPC Material / Data Transfer Agreement. Within Finland, we promoted services in the Common Service ELSI and discussed topical ELSI subjects in a local workshop in December.

Expert Centres: Through the BBMRI-LPC project, Finland has been actively involved in the BBMRI-LPC – BBMRI-ERIC collaborative effort producing the published survey of the development of biobank-based Expert Centres [27]. In Finland, Auria and THL Biobanks have initiated significant public-private partnerships.

Education & Training: -



[26] http//www.bbmri-lpc.org | [27] van Ommen et al, 2015

BBMRI.fr

National Node Director: Georges Dagher
Web: www.biobanques.eu
Staff: 13 FTE/year
Funding: €17 million over a ten-year period (2011-2020)
Joined BBMRI-ERIC: 2013
Number of biobanks and stand-alone collections as specified in Directory 2.0: 89

About: : BIOBANQUES/BBMRI.fr is a distributed infrastructure dedicated to biomedical research. It aims to: (1) foster translational research and biomarkers development, (2) elicit national and international consortia and (2) develop public-private-partnerships. It builds on a landscape of 85 biobanks distributed all over France including disease-oriented studies and population-based cohorts. It covers the whole spectrum of human diseases with more than 700 on-going biological and clinical research programmes, 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.

Partners: All research institutes and hospitals as well as patient associations such as Institut national de la santé et de lat recherché médicale (Inserm), CNRS, Inra, Institut Pasteur, CEA, CNCR, Université claude Bernard (Lyon), GRAM.

National Roadmap: The 2012-2020 French Roadmap for Research Infrastructures includes three sets:

- Three long-term research infrastructures that have been built in the framework of international agreements.
- 18 very large research infrastructures including those of the ESFRI Research Infrastructures
- 45 research infrastructures, considered by national programmes.

The commitment for BBMRI-ERIC is part of the French research infrastructure roadmap with a committed funding of about €17 million over a ten-year period (2011-2020).

Specific strength:

The network of biobanks is active since 2000.

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure:

Participation to the MIABIS meetings.

Quality: In order to follow the contribution of biobanks to published results, BBMRI.fr has implemented the unique identifier for biobanks (Bioresource Research Impact Factor, BRIF) in all 85 biobanks in France. Additional key activities: Setting up and coordinating a Working Group at the international level (ISO TC 276) to develop a set of international standards for biobanks; training of Quality Managers (details below); one training session at the European

Organisation for Research and Treatment of Cancer (EORTC) in Brussels; advising biobanks on quality control and quality management issues; replying to 19 requests from biobanks including nine internal audits.

Clinical Biobanks:
Participation to clinical biobanks meetings.

Population-based Cohorts:
Participation in the BBMRI-LPC project.

ELSI: Active participation to the analysis and information related to the EU directive on data protection. National Workshops on (1) patient's informed consent in May (Paris), (2) contribution to the Workshop at the European Parliament on data protection in June (Brussels) and on sharing and access to data and human biospecimens for the benefits of patients in September (Paris) as well as on sharing science in December (Toulouse). Contributions to the public consultation of the European council draft declaration on health databases and biobanks.

Education & Training: Organisation of a master's course in biobanking in France. The University of Nice in partnership with the catholic University at Lyon delivers the diploma. Organising a Masters programme in quality management in collaboration with the Rennes University. Training of 33 Quality Managers to implement quality management in biobanks and training of four managers for cross auditing, one training session at the European Organisation for Research and Treatment of Cancer (EORTC) in Brussels, contribution to master's courses for lawyers, contribution to PhD courses for biomedical researchers and medical doctors.

Expert Centres: -

BBMRI.gr

National Node Director: Dimitris Thanos
Web: www.biobank.bioacademy.gr
Staff: 1.5 FTE/year
Funding: -
Joined BBMRI-ERIC: 2013
Number of biobanks and stand-alone collections as specified in Directory 2.0: 1

About: Creating a network of Greek biobanks and connecting them with the BBMRI-ERIC will allow faster integration of Greece to the European Research Area (ERA). The establishment of the Hellenic BBMRI Network will facilitate the integration of scientific resources from the neighboring countries, and will greatly upgrade the biomedical research in Greece and will allow for high quality collaborations in the field of translational medicine. It will also have major positive impact in the health services for Greek citizens and in the Greek economy. The Greek government assigned to the Biomedical Research Foundation of the Academy of Athens (BRFAA) the role of the coordinator of the BBMRI.gr, which is based on peripheral nodes all over the Greek territory.

Partners: National Node: Biomedical Research Foundation of the Academy of Athens, Athens (Contact person: Dimitris Thanos). Peripheral Nodes: University of Athens Medical School, Athens (Contact person: Efstratios Patsouris), Associated Biobanks: Anticancer Hospital ‚Metaxa', Athens (Contact person: Christos Valavanis), Evangelismos Hospital, Athens (Contact person: Theodora Papadaki) Centre for Research and Technology Hellas, Thessaloniki (Contact person: Kostas Stamatopoulos), University of Patras Medical School, Patras (Contact person: Nikolaos Moschonas), University of Crete Medical School, Herakleion and Foundation for Research and Technology, Hellas, Herakleion (Contact persons: John Souglakos and Dimitris Kafetzopoulos), University of Ioannina Medical School, Ioannina (Contact person: Evangellos Briasoulis), University of Thrace Medical School, Alexandroupolis (Contact person: George Kolios), University of Thessaly, Larissa (Contact person: Anastasios Germenis).

National Roadmap: INTEGRA-BIOMED is a sustainable, pan-Hellenic state of-the-art integrated platform of research infrastructures (BBMRI.gr, EATRIS.gr and ISBE.gr) serving biobanking, translational research and systems biology approaches. The aim of this ‚catalytic' clustering is to enhance research excellence in these areas and achieve functional optimisation which, in addition to economy of scale, will foster synergistic interactions and added value between these distributed RIs through effective management and coordination of nodes throughout Greece, and efficient storage and transfer of knowledge (electronic data; e-infrastructure). The objectives of INTEGRA-BIOMED are:

- To offer users a single centralised access-point to a large number of complementary research infrastructures, refined biological samples and cutting-edge specialised technologies using standardised and harmonised experimental procedures. This will forge effective partnerships between the users of both academia and industry (mainly

pharmaceutical and biotechnology companies).

- To allow the users to gain access to various complementary infrastructures acting in a synergistic fashion to: drive research projects effectively; increase research quality, while reducing redundancy; and effectively catalyse the identification of funding sources (public and private).
- To develop and deliver advanced training programmes meeting the current standards and needs.

The BBMRI.gr has already completed its preparatory phase and entered the construction phase. BBMRI.gr consists of a central node and 7 peripheral nodes (located in practically all Greek Medical Schools) collecting human biological specimens and biomolecular resources with detailed assorted information stored and processed electronically. BBMRI.gr is a member of BBMRI-ERIC. Researchers from academia, industry and SMEs will benefit from the effective networking and user/client matchmaking and specifically designed services provided under the auspices of INTEGRA-BIOMED. Streamlined services to execute projects in a timely and cost-effective fashion will be offered by highly trained research personnel with several types of complementary expertise.

Specific Strength: -

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure: -
Quality: -
Clinical Biobanks: -
Population-based Cohorts: -

ELSI: In order to address numerous ethical and legal issues on complicated matters such as the procedures of obtaining an informed consent of the subjects participating in a biobank research project, the ethical checks procedure of the research projects and the protection of the personal data of the participants/data subjects, a legal expert on bioethics and data protection has been hired to consult on relevant issues. Special focus has been given to the impact assessment that the new European Regulation on Data Protection will have in biobanking research and to the required steps to be prepared to adjust to the new rules by 2018, when the regulation will be set in force as part of the Greek national legislation.

Expert Centres: -

Education & Training: A member of the BBMRI.gr, Aristidis Charonis, participates in the education and training Working Group, which had two telephone conferences in 2015. This working group aims to develop a policy framework from Europe and beyond in the field of education and training for biobank employees and for the scientific community at large. So far, existing courses in Europe related to biobanking have been catalogued and discussed. A consensus on required skills is expected, in order to draft the first Education and Training Policy Document.

BBMRI.it

National Node Director: Marialuisa Lavitrano

Web: www.bbmri.it/home

Staff: Management Committee (Elena Bravo, Maria Grazia Daidone, Marialuisa Lavitrano, Luciano Milanesi, Angelo Paradiso, Barbara Parodi, Luca Sangiorgi, Giorgio Stanta), Secretariat (Alessia Calzolari, Mariarosaria Napolitano, Filippo Santoro, Laura Farina), Common Service Quality (Barbara Parodi, Paola Visconti) Common Service ELSI (Marialuisa Lavitrano, Sara Casati), Common Service IT (Luciano Milanesi, Matteo Gnocchi, Marco Moscatelli)

Funding: The Italian National Node of BBMRI (BBMRI.it) has been funded in a joint effort by the Ministry of Health and the Ministry of University and Research. From 2013 onwards, CNI-PNIR is committed to cover the BBMRI-ERIC membership fee and national coordination costs of €800,000/year.

Joined BBMRI-ERIC: 2013

Number of biobanks and stand-alone collections as specified in Directory 2.0: 69

About: BBMRI.it is a research infrastructure involving biobanks and biological resource centres located throughout Italy. BBMRI.it includes the National Institute of Health, CNR, 18 universities, 23 research hospitals (IRCCS), 40 hospitals, many associations of patients and 90 biobanks and bioresources centres organised in thematic networks and regional networks with matrix architecture.

Partners: -

National Roadmap: The Italian National Programme for Research Infrastructures (PNIR) includes 95 research infrastructures, of which 11 are global research infrastructures, 33 European research infrastructures and 51 national research infrastructures. To guarantee the long-term sustainability of the research infrastructures, Italy created a special fund (FUIR) of about €1,300 million for the 2014-2020 PNIR. The Strategic National Committee (CNI-PNIR) has established the membership of Italy in six ESFRI research infrastructures in the biomedical sector and BBMRI is one of them.

Specific strength: Number and quality of Italian biobanks link between biomedical research and clinical care in the IRCCS network, in close collaboration with patient associations, scientific societies and the bio-industries, matrix architecture of the Italian biobank network, collaboration with the Regional Authorities, thematic networks of excellence (e.g., Telethon Network of Genetic Biobanks), Network of Italian Pathology Archives Biobanks (NIPAB). Organised HandsOn: Biobanks 2015 (page 26).

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure: BBMRI.it has actively participated in the construction of the Directories 1.0 and 2.0. BBMRI.it has adapted the data structure of its portal in order to allow direct transfer of the data from Italian biobanks to the Directory 2.0, and continuously curates the update of information by the biobanks which belong to the infrastructure. BBMRI.it has set up the National IT Common Service. Objectives: Create and maintain the BBMRI.it portal, sustain the matrix

architecture of the network, offer services to the network, promote collaborative studies at the national and international level, guarantee the secure transfer of information, provide visibility to biobanks through the construction of a dedicated web page, adopt the BBMRI-ERIC standards and create the national IT infrastructure, and maintain the BBMRI Lexicon interface portal.

Quality: BBMRI.it has actively participated in the Work Plan Quality 2015. In particular, the ISO/TC 276 and ISO/TC 212 documents provided by BBMRI-ERIC were analysed in the frame of the National Nodes Quality Manager Working Group and comments were provided. BBMRI.it has already implemented an on-line self-evaluation tool, taking into account all parameters for compliance with the Partner Charter. BBMRI.it has offered its experience and has provided the questionnaire used and the procedure for assessment, to be discussed and adapted to the needs of the European research infrastructure. BBMRI.it coordinates the Bioresource Research Impact Factor (BRIF) Working Group which has identified the parameters allowing measuring the impact of bioresources on research with indicators of research productivity, of bioresource value, of workflow and efficiency. The procedure for biobank evaluation has been applied to the Italian biobanks willing to join the infrastructure. Also, a Common Service Quality has been implemented, with the objectives of monitoring biobanks and biomolecular resources, providing information on guidelines/best practices, harmonising operational procedures, developing criteria for biobank accreditation and certification of biobanks, implementing the quality management criteria of BBMRI-ERIC, improving interoperability, and promoting training activities.

Clinical Biobanks: BBMRI.it includes a large community of researchers implicated in disease-oriented projects that relies on the use of collections of biological resources. These resources include among others: collections of frozen tissues, archive tissues (FFPE), liquid biopsies, immortalised cell lines, microbioma. BBMRI.it started a fruitful collaboration with the laboratory medicine community in order to identify critical steps in pre-analytical procedures and share quality assurance schemes with the ultimate goal of improving healthcare quality and safety for better patient care outcomes. BBMRI.it leads the Working Group on Archived Tissues constituted in September 2014. The Working Group aims at developing a BBMRI-ERIC Archived Tissue Network based on the hubs-and-spokes model. BBMRI.it leads the European Society of Radiology dedicated Working Group on Imaging Biobanks aimed at monitoring the existing imaging biobanks in Europe. Pathology archives of FFPE tissues compose the network as a virtual network to be developed in every BBMRI-ERIC member country. BBMRI.it promoted the Health Integrated Biobanking Working Group with a dedicated work stream to be included in the BBMRI-ERIC ‚Work Programme 2016'.

Population-based Cohorts: BBMRI.it participates in the BBMRI-LPC project with the Italian Network of Population Biobanks. It provides an added value to BBMRI-LPC in terms of expertise, reliable biospecimens and socio-demographic, clinical and epidemiological data on representative cohorts followed longitudinally of a large South European population.

Data and samples collected are extremely useful for biomarker studies at a European level, due to the peculiar characteristics of the Italian population, such as the long life expectancy and a large number of small isolated communities. The Italian network has already enrolled a total of more than 100,000 subjects in several ongoing studies, dealing with the genetics of ageing and longevity; the genetics of chronic diseases such as cancer, diabetes, cardiovascular disorders; geographically isolated populations, characterised by old settlement, small number of founders, high endogamy rates, slow/null population expansion; prospective cohorts. Most of the studies also participate in larger European and international initiatives.

ELSI: On the BBMRI.it website, we launched a public consultation to collect Italian comments on WMA declaration. This reinforced the participatory approach within Italy. Results were communicated to the Common Service ELSI. Equally so, the national biobanks contributed to the evaluation of the ethics check. Moreover, a national survey identified the most urgent ELSI issues: ownership and accessibility of data/results; good practice of informed consent with specific focus (minors and vulnerable people, the industrial use of materials, patenting, ...); good practice of biobanking from clinical studies; modeling a biobanking agreement with POs or specific communities. Ultimately, the Italian ELSI help desk is a service for all stakeholders, from biobanks to ethics committees and links to BBMRI-ERIC's Common Service ELSI.

Expert Centres: BBMRI.it started to develop the Archive Tissue Molecular Analysis (ATMA) platform as a technological hub to perform research projects to Accelerate Clinical Research with focus on Biomarker verification and validation. BBMRI.it is specialised in molecular analyses on archive tissue samples, thus is developing a technological hub where analysis of thousands of cases is possible in a short time. A formal application as Expert Centre/Trusted Partner is foreseen in 2016.

Education & Training: BBMRI.it actively participates in the BBMRI-ERIC Working Group Education & Training. BBMRI.it carries out training activities on site and has collaborated in the organisation of six courses on methods for cell culture, pre-analytical methods and molecular pathology in Italy and abroad.

BBMRI.mt

National Node Director: Alex Felice
Web: www.um.edu.mt/biobank
Staff: 1.5 FTE/year
Funding: Institutional Funds
Joined BBMRI-ERIC: 2013
Number of biobanks and stand-alone collections as specified in Directory 2.0: 1

About: The Malta BioBank forms part of the new inter-faculty Centre for Molecular Medicine and Bio-Banking at the University of Malta. It hosts the Maltese National Node (BBMRI.mt) in BBMRI-ERIC. The Malta BioBank is the first national archive of biological samples. It houses 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. The Malta BioBank is a founding partner in: EuroBioBank, RD-Connect and ITHANET.

Partners: Malta has one central biobank located at the University of Malta. The clinical catalogue holds a number of specific disease collections including: the Globin Bank; Parkinson's Disease; Diabetes; Multiple Sclerosis; Renal Disorders; various cancers including breast, colorectal, lung and gastric cancer, and a number of rare diseases.

National Roadmap: The RI landscape is slowly developing in Malta. In the health sector, the University of Malta has launched a new Centre for Molecular Medicine and Bio-banking that with the financial support of the Malta Council for Science and Technology and through the Malta Biobank is developing the Malta Human Genome Project. The voluntary sector has joined efforts in support of rare disease research through the Marigold Foundation to encourage the set up of a National Rare Disease Patient Registry and the National Alliance for Rare Diseases Support. A research co-operative is being setup whereby the donor of a sample is not only a participant of the study but also an owner of the research, thus a partner in the research.

Specific strength: Rare diseases, science communication and public engagement. The poster of BBMRI.mt on Thalassaemia Research won the HandsOn: Biobanks Poster Prize in 2015. Over the past four years, The Malta BioBank/BBMRI.mt was 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. Moreover, BBMRI.mt have also supported webcast courses in Medical Genetics and Next Generation Sequencing which are organised by the cooperation of the European Society of Human Genetics and the European School of Genetic Medicine in Bertinoro. These courses are webcast at the Malta Remote Training Centre of the ESGM, based at the University of Malta.

The courses are ideal for those starting their careers in Medical Genetics, both clinical and research.

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure: BBMRI.mt currently has an online catalogue which can be accessed from the EuroBioBank website. This catalogue will soon be hosted on the RD-Connect platform as partner in Work Package 3 ‚BioBank Catalogues'. Some collections available in the Malta BioBank will also be linked to patient registries on the RD-Connect platform.

Quality: BBMRI.mt has a quality management team which is developing the Quality Management System of the Malta BioBank. There are various experts which are participating in all five Working Groups to review the CEN/Technical standards for pre-examination processes and existing Guidelines and Best Practices and Standards appropriate for biobanks.

Clinical Biobanks: In 2015, BBMRI.mt setup and developed a rare renal disorder collection and will contribute to ADOPT-ERIC with a new colorectal cancer collection.

Population-based Cohorts: New funding for the Maltese Genome Project will further develop the Population Bank. A new Maltese population cohort (1% of the population ~4,000 samples) is being setup based on families.

ELSI: BBMRI.mt has an ELSI team which include various experts in: Ethics (Bridget Ellul -Department of Pathology, UoM, Pierre Mallia (Department of Family Medicine, UoM); Law (Ruth Vella Falzon – UoM Legal Office, Daniel Bianchi - Department of Law UoM, Alistair Degaetano – disability research) and Sociology (Gillian Martin, Department of Sociology, UoM).

Expert Centres: The Malta BioBank forms part of the new inter-faculty Centre for Molecular Medicine and BioBanking at the University of Malta. It may apply as Expert Centre/Trusted Partner.

Education & Training: BBMRI.mt has an Education Officer Nikolai Pace (Department of Anatomy, UoM). BBMRI.mt planned the second Euro-Mediterranean workshop in BioBanking at the University of Malta for 2016. Among other activities, BBMRI.mt planned a DegreePlus ten week course in: ‚Communication, Medicine and the Public Imagination' for the second semester of the academic year 2015-2016. The course debates biobanking and genomic research.

BBMRI-NL

National Node Director: Cisca Wijmenga and Gerrit Meijer (Scientific directors), Erna Erdtsieck-Ernste (Operational Manager), GertJan van Ommen (National Node liaison to BBMRI-ERIC)
Web: http://www.bbmri.nl
Staff: 14.2 FTE/year
Funding: BBMRI-NL has received 32.3 M€ Dutch governmental funding from 2009-2018.
Joined BBMRI-ERIC: 2013 (as a founding member)
Number of biobanks and stand-alone collections as specified in Directory 2.0: 189

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 & health research. BBMRI-NL enables the (re)-use of human samples, data and images, to advance biomedical research with compliance with ethical, legal and privacy demands and active participation of donors.
In 2009 the first phase of BBMRI-NL obtained 22.5 M€ Dutch governmental funding and in 2009-2015 successfully united >200 Dutch population and clinical biobanks, jointly containing materials and data from >900 000 individuals, 13 million biobanked samples, and a wide spectrum of accessory data. It laid the foundation for a well-organised national biobanking infrastructure for Dutch biomedical research for collecting, managing and distributing data, samples and imaging for personalised medicine and health research. In 2014, the second phase, BBMRI-NL 2.0, has received 9.8 M€ (2015-2018) to build a national infrastructure that integrates the full range of biobanking, population imaging and (translational) research IT activities in the Netherlands. BBMRI-NL 2.0 has the ambition to transform from an emerging infrastructure to a long-term, innovative and open-access national organisation, the NL Biobank Facility, for collection, accessibility and re-usability of data, imaging and samples for research and evidence-based studies on all aspects of personalised precision medicine and health research. For this purpose, BBMRI.nl will also link up with other national infrastructures and involve relevant stakeholders to develop a comprehensive national research infrastructure for personalised medicine and health. In addition, BBMRI-NL also plans to reach out to citizens, patients and other societal stakeholders, and building an IT infrastructure that makes all existing bio specimen accessible to all stakeholders. BBMRI-NL is partly financed by the Netherlands Organisation for Scientific Research (NWO).

Partners: 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, Dutch Institute for Clinical Auditing, PALGA, Netherlands Heart Institute, SURFsara, Dutch Techcentre for Life Sciences, Legal Pathways, The Hyve **Collaborations:** Co-applicants

to national roadmap grant: CTMM-TraIT & European Population Imaging Infrastructure (EPI2). Co-initiators of Health-RI (i.e. the comprehensive Dutch personalised medicine&health research infrastructure: Dutch Techcentre for Life Sciences (DTL), ELIXIR-NL, EATRIS-NL, Nederlandse Federatie van Universitair Medische Centra (NFU), Health-Holland. Other structural collaborations: FEDERA, Federatie Medisch Specialisten (FMS), Federatie van Technologiebranches (FHI), Integraal Kankercentrum Nederland (IKNL), Orphanet-NL. **BBMRI-NL-affiliated scientists and staff:** Researchers and staff of the BBMRI-NL partners (~1000 fte), researchers connected to >200 biobanks (~500 fte), scientists and staff on affiliated International, collaborative biobanking and epidemiological projects e.g., CORBEL, -BioShare, BBMRI-LPC, BioMedBridges, Neuromics, BioNMD, RD-Connect etc (~100 fte). Scientist and staff of large International consortia using the BBMRI-NL infrastructure e.g. the Michigan Imputation Server which includes the GoNl data as part of the new reference set, ENIGMA, MAGIC, CHARGE, GIANT, IMI-DIRECT etc. (~100 fte).

National Roadmap: The NL Roadmap has been updated in 2012, and the European ESFRI RI BBMRI was maintained from the previous Roadmap of 2009. In the funding round of 2014, in which no new RI were allowed to submit, BBMRI-NL (previously funded in 2009 with 22.5 million euro), teamed up with CTMM-TRaIT that aimed at developing start to end IT solutions for supporting translational research, and EPI2, aimed at developing population-oriented imaging. This effort was succesful, resulting in a 9.8 million Euro grant for the next 3 years. In 2016, BBMRI-NL, EATRIS-NL, and DTL/ELIXIR-NL have developed a common vision and roadmap on how The Netherlands can set course for a comprehensive Nation-wide Personalised Medicine & Health Research infrastructure. The goal is to bundle and connect a wide range of resources including biobanks, IT-technologies, facilities and data collections into one large-scale research infrastructure (working title: 'Health-RI')[28].

Specific strength:

- 4P biobanking: Personalised medicine – oriented.
- Donor participation.
- Access to decentralised pathological tissue bank Dutch National Tissue Portal DNTP.
- Multilevel 'Omics'- integration: Genotypes/epigenomics/transcriptomics/metabolomics.
- Imaging integration.
- Legal expertise in synergy with BBMRI-ERIC Common Service ELSI.
- ICT systems and –application development in synergy with BBMRI-ERIC CS-IT.

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure: Various systems and applications development

Quality: QC/QA systems not national but Biobank-specific; participation in BBMRI-ERIC QA/QS working group

Clinical Biobanks: Coordinated activities in Pearl String Institute: decentralised activities of clinical biobanks in European disease specific projects, partly in connection with BBMRI-ERIC activities.

Population-based Cohorts: : Close ties of major population biobanks and epidemiology with BBMRI-ERIC and international infrastructure (among others, BBMRI-LPC, BioShare, ADOPT BBMRI-ERIC, CORBEL).

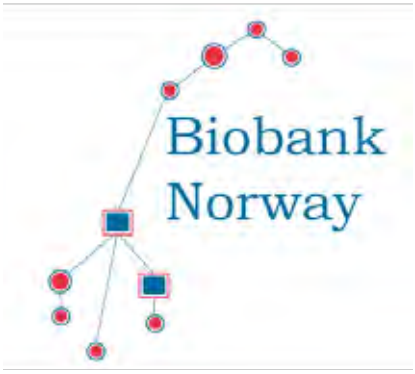
ELSI: Dissemination of BBMRI.nl tool development in BBMRI-ERIC CS-ELSI and Common Service IT respectively (e.g. Wiki-Legal, My Biobank, Miabis Calalogue development).

Expert Centres: Expert Centres in development on biomarker discovery, metabolomiCommon Service and technology.

Education & Training: Joint training programme in development with BBMRI-ERIC.

[28] www.bbmri.nl/?p=907

BBMRI.no



National Node Director: Kristian Hveem
Web: www.ntnu.edu/bbmri.no
alias www.ntnu.edu/biobanknorway
Staff: 7 FTE/year throughout all Work Packages
Funding: €8.6 million (NOK 80 million) funded by the Research Council of Norway (2011-2013)
Joined BBMRI-ERIC: 2013 (as an observer), 2015 (as a full member)
Number of biobanks and stand-alone collections as specified in Directory 2.0: 1

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.

Partners: University of Tromsø, University of Bergen, University of Oslo, Norwegian University of Science and Technology, 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

National Roadmap: The Research Council of Norway (RCN) initiated a national European Strategy Forum on Research Infrastructure (ESFRI) group for biobanks already in 2008, preceding the establishment of a national biobank infrastructure. Following the BBMRI Preparatory Phase, BBMRI.no was funded in 2009/10 by the RCN as one of four infrastructures based on the first call from the RCN Infrastructure programme, INFRA. The RCN put together its first roadmap for research infrastructures in 2010, including BBMRI.no as one of the ten initial infrastructures. Major infrastructures such as BBMRI.no and ELIXIR.no collaborate on a national level. Subsequently, European life science infrastructure for biological information (ELIXIR) has become a co-lead of the IT-work package within the second BBMRI.no Work Programme. There are also ongoing initiatives for collaboration between BBMRI.no and EATRIS.

Specific strength: 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 organised already 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 standard operating procedures (SOPs) and an interactive Best Biobanking Practice. ELSI has

been a strong component in the BBMRI.no network, presently with a special attention to the ethics involved in genetic studies and Next Generation Sequencing. In the past year, almost 150,000 samples from the largest population biobanks have been genotyped and recorded, soon to be available for researchers on a national and international level.

CONTRIBUTION TO THE JOINT EFFORTS:

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

Quality: NTNU (Coordinator of BBMRI.no) is holding the co-leadership 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. 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: Both the HUNT study (130,000) and the Tromsø Study (50,000) are organising new surveys (HUNT 4 and Tromsø 7), using new sensor technologies, 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.

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 bilateral agreements are under evaluation.

Education & Training: BBMRI.no has organised PhD-courses in Genome-wide association study (GWAS) analyses and it´s part of an annual national PhD-course in molecular medicine. A newly established national Common Service-biobanking offers guidance and training opportunities through internships.

BBMRI.pl

National Node Director: Łukasz Kozera
Web: forthcoming
Staff: 0.25 FTE/year
Funding: Submitted application for funding of BBMRI.pl biobanking network
Joined BBMRI-ERIC: 2013
Number of biobanks and stand-alone collections as specified in Directory 2.0: 4

About: BBMRI.pl is a new initiative in Poland. Currently our country is in the Preparatory Phase to join BBMRI-ERIC as a full member. Temporarily the National Node has been located at the Wroclaw Research Centre EIT+ Biobank. In December 2014 a group of biobankers from Poland created the BBMRI.pl consortium in order to prepare National Biobanking Network proposal for the Ministry of Science

and Higher Education, which has been submitted in December 2015. The entire population of biobanks and biorepositories in Poland might be bigger than 50 units. In fact, 37 declared potential participation in the BBMRI.pl initiative. The majority of them are disease-oriented biobanks, there are only two local population-based biobanks. With a population of over 38.5 million, we are in the process of mapping all biobanking activities in our country and starting a national population-based cohort, allowing further population-based studies. Polish biobanks are actively involved in trainings and conferences organised by BBMRI-ERIC and BBMRI-LPC. The National Node is already involved in two grants as a co-applicant, which are the FP7 BBMRI-LPC, and HORIZON 2020 ADOPT BBMRI-ERIC. In November 2015, the BBMRI.pl consortium signed the agreement for bilateral co-operation with the UK Biobank.

Partners: University of Lodz, Gdansk Medical University, Warsaw Medical University, Wroclaw Medical University, Regional Centre for Science and Technology in Checiny, Lublin Medical University.

National Roadmap: BBMRI is currently not included in the National Roadmap.

Specific strength: Very enthusiastic environment of people involved in biobanking from different fields.

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure: National IT expert:
Dominik Strapagiel

Quality: National experts:
Łukasz Kozera, Katarzyna Ferdyn, Malgorzata Witon

Clinical Biobanks: National experts:
Jaroslaw Skokowski and Leszek Kalinowski

Population-based Cohorts: National experts:
Dominik Strapagiel, Łukasz Kozera

ELSI: National expert: Jakub Pawlikowski

Expert Centres: none in Poland.

Education & Training: -

BBMRI.se

National Node Director: Joakim Dillner
Web: www.bbmri.se
Staff: 23.5 FTE/year
Funding: €17 million (2010-2015)
Joined BBMRI-ERIC: 2013
Number of biobanks and stand-alone collections as specified in Directory 2.0: 114

About: The Biobanking and Molecular Resource Infrastructure of Sweden (BBMRI.se) was founded in 2010 as the first national BBMRI node. It is the largest investment that the Swedish Research Council has made so far within the area of medical infrastructure. BBMRI.se is organised in Service Centres that provide national services to users independent of their home organisation, notably the National Sample Management Service Center, the National Repository for Legacy Collections, the ELSI Service Center, the Service Center for Analyses Technologies and Reagents, IT Services and Services to Support Healthcare Biobanking. Strategic initiatives by the BBMRI.se management include for example communication and service for promoting Open Science. BBMRI.se has Karolinska Institutet as the host university and has all medical universities in Sweden as partners.

Partners: All medical universities in Sweden and the Royal Institute of Technology.

National Roadmap: BBMRI is on the national Roadmap. BBMRI.se was funded for 2010-2015 with about €17 million. An application will be sent in for funding from 2017. In this new application, the consortium will be a joint application with healthcare biobank organisations. BBMRI.se is committed to aligning its policies and formats with those of BBMRI-ERIC. We work in collaboration with a multitude of national and international RI as for example SNIC, NeIC, Elixir and EUDAT. pan-EUropean DATa infrastructure) We are a founding partner of the IARC-coordinated biobank and cohort-building network for Low and Middle Income Countries (BC-Net) and are currently collaborating with BCNet in the programming of an international biobank catalogue for BCNet. Both the BBMRI.se host university and the BBMRI.se ELSI Center are partners in 'Bridging Biobanking and Biomedical Research across Europe and Africa (B3Africa)', a HORIZON 2020 project focusing on development of Open Source IT systems for global use in building and using biobanks. We are also represented in several European projects, for example BiobankCloud, RD-Connect and BioMedBridges (Building data bridges and services between biological and medical infrastructures in Europe). Also, we are part of the EGI (European Clinical Research Infrastructures Network) ENGAGE, which includes the EGI Competence Center for BBMRI-ERIC.

Specific strength: The work of BBMRI.se has a clear basis and a clear vision. The basis is high ethical, legal and moral standards. All activities should have patient benefits as the ultimate aim and should be based on respect for human values. We also recognise that high ethicolegal standards require involvement in ethicolegal research in the international frontline. The vision is to contribute to the development of a

new era of biomedical research characterised by international research that effectively uses openly accessible and large-scale international resources, including both data and biological samples. We believe that for optimal patient benefit medical research and development must be able to develop faster, be more reliable and more generalisable. Large-scale, well-characterised resources openly accessible for international research use should enable larger (and thus more reliable) studies that should be more generalisable (when performed using resources from many countries) and be possible to perform faster (when samples and data have already been collected and have already been followed up). Between the basis and the vision is our mode of operation. We believe that operation of a national infrastructure must be based on a clear catalogue of national services provided, that will be regularly updated based on customer demands. We also believe that scientific excellence in leadership is a must, as also service operations need to be able to develop innovative services fast and in accordance with the service needs of international frontline research.

CONTRIBUTIONS TO THE JOINT EFFORTS:

e-Infrastructure: BBMRI.se IT services are part of the BBMRI-ERIC Common Services on IT for biobanking. We have developed the data standard Minimum Information About Biobank data Sharing (MIABIS) and Roxana Merino Martinez is chairing the international MIABIS group. We have several early developments of biobank registries, such as the bbmriregister.se and are involved in several international projects in this area. We provide services with implementation and custom modification of various Open Source software.

Quality: Work on quality has focused in particular on the quality of data management, the quality of registry linkages, biological quality as well as quality of operations. BBMRI.se is also part of the international initiative aiming to define a technical ISO standard for biobanks.

Clinical Biobanks: We wish to promote efficiency, quality and comparability by providing a nationally developed biobanking system to collaborating hospitals all over the country. BBMRI.se performs development and optimisation of a system and performs national purchasing tenders for equipment, supplies and IT solutions. Collaborating hospitals can then access these at low cost, provided they promise to adhere to the Open Access principle. This greatly reduces costs for development and operation of clinical biobanks, while at the same time ensuring comparability of resources (everything collected using exactly the same national system). National clinical cytology biobanking is launched in seven healthcare regions

(with samples from almost 500,000 women already stored) and national clinical microbiology biobanking is piloted in regions.

Population-based Cohorts: As cervical cytology is performed in a population-based screening programme, the national clinical cytology biobanking is actually also a population-based cohort. Several investigators from all over Sweden use the services of the National Sample Management Centre. In total, samples from almost 500,000 volunteer individuals collected in different epidemiological and clinical studies are stored at the same location, have the same sample management services (e.g., DNA extraction, RNA extraction) and the same pick-up and shipment services. The volunteers are regularly followed-up using linkages to population-based health data registries (e.g., cancer registry) to add data on disease endpoints that may have occurred on follow-up to the cohort. The same applies for the clinical cytology cohort.

ELSI: BBMRI.se has an ambitious national service on ELSI issues, situated at Uppsala University Center for Research on Bioethics. Overarching concepts are that researchers should seek competent advice on ethical and legal issues already at the outset of their projects and that high ethical and legal standards require active ethicolegal research in the international frontline. The BBMRI.se ELSI service center is one of four centers in the pan-European BBMRI-ERIC Common Services on ELSI.

Expert Centres: -

Education & Training: BBMRI.se has over the years arranged a series of postgraduate courses in biobanking and biobank-based research. BBMRI.se jointly with Karolinska Institutet has been running a successful biobank course focused on the value of biobanks as a part of the PhD programme since 2013. Since 2015, we make courses available as Open Online Courses (Biobanking OpenOnline Courses, BOOC), meaning that anyone anywhere in the world who has an internet connection can take part in the course by logging in to booc.bbmri.se. Resources available to students include for example the slides, videos on the lectures, reading materials and a chat module where students from anywhere in the world can easily convey comments to improve the lecture for the future.

BBMRI.tr

National Node Director: Nese Atabey

Web: www.biobank.gen.tr

Staff: 1.5 FTE/year

Funding: The Turkish National Node of BBMRI (BBMRI.tr) has been funded in a joint effort by the Ministry of Development and the Dokuz Eylul University (DEU). From 2014 onwards, DEU is committed to cover the BBMRI-ERIC observership fee and national coordination costs up to 150,000 euros per year.

Joined BBMRI-ERIC: 2013

Number of biobanks and stand-alone collections as specified in Directory 2.0: not yet

About: Turkey is a BBMRI-ERIC observer country. The National Node BBMRI.tr is part of Dokuz Eylul University (DEU), which was established in 2014 with a joint protocol by the Ministry of Development and DEU. In 2015, BBMRI.tr became a partner in the ADOPT BBMRI-ERIC proposal that aims to boost and accelerate the implementation of BBMRI-ERIC and its services. DEU, Izmir International Biomedicine and Research Institute (iBGizmir) is the coordinator and Hacettepe University Center for Biobanking and Genomics (HUBİGEM) and Istanbul University (Institute of Experimental Medicine (DETAE) H. Behcet Life Science Center Biobank Facility are partners of the ADOPT-BBMRI-ERIC project. A grant proposal was submitted to the Ministry of Development for the infrastructure and staff costs of BBMRI.tr. BBMRI.tr has five main goals: (1) Play an advisory role in the establishment of biobanks in Turkey to create a harmonised and efficient biobanking infrastructure; (2) Increase the awareness of biobanking among the public as well as the scientific community; (3) Create a coordination structure among biobanks. (4) Harmonise the ethical and legal guidelines; (5) Share best practices acquired from BBMRI-ERIC and disseminate the knowledge in national biobanks, while contributing to the panEuropean research infrastructure BBMRI-ERIC. To achieve these aims BBMRI.tr focuses on: (a) Harmonisation and dissemination of standard operating procedures (SOPs) for the collection, storage, quality control and access procedures of biological material and related data among biobanks.(b) Coordination of the funding of an IT infrastructure for interoperability between biobanks for the use of patient registries and clinical data.(c) Organisation of training activities, quality assurance of biobanks and registries. (d) Educational activities to enhance the awareness of biobanking in the general public, policymakers, and healthcare providers. (e) Increase the awareness of decision makers to develop tools to ensure the sustainability of biobanks.

Partners: Center for Biobanking and Genomics (HUBİGEM)/Hacettepe University, Institute of Experimental Medicine (DETAE), H. Behcet Life Science Center Biobank Facility/Istanbul University, Izmir International Biomedicine and Research Institute (iBGizmir)/DEU, Dokuz Eylul Technology Development Zone (DEPARK), Ministry of Development, Turkish National Commission for UNESCO Bioethics Committee, Scientific and Technological Research Council of Turkey (TUBITAK), Turkish Health

Institutions (TUSEB)

National Roadmap: The National Roadmap of Research Infrastructures is currently under preparation. The ERIC regulation is also under preparation to facilitate multinational partnerships. In 2014, steps were taken at the national level to strengthen largescale research infrastructures in Turkey. TUBITAK and the Ministry of Development are responsible for the regulatory processes regarding largescale research infrastructures. Turkey's research infrastructure development in its 10th Development Plan (2014–2018) prioritises nanotechnology, biotechnology, nuclear technologies, material sciences and environmental technologies. The 10th Development Plan foresees to increase the rate of research and development (R&D) expenditures from 0.98% to 1.8% GDP by 2018. In addition, Turkish Health Institutions (TUSEB) initiated The Turkish Genome Project and support for disease/hospital-based biobank infrastructures and established a Population Biobank. BBMRI.tr focuses on the dissemination of standard operating procedures for the collection, storage, quality control and access procedures of biological material and related data, the coordination of the funding of an IT infrastructure for interoperability between biobanks for the use of patient registries and clinical data, the organisation of training activities to assure the quality of biobanks and registries, and educational activities to enhance the awareness of biobanking in the general public, policymakers, and healthcare providers. BBMRI.tr roadmaps include: Mapping Turkish biobanks in terms of quality by a selfassessment questionnaire, encouraging Turkish Biobanks to become members of BBMR.tr, improving the BBMR.tr web page (by creating interactive elearning tools and an information desk for common services and ongoing research projects etc.), motivating the creation of a Turkish National Biobanking Network, supporting the harmonisation and standardisation of SOPs, stimulating the involvement of stakeholders in the BBMR.tr structure, organising handson training courses for biobankers, supporting certification and accreditation programmes.

Specific strength: Hacettepe Rare Disease Biobank is already a member of the EuroBioBank network since 2014. Additionally, there is an increasing public awareness and support for biobanks. The Ministry of Health and UNESCO Bioethics Committee have initiated an ethical reflection on biobanking in collaboration with the BBMRI.tr National Node and some local ethics committee members. Moreover, Turkey is a partner in some other ESFRI projects (ECRIN, ELIXIR, EURO-BIOIMAGING, INFRAFRONTIER).

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure: An inventory of existing biobanks in Turkey has been collected. We have also studied the proposed standards of the BBMRIERIC consortium and decided on the necessary infrastructure and personnel to carry out the project. We applied for funding from the Ministry of Development to fund

this project.

Quality: Standard Operating Procedures (SOPs) based on OECD Guidelines, International Society for Biological and Environmental Repositories (ISBER) recommendations and EuroBiobank have been followed by existing biobanks. A workshop is organised to harmonise SOPs and to train biobankers on Quality Management System (QMS) systems in biobanks for 2016.

Clinical Biobanks: We have been collecting the inventory of available clinical biobanks in Turkey. Turkish Gastroeintestinal Pathology Working Group has been informed about the ADOPT BBMRI-ERIC project. Main centres are sent a questionnaire about colorectal carcinoma cases with follow up information and/or formalin fixedparaffin embedded and/or material stored at 80°C.

Population-based Cohorts: We are conducting followup studies on subsamples of the BHS (Balçova Heart Study) Cohort. These follow-up studies include the development of diabetes in the population with impaired glucose and a nested case control study of vitamin D and cancer. Additionally, we are collaborating with the Greifswald Univ SHIP cohort, and the first meeting was held in Germany in January 2015 and the second in Turkey in Sept 2015, to plan further activities. We also joined the European Cohort Consortium, which will apply to the call in Horizon 2020.

ELSI: We organised a joint workshop with national stakeholders for the standardisation of informed consent forms and ethicallegal guidelines of biobanks, and a position paper has been prepared. A workshop has been organised to standardise biobanks‘ informed consents and to train biobankers on ethical and legal issues in 2016.

Expert Centres: -

Education & Training: Curriculum proposal: ethics and biobanking as a topic at graduate level courses in medical schools and life science programmes. Two research courses called ‚special study modules (SSM)‘ for 2nd grade medical students have been opened in September 2015 at DEU Medical School. Ten MD students have been working on a survey to assess the awareness of medical students and health professionals regarding clinical biobanks. The analysis of the survey data is in progress. According to the results of the survey, if necessary the MD students will train their peers in clinical biobanking. A workshop for the quality assurance of biobanks and ELSI issues has been organised for 2016.

BBMRI.uk

National Node Director: Philip Quinlan (since 2016), Anne Carter (until 2015)
Web: http://www.biobbankinguk.org
Staff: It will peak at 4.6 FTE/year
Funding: The UKCRC Tissue Directory and Coordination Centre receives a total funding of approx. £900,000 over three years for its national activities including BBMRI.uk.
Joined BBMRI-ERIC: 2015
Number of biobanks and stand-alone collections as specified in Directory 2.0: 0 (inclusion in preparation for Directory 3.0)

About: The UK joined BBMRI-ERIC in April 2015, and nominated the UKCRC Tissue Directory and Coordination Centre (the Centre) as the UK's National Node (BBMRI.uk). The Centre was formed in December 2014 with support from a consortium of UKCRC funders. It is run as a partnership between University College London and the University of Nottingham and its main aim is to provide strong leadership in making progress towards the UKCRC Funders' Vision for Human Tissue Resources by increasing the quality, visibility and accessibility of the UK's world-class human tissue and biosample collections.

Partners: -

National Roadmap: The UK Clinical Research Collaboration (UKCRC) Tissue Directory and Coordination Centre (the Centre) has been set up to support the UKCRC Experimental Medicine Funders Group in achieving their Vision for Human Tissue Resources. The Centre is funded until the end of 2017 and took the role of BBMRI.uk in April 2015. The first three years (running to December 2017) is more akin to a pilot study for the expected next phases. As such evaluation is at the heart of everything the Centre seeks to achieve. Directory 1.0 is designed to explore the current abilities and evaluate based on whether the Directory can be used by the vast majority of sample custodians. Equally the Centre wishes to explore whether researchers find such a resource useful and seek suggestions for how it could be improved. Further prototyping of technical options will be undertaken with close attention being paid to the solutions made available by the BBMRI IT Common Service community. Equally further work will be undertaken in relation to full stakeholder that can be included in our work with BBMRI. The primary role of BBMRI.uk is to build community support and agreement surrounding the next steps for achieving an integrated biobanking infrastructure. Such a goal can only be achieved by wide engagement with the vast array of organisations that influence how biobanking can be performed in the UK and we wish to bring this insight to the wider BBMRI community.

Specific strength: The focus in the UK is on making small but continual steps as a community ensuring that challenges are understood and solved together.

As such the work in the UK brings a novel angle to the work undertaken by many other BBMRI countries. An example of this would be the user persona work where we have characterised the different types of users who may use a national network. Biobanking is such a complex mix of different needs, desires, motivations and purpose and gathering understanding of these often conflicting measures is vital in delivering any form of network and coordinated effort. All the work the Centre undertakes in the UK is fed into the appropriate BBMRI group.

CONTRIBUTION TO THE JOINT EFFORTS:

The UK joined BBRMI-ERIC after the creation of the Centre and therefore the exact role has only become clearer in the last few months. The UKs current largest contribution is within the Common Service IT where we have sought to guide and advise based on our experiences and user-engagement activities. BBMRI.uk has nominated individuals to the majority of BBMRI-ERIC activities and the Centre creating BBMRI.uk Centres of Excellence is extending this effort. These centres will bring together multiple experts from the UK to form effectively a mirror committee and therefore ensure those representing BBMRI.uk have support and greater breadth of knowledge from UK experts.

e-infrastructure: The UK has been undertaking the development of a tissue directory and the directory has just launched. In the coming months the UK will be exploring the optimal methods to ensure those registering in the national Directory are then also represented in the BBMRI-ERIC Directory. The UK continues to play a major role in the development of the use cases and bringing the user perspective into the discussions surrounding the IT Common Service.

Quality: The UK has supplied the previous work of the Confederation of Cancer Biobanks to this effort and it appears that this will have saved BBMRI-ERIC countless months in preparing such a quality manual and process. Therefore demonstrating the leadership the UK can play but also the benefits BBMRI-ERIC can enjoy when national leadership can be translated across Europe.

Clinical Biobanks: The UK has no formal role within ADOPT BBMRI-ERIC, yet we have asked our biobanks to participate in the discussions around the colon datasets. Several have responded and are actively engaged.

Population-based Cohorts: The UKs retains a strong involvement via the BBRMI-LPC (see relevant section)

ELSI: The UK has many experts that are actively contributing to the ELSI Common Service.
Education & Training: No current activities in relation to BBMRI-ERIC.

Expert Centres: -

Education & Training: -

WHO/IARC

National Node Director: Maimuna Mendy
Web: http://www.iarc.fr
Staff: -
Funding: -
Joined BBMRI-ERIC as an Observer: 2013
Number of biobanks and stand-alone collections as specified in Directory 2.0: not yet

About: The International Agency for Research on Cancer (IARC) is a unique organisation. For almost 50 years, since its creation by the World Health Assembly of the World Health Organisation (WHO), the Agency 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 among the international cancer community. Through the generosity and vision of its Governing Council, IARC has a global mandate, permitting a focus on developing countries where resources are most needed and cancer remains an often neglected disease. Furthermore, the independence of IARC enables it to provide reliable and authoritative assessments of many facets of cancer information valued by scientists, governments, non-governmental organisations and the public the world over. The Agency is a catalyst for progress. 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 translating research into tangible benefits in improved health for people everywhere.

Partners: -

National Roadmap: IARC has joined BBMRI-ERIC as International Organisation. IARC is the coordinator of BCNet, a Biobank network for low and middle-income countries and a partner in the Horizon 2020 B3Africa (Bridging Biobanking and Biomedical Research across Europe and Africa) project. IARC per se has no national Roadmap.

Specific strength: LMIC biobank networking (BCNet); international collaboration; Ethics, Legal and Social Issues.

CONTRIBUTION TO THE JOINT EFFORTS:

e-Infrastructure: -

Quality: -

Clinical Biobanks: -

Population-based Cohorts: IARC is the custodian of the EPIC biobank

ELSI: -

Expert Centres: -

Education & Training: -

Other: IARC contributes specifically to the expansion of BBMRI outside of Europe.

EXTERNALLY FUNDED PROJECTS

OVERVIEW ON PROJECT INVOLVEMENTS

OVERVIEW ON PROJECT INVOLVEMENTS

To date, BBMRI-ERIC has allocated a total of €6.6 million through its participation in research projects. Notably, the HORIZON 2020 project **ADOPT BBMRI-ERIC** enables us to boost and accelerate our key duties in providing better IT and ELSI services for users, and promote access to samples and data.

In the context of the INFRADEV-3-2015 call, BBMRI-ERIC was the only purely health related research infrastructure to receive the grant. Therefore, the decision on a particular disease was of utmost importance. For a common disease, colon cancer was chosen, as a model disease as this cancer is one of the most commonly diagnosed cancers worldwide; 447,136 cases per year (2012), making it the 2nd most diagnosed cancer in the European Union. ADOPT BBMRI-ERIC will thus allow us to develop the most globally advanced and most comprehensive cohort of colon cancer cases including biosamples and detailed medical information by simply pooling together the cases from the National Nodes and their associated biobanks.

Such a high quality cohort of 10,000 colorectal cancer cases has so far never been established. In the long run, this cohort will allow key unsolved medical problems to be addressed, such as individual risk assessment of stage II colon cancer, which is critically needed to optimise therapy. Furthermore, the experience gained will allow detailed calculation of timelines and costs to establish similar high quality cohorts for any other disease, therewith demonstrating the capabilities of an effort such as BBMRI-ERIC. For rare diseases, we opted for osteogenesis imperfecta.

Acronym	Coordinator	Role of BBMRI-ERIC	Total	€ BBMRI-ERIC	Duration	Start Date	# BBMRI-ERIC
ADOPT BBMRI-ERIC	J-E. Litton	COOR-DINATOR	**€5 million**	€3,790,179	36	01/10/15	**01/10/15**
B3Africa	E. Bongcam	PARTNER	**€0.2 million**	€70,000	36	01/07/15	**01/07/15**
BBMRI-LPC	M. Perola GJ. van Ommen	PARTNER	**€8 million**	€14,552	48	01/02/13	**01/04/14**
BioMedBrid-ges	J. Thornton	PARTNER	**€10.5 million**	€8,400	48	01/01/12	**01/10/14**
CORBEL	N. Blomberg J-E. Litton	CO - COOR-DINATOR	**€15 million**	€1,799,468	48	01/09/15	**01/09/15**
CY-Biobank	C. Deltas	PARTNER	**€0.5 million**	€64,475	12	01/06/15	**01/06/15**
EGI-Engage	T. Ferrari	PARTNER	**€8 million**	€128,550	30	01/03/15	**01/03/15**
EMTRAIN	M. Hardman	PARTNER	**€4 milion**	€9,754	84	01/10/09	**01/10/14**
PhenoMeNal	K. Holmes	PARTNER	**€8.8 million**	€145,076	36	01/09/15	**01/09/15**
RD-CONNECT	H. Lochmüller	PARTNER	**€12 million**	€100,000	72	01/11/12	**01/04/15**
RItrain	M. Pasterk	COOR-DINATOR	**€2 million**	€514,423	48	01/09/15	**01/09/15**

Table 2: Facts & Figures of Project Participation of BBMRI-ERIC

Furthermore, BBMRI-ERIC was successful with all project applications which we coordinated; ADOPT BBMRI-ERIC, **CORBEL** and **RItrain**. Some projects BBMRI-ERIC is involved in today started prior to the existence of BBMRI as an ERIC, namely **RD-Connect**, **EMTRAIN**, **BioMedBridges** and **BBMRI-LPC**.

The inclusion in these projects started with a Memorandum of Understanding and culminated in the formal inclusion as a participant following an amendment process to the Grant Agreement. In most cases, several National Nodes were guaranteeing the inclusion of BBMRI prior to its existence as an ERIC.

The main benefit of BBMRI-ERIC's involvement is to build on the scientific and strategic outcomes (e.g., access procedure of BBMRI-LPC and rare disease catalogue of RD-Connect). **B3Africa** enables connection to stakeholders from the African continent and **CY-Biobank** allows to provide expertise and advice to Cyprus in setting up their own national infrastructure. Both projects ensure close collaborations with BBMRI-ERIC and its pan-European scope. **EGI-Engage** and **PhenoMeNal** ensure the collaboration and future interconnectivity with European e-infrastructures (a detailed overview see Table 2 and EXTERNALLY FUNDED PROJECTS, page 89ff).

ADOPT BBMRI-ERIC

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: 1 October 2015

Grant Agreement Nr: 676550

Web: http://bbmri-eric.eu

Coordinator: Jan-Eric Litton

Total requested Grant by Consortium: €4,950,860.00

Total requested Grant by BBMRI-ERIC: €3,786,840.00

(includes funds for Headquarters, Common Service ELSI, Common Service IT, linked third parties)

Linked third parties/BBMRI-ERIC Framework Agreement:

BBMRI.at/MUG; BBMRI.fi/THL; BBMRI.mt/UoM; BBMRI.it/UNIMIB

Benefit/tasks for BBMRI-ERIC: Coordinated by BBMRI-ERIC, funding for key activities

Abstract: Led 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 of the Research Infrastructure as required for European Strategy Forum on Research Infrastructure (ESFRI) -projects ‚under implementation', reflecting the targets of the European Research Area (ERA). One of the challenges in the post-genomic era is the research on common complex diseases, such as cancer, diabetes and Alzheimer's disease. Understanding these 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 will result in an increase in many of those diseases and consequently an increased healthcare expenditure for senior citizens. 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. linked third 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 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

B3Africa

Bridging Biobanking and Biomedical Research across Europe and Africa

Topic: INFRASUPP-6-2014

Type of Action: CSA

Duration: 36 months

Start Date: 1 July 2015

Grant Agreement Nr: 654404

Web: http://www.b3africa.org/

Coordinator: Erik Bongcam-Rudloff

Total requested Grant by Consortium: €201,250.00

Total requested Grant by BBMRI-ERIC: €70,000.00

(includes funds for Headquarters, Common Service ELSI, Common Service IT, linked third parties)

Linked third 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

Abstract: Led 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

BBMRI-LPC

Biobanking and Biomolecular Resources Research Infrastructure – Large Prospective Cohorts

Topic: INFRA-2012-1.1.9

Type of Action: CP&CSA

Duration: 48 months

Start Date: 1 February 2013

BBMRI-ERIC full partner: as of 1 April 2014

Web: http://www.bbmri-lpc.org/

Coordinator: Markus Perola;

Total requested Grant by Consortium: €8,000,000.00

Co-Coordinator: Gertjan van Ommen

Total requested Grant by BBMRI-ERIC: €14,552.00

Linked third parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: BBMRI LPC Forum, BBMRI-ERIC

Abstract: Led by UH-FIMM: BBMRI-LPC unites the large study sets of the European Biobanking and Biomolecular resources 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: Helsingin Yliopisto (UH-FIMM); Academisch Ziekenhuis Leiden Leid Universitair Medisch Centrum (LUMC); Centre International de Recherche Sur le Cancer (IARC-WHO); Imperial College of Science, Technology and Medicine (ICL); Medizinische Universitat Graz MEDUNI Graz (MUG); Karolinska Institutet(KI); Genome Research Limited (WTSI); Academisch Ziekenhuis Groningen (UMCG); Helmholtz Zentrum Muenchen Deutsches Forschungszentrum fuer Gesundheit un Umwelt GmBh (HMGU); Norges Teknisk Naturvitenskapelige Universitet (NTNU); Tartu Ulikool (UTARTU); Uppsala Universitet (UU); Centre Nacional D'Anàlisi Genòmica Fundacio Centre de Regulacio Genomica (CNAG-CRG); Cambridge Protein Arrays LTD (CPA); Pecsi Tudomanyegyetem University of PECS (UP); The Research Institute of the Mc Gill University Health Centre (RI MUHC); Legal Pathways BV (Legal Pathways); Islensk Erfdagreining EHF (DECODE); Terveyden Ja Hyvinvoinnin Laitos (THL); International Prevention ResearchInstitut IPRI Management (IPRI); Latvijas Biomedicinas Petijumu un Studiju Centrs (LBMC); Sveuciliste U Splitu University of SPLIT (CCGH); Wroclawskie Centrum Badan EIT + Sp. z o.o. (EIT+); Klinikum Rechts der Isar der Technischen Universitat Munchen (TUM-MED); Institut national de la Sante et de lat Recherche Medicale (INSERM); MedLawconsult (Medlaw); Universiteit Maastricht (MU); Nasjonalt Folkehelseinstitutt (NIPH); Statens Serum Institut (SSI), University of Bristol (UBRIS), BBMRI-ERIC, Universita Degli Stufi di Milano Bicocca (UNIMIB)

BioMedBridges

Building data bridges and services between biological and medical infrastructures in Europe

Topic: FP7 INFRA-2011-2.3.2

Type of Action: CP-CSA Infra

Duration: 36 months

Start Date: 1 January 2012

BBMRI-ERIC full partner: as of 1 October 2014

Web: http://www.biomedbridges.eu/

Grant Agreement Nr: 284209

Total requested Grant by Consortium: €10,494,998.69

Coordinator: Janet Thornton

Total requested Grant by BBMRI-ERIC: €8,400.00

Linked third parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: Connecting BMS RIs

Abstract: Led by European Molecular Biology Laboratory: BioMedBridges (Building data bridges and services between biological and medical infrastructures in Europe) will form a cluster of the emerging biomedical sciences research infrastructures (BMS RIs) and construct the data and service bridges needed to connect them. The BMS RIs are on the ESFRI (European Strategy Forum on Research Infrastructure) roadmap. The missions of the BMS RIs stretch from structural biology of specific biomolecules to clinical trials involving thousands of human patients. Most serve a specific part of the vast biological and medical research community, estimated to be at least two million scientists in Europe across more than 1,000 institutions from more than 36 ESFRI member States and Associated Countries. Each of them brings together its own large community of users to build a coordinated infrastructure. This process has already had a major impact on coordination of national infrastructures within each member state. Essentially all BMS RIs are distributed infrastructures, with nodes in many European member states.

List of Participants: European Molecular Biology Laboratory/ELIXIR, University of Oxford, Karolinska Institutet, Science and Technology Facilites Council, Heinrich Heine Universität Düsseldorf, Leibnitz-Institut für Molekulare Pharmakologie, Technische Universität München, Stazione Zoologica Anton Dohm, Erasmus University Medical Center Rotterdam, Technologie- und Methodenplattform für die vernetzte medizinische Forschung e.V, Helmholtz Zentrum München, Medizinische Universität Graz, Stichting VU-VUmc, Institut national de la santé et de la recherche médicale, University of Copenhagen, University of Helsinki/Institute for Molecular Medicine Finland, European Grid Infrastructure, CSC-IT Center for Science Ltd., University Medical Center Groningen, Consorzio Interuniversitario di Risonanze Magnetiche di Metalloproteine, Delivery of Advanced Network Technology to Europe

CORBEL

Coordinated Research Infrastructures Building Enduring Life-science services

Topic: H2020 INFRADEV-4

Type of Action: RIA

Duration: 48 months

Start Date: 1 September 2015

Grant Agreement Nr: 654248

Web: http://bbmri-eric.eu

Coordinator: Niklas Blomberg;

Total requested Grant by Consortium: €14,000,000.00

Co-Coordinator: Jan-Eric Litton

Total requested Grant by BBMRI-ERIC: €1,799,468.00

(includes funds for Headquarters, Common Service ELSI and linked third parties)

Linked third parties/BBMRI-ERIC Framework Agreement:

BBMRI-NL/LUMC, BBMRI.fi/THL, BBMRI.no/NIPH,NTNU, BBMRI.ee/UTARTU, BBMRI.at/MUG

Benefit/tasks for BBMRI-ERIC: Co-Coordinated by BBMRI-ERIC, Work Package 3: case studies (National Nodes); Work Package 7: Common Service ELSI; Work Package 9: Training

Abstract: Led by EMBL/ELEXIR: 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: European Molecular Biology Laboratory (EMBL), Universitair Medisch Centrum Utrecht (UMC UTRECHT), Fundacio Institut de Ciencies Fotoniques (ICFO), Fundacio Centre de Regulacio Genomica (CRG), University of Dundee (UNIVDUN), Biobanking and BioMolecular Resources Research Infrastructure (BBMRI-ERIC), Foundation of Biomedical Research of the Academy of Athens (BRFAA), Erasmus University Medical Centre Rotterdam (ErasmusMC), EATRIS (EATRIS-ERIC), European Clinical Research Infrastructure Network (ECRIN-ERIC), University of Liverpool (U-LIVERPOOL), Istituto di Ricerche Farmacologiche Mario Negri (IRCCS-IRFMN), Heinrich-Heine-Universitaet Duesseldorf (UDUS), Infrafrontier GmbH (INFRAFRONTIER GmbH), Helmholtz Zentrum Muenchen Deutsches Forschungszentrum fuer Gesundheit und Umwelt GmbH (HMGU), Instruct Academic Services Limited (INSTRUCT), Consorzio Interuniversitario Risonanze Magnetiche di Metallo Proteine (CIRMMP), Agencia Estatal Consejo Superior de Investigaciones Cientificas (CSIC), Centre National de la Recherche Scientifique (CNRS), Stazione Zoologica Anton Dohrn (SZN), The University Court of the University of St Andrews (USTAN), Forschungsverbund Berlin e.V. (FVB), Imperial College of Science, Technology and Medicine (Imperial), Max Delbrueck Centrum fuer Molekulare Medizin (MDC), The University of Manchester (UNIMAN), Stichting VU-VUMC (VU/VUmc), Deutsches Krebsforschungszentrum (DKFZ), Leibniz-Institut DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ), Jacobs University Bremen GGmbH (JACOBS UNI), Koninklijke Nederlandse Akademie van Wetenschappen (KNAW), Tieteen Tietotekniikan Keskus Oy (CSC), CAB International (CABI), Medical University of Vienna (MUW), Academisch Ziekenhuis Groningen (UMCG), Universita Degli Studi di Torino (UNITO), Erasmus MC, Univ Groningen

CY-Biobank

Biobanking and the Cyprus Human Genome Project

Topic: H2020-WIDESPREAD-2014-1

Type of Action: FPA-SGA

Duration: 12 months

Start Date: 1 September 2015

Grant Agreement Nr: 664561

Web: http://www.ucy.ac.cy/cybiobank/en/

Coordinator: Constantinos Deltas

Total requested Grant by Consortium: €460,637.50

Total requested Grant by BBMRI-ERIC: €64,475.00

Linked third parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: Work Package 5: Standards, ELSI Compliance and Data Management; Task 5.1: Standards/Procedures Adoption & Quality Processes; Task 5.2: ELSI Compliance; Task 5.3: Data Management Plan (raw data availability and Gold access policy); Task 5.1/Deliverable 5.1, Task 5.2/Deliverable 5.2, Task 5.3/ Deliverable 5.3

Abstract: Led by University of Cyprus: The upgrading of MMRC into a CoE and its close partnership with the named Advanced Partners is a safe and sound strategy that will assist Cyprus over the next decade to enter large European networks and participate at ongoing and future epidemiological studies with mutual benefit to the Cypriot and the European patients.

List of Participants: University of Cyprus, Medical University of Graz/BBMRI.at, BBMRI-ERIC, RTD Talos Limited

EGI-Engage

Engaging the EGI Community towards an Open Science Commons

Topic: H2020 EGI-EINFRA-1-6

Type of Action: RIA

Duration: 30 months

Start Date: 1 May 2015

Grant Agreement Nr: 654142

Web: https://www.egi.eu/about/egi-engage/

Coordinator: Tiziana Ferrari

Total requested Grant by Consortium: €8,000,000.00

Total requested Grant by BBMRI-ERIC: €128,550.00 (includes funds for linked third parties)

Linked third parties/BBMRI-ERIC Framework Agreement:

BBMRI.cz/Masaryc University, BBMRI.se/KI, BBMRI-NL/LUMC

Benefit/tasks for BBMRI-ERIC: Work Package 1: Technology exchange, outreach, training and support with the following deliverables; Task 1.1: Support and outreach to the user community Task 1.3: Coordination.

Abstract: Led 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 (European Clinical Research Infrastructures Network) 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, Oesterreichische Akademie der Wissenschaften, 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, Fraunhofer-Gesellschaft zur Foerderung der Angew Andten Forschung E.V, Gesellschaft fur Wissenschaftliche Datenverarbeitung MBH Gottingen, 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, Consorzio Interuniversitario Risonanze Magnetiche di Metallo Proteine, Provincia Lombardo Veneta Ordine Ospedaliero di San Giovanni di Dio - Fatebenefratelli, Consiglio Nazionale delle Ricerche, 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 - Instituto de Ciências e Tecnologias Agrárias e Agro-Alimentares, 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, Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium, European Molecular Biology Laboratory, European Organisation for Nuclear Research, EISCAT Scientific Association, Food and Agriculture Organisation of the United Nations, Agro-Know I.K.E, Maat France SARL, The Trustees of Indiana University, Academia Sinica, Advance Science and Technology Institute, Institut Teknologi Bandung BHMN, Korea Institute of Science and Technology Information, Universiti Putra Malaysia, National Science & Technology Development Agency

EMTRAIN

European Medicines Research TRAIning Network

Topic: FP7/2007-2013

Type of Action: IMI

Duration: 84 months

Start Date: 1 October 2009

BBMRI-ERIC full partner: as of 1 October 2015

Web: http://www.emtrain.eu/

Grant Agreement Nr: 115015

Total requested Grant by Consortium: €4,000,000.00

Coordinator: Mike Hardman

Total requested Grant by BBMRI-ERIC: €9,754.45

Linked third parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: Education & training platform, IMI (Innovative Medicines Initiative)

Abstract: Led by Astra Zeneca: EMTRAIN will establish a pan-European platform for education and training covering the whole lifecycle of medicines from basic research through clinical development to pharmaco-vigilance. The public consortium consists of the six pan-European biomedical research infrastructures from the ESFRI roadmap, that cover a broad spectrum of competencies from molecules to humans, with a pan-European dimension. The EFPIA consortium has considerable experience in training and education, management, pan-European geographical outreach, and an extensive external network of contacts. The participants, together with the coordinators of IMI&T topics will participate in the Strategic Co-ordination Board to ensure coordination between the IMI&T topics whereas the Steering Committee will supervise the management of the project. E&T (Education and Training) topics representatives will be invited to participate in work packages activities. Based on extensive mapping of existing resources and on a gap and overlap analysis (Work Package 3) the consortium will develop and implement a strategy for harmonisation and accreditation (Work Package 4) of Master level Work Package 5) and PhD programmes (Work Package 6) as well as continuous education programmes (Work Package 7). It will develop innovative concepts and methods in conjunction with the other topics (Work Package 8) that will support the content for the IMI education programmes. National implementation will be facilitated through contacts with university authorities, ministries of higher education, and through national liaison offices. After implementation in a core group of institutions, extension is planned both within countries represented and in additional countries (Work Package 4), with the support of a dissemination and communication activity (Work Package 9). The harmonisation and the modular nature of these programmes will allow trans-disciplinary curricula as well as trans-border mobility, and PhD programmes will be designed to foster industry/academia mobility and collaboration.

List of Participants: AstraZeneca, Genzyme, Novartis, Bayer, Pfizer, Roche, GSK, UCB, Novo Nordisk, Sanofi, Boehringer Ingelheim, Janssen Pharmaceuticals, Orion, Almirall, Ludnbeck, Esteve, Medizinische Universität Wien (ECRINpartner), Karolinska Insititute (EATRIS partner), KUK (ECRIN partner), UniMan (BBMRI partner) ECRIN-ERIC, BBMRI-ERIC, EMBL-EBI (ELIXIR partner), HZI (EATRIS partner), GIE-CERBM (Infrafrontier partner), UOX (Instruct partner), MRC-HU (ECRIN partner)

PheNoMenal

A comprehensive and standardised e-infrastructure for analysing medical metabolic phenotype data

Topic: H2020 -EINFRA-1-2014

Type of Action: RIA

Duration: 36 months

Start Date: 1 September 2015

Grant Agreement Nr: 654241

Web: http:/bbmri-eric.eu

Coordinator: Christoph Steinbeck

Total requested Grant by Consortium: €8,810,922.00

Total requested Grant by BBMRI-ERIC: €145,076.00

Linked third 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.

Abstract: Led by European Molecular Biology Laboratory: During the next 10 years, 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-Institut 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 à l'énergie atomique et aux énergies alternatives, Institut national de la recherche agronomique, SRI International, The Governors of the University of Alberta/University of Alberta

RD-Connect

An integrated platform connecting registries, biobanks and clinical bioinformatic for rare disease research

Topic: FP7 -HEALTH-2012-INNOVATION

Type of Action: SP1 Collaboration

Duration: 72 months

Start Date: 1 November 2012

BBMRI-ERIC full partner: as of 1 April 2015

Web: http://www.emtrain.eu/

Grant Agreement Nr: 305444

Total requested Grant by Consortium: €11,997,111.00

Coordinator: Hanns Lochmüller

Total requested Grant by BBMRI-ERIC: €100,000.00

Linked third 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.

Abstract: Led by University Newcastle upon Tyne: Despite examples of excellent practice, rare diseases (RD) research is still mainly fragmented by data and disease types.

Individual efforts have little interoperability and almost no systematic connection between detailed clinical and genetic information, biomaterial availability or research/trial datasets. By developing robust mechanisms and standards for linking and exploiting these data, RD-Connect will develop a critical mass for harmonisation and provide a strong impetus for a global ‚trial-ready' infrastructure ready to support the IRDiRC goals for diagnostics and therapies for RD in close collaboration with the successful A/B projects. It will build on and transform the current state of the art across databases, registries, biobanks, bioinformatics, and ethical considerations to develop a quality assured and comprehensive integrated hub/platform in which complete clinical profiles are combined with -omics data and sample availability for RD research. The integrated, user-friendly RD-Connect platform, built on efficient informatics concepts already implemented in international research infrastructures for large-scale data management, will provide 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. RD-Connect has the RD field at its heart and brings together partners with a strong track record in RD research (gene discovery and development of innovative treatments), as well as committed IRDiRC funding partners and representatives of all major international RD initiatives (EU/US/AU/JP) spanning patient organisations, research and public health, to maximise impact to RD patients.

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

RItrain

Research Infrastructures Training Programme

Topic: H2020 INFRASUPP-3

Type of Action: RIA

Duration: 48 months

Start Date: 1 September 2015

Grant Agreement Nr: 654156

Web: http://ritrain.eu/

Coordinator: Markus Pasterk

Total requested Grant by Consortium: €1,999,075.95

Total requested Grant by BBMRI-ERIC: €514,423.20

Linked third 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.

Abstract: Led by BBMRI-ERIC: The overarching goal of RItrain is to identify the competency requirements for the leadership of European research infrastructures (RI) and design a training programme to fulfil these requirements. Our highest priority is those professionals who are already working in research infrastructures, including directors, coordinators, senior project managers, legal representatives, heads of Finance and HR, and heads of 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 RIs, including the new European Strategy Forum on Research Infrastructures (ESFRI) RIs have a distributed operations structure, building on existing RIs or networks of RIs. These RIs 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. They face those challenges that the European Commission (EC) has identified as roadblocks for the establishment of the European Research Area: (i) increased effectiveness of national research systems, (ii) improved trans-national cooperation and competition including establishing and effectively operating key research infrastructures, (iii) a more open labour market for researchers, (iv) gender equality and mainstreaming 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 BioinformatiCommon Service 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 Service 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

FINANCIAL REPORT 2015

BBMRI-ERIC®
Biobanking and
BioMolecular resources
Research Infrastructure

INTRODUCTION

The Annual Report on Budgetary and Financial Management of BBMRI-ERIC for the calendar year 2015 including the Financial Statement (thereafter Annual Financial Report 2015) and the Report of the External Auditor are submitted in accordance with Article 10 of the BBMRI-ERIC Statutes to the Assembly of Members for approval.

This is the second Annual Financial Report since the creation of BBMRI-ERIC. Due to the very late finalisation of the Annual Accounts by our accountant, Deloitte Graz (agreement on the accounts on 30 March, 2016), this report could not be submitted in advance to the Steering Committee.

The Annual Financial Report 2015 and all accounts have been audited by the External Auditor Ernst & Young Vienna as nominated by the Assembly of Members during their 5th Session on 27 October 2015. The Report of the External Auditor is included here.

The Annual Financial Report 2015 highlights the healthy financial status of BBMRI-ERIC despite some minor unexpected losses and expenses.

FINANCIAL HIGHLIGHTS *

CORE BUDGET

During the 3rd Session of the Assembly of Members, on 27 October 2015, the Budget for 2015 was approved at €2,028,739 (plus indirect costs from EU contributions of €106,113, giving a total of €2,135,181). This included Membership contributions of €1,770,719 plus €258,000 as Hosting Country contributions. In contrast to these earnings, expenses were foreseen of €1,324,105 for the HQs and €704,634 for Common Services. The annual accounts have shown total of earnings of €1,779,059 and expenditures of €1,506,174.

	expected 2015	actual 2015
Earnings	**€2,135,181**	**€1,779,059**
Membership contributions	€1,771,048	€1,614,998
Hosting country contributions	€258,020	€127,590
Indirect costs EU contributions	€106,113	€36,471
Expenditures	**€2,029,068**	**€1,506,174**
HQs	€1,324,434	€1,259,903
Common Services	€704,634	€246,271

* as approved by the AoM in the Resolution 2 on 28 April 2016 (AoM/6/R2)

This leads to net earnings of €272,885. The overall reason for the lower amount in earnings is due to an unpaid Membership contribution by the Republic of Greece, the unexpected lack of request for admission of Luxembourg and the fact that Poland did not change from observer to member during that year as originally hoped and foreseen. Due to the current economic and liquidity situation of Greece, the Director General of BBMRI-ERIC, who is responsible for preparing the financial statements, decided to book a 100% allowance for doubtful receivables relating to the already due member fee 2015 from Greece in line with Austrian generally accepted accounting principles. On the other hand the Czech Republic overpaid their contribution slightly. The reason for the significant reduction in earnings from indirect costs of EU grants is due to time factors. In the meantime these payments have been made and will appear on the accounts of 2016. The massively reduced expenditures in the area of Common Services are explained by the delayed start of the Common Service IT (it became operational and therefore expenditures only necessary in February 2016) and of the Stakeholder Forum Secretariat. For Common Service ELSI personnel costs were only invoiced during 2016. The details are shown in the tables under section 'detailed annual accountings' later.

OTHER INCOME

During 2015, additional income was generated in cash figures of €3,680,298 with major contributions from the ADOPT BBMRI-ERIC project as well as from the RItrain and CORBEL projects. Minor income came from those projects where BBMRI-ERIC is not coordinating but only participating. It is important to stress that these EC payments include the total pre-financing for all partners and are to be used beyond the first year. As payments for partners and linked 3rd parties were made largely during early 2016, the cash income at the end of the accounting year looks rather high but does not represent today´s situation. Expenditures from EU grants during 2015 were also lower than expected due to the late payments, some delays in requests for reimbursement and careful budgeting. VAT reimbursement is not considered in the budget tables but in the annual accounts (see the E&Y Auditor‘s report).

PROCUREMENT AND TAX EXEMPTION

According to the Statutes (Article 6), BBMRI-ERIC shall treat procurement candidates and tenders equally and without discrimination. During 2015, no major investments were carried out; for 3 additional rooms furniture was ordered using the same conditions as in 2014. In accordance with the ERIC Regulation (Official Journal L 206, 2009), BBMRI-ERIC asked the local tax authorities for tax exemption. This was granted late 2014 and BBMRI-ERIC is now treated as a company in terms of VAT. Local corporate tax is also exempted as well as municipal tax. VAT paid on invoices from Austrian customers is requested back from the certified accountant on a 3 months basis. With several months of delay the local tax authorities then reimburse BBMRI-ERIC.

BBMRI-ERIC CORE BUDGET 2016

cash method of accounting

EARNINGS	2015 approved	2015 actual	2016 expected	2017 expected	2018 expected
Membership contributions					
Austria	62,104	62,095	**61,639**	60,298	60,232
Belgium	70,356	70,345	**69,949**	68,173	68,091
Croatia			**9,064**	8,927	8,924
Cyprus			**6,623**	22,004	22,001
Czech Republic	42,717	46,059	**43,250**	42,204	42,171
Denmark			**0**	52,732	52,680
Estonia	22,185	22,184	**22,083**	22,014	22,010
Finland	47,927	47,921	**47,898**	47,132	47,091
France	269,130	269,072	**267,858**	255,749	255,314
Germany	349,456	349,378	**344,394**	334,246	333,663
Greece	46,577	0	**48,273**	45,239	45,201
Ireland			**44,552**	44,410	44,373
Italy	209,891	209,847	**212,593**	201,299	200,967
Latvia			**6,787**	6,760	6,758
Luxembourg	25,390		**0**	25,073	25,064
Malta	20,861	20,860	**20,832**	20,826	20,824
Moldova			**7,738**	6,218	6,217
Netherlands	96,426	96,409	**96,781**	96,337	96,203
Norway	70,718	21,212	**69,951**	67,493	67,413
Poland	53,574	16,069	**70,515**	51,035	50,953
Portugal			**13,501**	43,604	43,569
Spain				42,056	41,991
Slovenia				7,193	7,191
Sweden	73,322	73,310	**73,389**	71,978	71,890
Switzerland	24,923	24,919	**24,902**	64,001	63,894
United Kingdom	250,078	250,024	**247,866**	253,769	253,339
Turkey	29,415	29,294	**28,846**	30,995	30,950
IARC	6,000	6,000	**6,000**	6,000	6,000
Subtotal	**1,771,048**	**1,614,998**	**1,845,284**	**1,997,764**	**1,994,974**
Hosting country contributions					
Austria, hosting HQ	100,000	100,000	**100,000**	100,000	100,000
Hosting country ELSI CS	21,500	15,070	**21,500**	21,500	21,500
Hosting country IT CS	124,000	0	**147,320**	143,080	143,080
Hosting country SF	12,520	12,520	**22,000**	22,000	22,000
Subtotal	**258,020**	**127,590**	**290,820**	**286,580**	**264,580**
EU contribution					
indirect costs	106,113	36,471	**66,351**	157,252	91,278
EARNINGS, total	**2,135,181**	**1,779,059**	**2,202,455**	**2,441,596**	**2,350,832**

BBMRI-ERIC CORE BUDGET 2016

cash method of accounting

EXPENDITURES	2015 approved	2015 actual	**2016 expected**	2017 expected	2018 expected
Headquarters					
Salaries	-747,220	-673,285	**-779,175**	-845,539	-1,033,975
fringe benefits	-65,285	-53,772	**-61,025**	-74,896	-75,696
investment	-13,500	-19,175	**0**	-13,000	-5,000
rent	-129,529	-147,826	**-190,195**	-193,395	-195,326
consumables	-15,250	-20,291	**-5,500**	-10,250	-7,250
travel	-101,650	-151,136	**-96,250**	-106,250	-110,250
Contracts	-252,000	-194,418	**-139,000**	-143,000	-143,000
Subtotal	**-1,324,434**	**-1,259,903**	**-1,271,145**	**-1,386,330**	**-1,570,497**
Common Services					
ELSI	-344,626	-235,820	**-351,340**	-375,540	-375,540
IT	-272,615	-235,820	**-513,619**	-522,475	-525,320
SF	-87,393	0	**-156,061**	-137,025	-137,025
Subtotal	**-704,634**	**-246,271**	**-864,959**	**-898,015**	**-900,860**
EU contribution					
indirect costs	106,113	36,471	**66,351**	157,252	91,278
EXPENDITURES, total	**-2,029,068**	**-1,506,174**	**-2,136,104**	**-2,284,344**	**-2,471,358**
NET EARNINGS	106,113	272,885	**66,351**	157,252	-120,525

BBMRI-ERIC EXTERNAL FUNDING 2016

cash method of accounting

EARNINGS	2015 approved by funder	2015 actual	**2016 expected**	2017 expected	2018 expected
BMWFW transition grant	6,376	18,091	**0**	0	0
FP7 BioMedBridges	8,400	13,020	**8,400**	0	0
FP7 BBMRI-LPC	14,552	0	**14,552**	0	0
FP7 RD-Connect	100,000	0	**37,500**	37,500	37,500
IMI-EMTRAIN	4,485	4,485	**2,634**	2,635	0
H2020 EGI-Engage	43,386	43,386	**57,848**	6,428	0
H2020 CY-Biobank	43,521	43,521	**20,954**	0	0
H2020 B3Africa	31,500	31,500	**0**	31,500	0
H2020 ADOPT BBMRI-ERIC	2,227,603	2,227,603	**0**	2,227,603	247,511
H2020 CORBEL	584,827	584,827	**0**	382,387	382,387
H2020 Ritrain	648,581	648,581	**0**	623,636	0
H2020 PhenoMeNal	65,284	65,284	**0**	65,284	
EARNINGS, total	**3,778,515**	**3,680,298**	**141,888**	**3,376,973**	**667,398**

Reserve for pre-financing					
ADOPT	-370,861	-1,001,936			
CORBEL	-190,442	-190,442			
EGI-Engage	-19,524	0			
Reserve total	-580,827	-1,192,378			
Total	**3,197,688**	**2,487,920**			

BBMRI-ERIC EXTERNAL FUNDING 2016

cash method of accounting

EXPENDITURES	2015 approved by funder	2015 actual	**2016 expected**	2017 expected	2018 expected
Headquarters					
personnel costs	-179,873	-75,343	**-117,382**	-162,509	-32,517
subcontracting	0	0	**0**	0	0
other direct costs	-181,909	0	**-228,953**	-298,668	-167,756
indirect costs	-106,113	-36,471	**-66,351**	-157,252	-91,278
access costs	0	0	**0**	0	0
Subtotal	**-467,895**	**-111,814**	**-412,686**	**-618,429**	**-291,550**
Common Services					
ELSI	-140,719	-15,035	**-193,214**	-256,854	-83,745
IT	-299,970	0	**-449,955**	-599,940	-149,985
SHFS	-25,000	0	**-37,500**	-50,000	-12,500
Subtotal	**-465,689**	**-15,035**	**-680,669**	**-906,794**	**-246,230**
for linked 3rd parties					
H2020 EGI-Engage	-162,473	-25,413	**-200,979**	-241,453	-92,066
H2020 ADOPT BBMRI-ERIC	-119,317	-10,264	**-112,844**	-238,634	-59,659
H2020 CORBEL	-83,366	-4,119	**-192,600**	-264,581	-83,366
Subtotal	**-365,156**	**-39,796**	**-506,422**	**-744,669**	**-235,090**
for other parties/partner					
H2020 ADOPT BBMRI-ERIC	-522,022	0	**0**	-522,022	-116,005
H2020 RItrain	-481,394	-481,394	**0**	-370,303	-314,757
Subtotal	**-1,003,416**	**-481,394**	**0**	**-892,325**	**-430,762**
EXPENDITURES, total	**-2,302,155**	**-648,040**	**-1,599,777**	**-3,162,216**	**-1,203,633**
NET EARNINGS	**1,476,359**	**3,032,258**	**-1,457,889**	**214,757**	**-536,235**

REPORT OF THE EXTERNAL AUDITOR

BBMRI-ERIC, Graz

Report on the Audit of the
Financial Statements
as of December 31, 2015

4. AUDITOR'S REPORT

Report on the Financial Statement

We have audited the accompanying financial statements, including the accounting system, of **Biobanking and BioMolecular resources Research Infrastructure – European Research Infrastructure Consortium, Graz,** for the fiscal year from January 1, 2015 to December 31, 2015. These financial statements comprise the balance sheet as of December 31, 2015, the income statement for the fiscal year ended December 31, 2015, and the notes. Our responsibility and liability as auditor is analogously to Section 275 UGB (liability regulations for the audit of small and medium-sized companies) limited with a total of 2 million Euro towards the Company and towards third parties.

Management's Responsibility for the Financial Statements and for the Accounting System

The Company's management is responsible for the accounting system and for the preparation and fair presentation of these financial statements in accordance with Austrian Generally Accepted Accounting Principles. This responsibility includes: designing, implementing and maintaining internal control relevant to the preparation and fair presentation of financial statements that are free from material misstatement, whether due to fraud or error; selecting and applying appropriate accounting policies; and making accounting estimates that are reasonable in the circumstances.

Auditor's Responsibility and Description of Type and Scope of the Statutory Audit

Our responsibility is to express an opinion on these financial statements based on our audit. We conducted our audit in accordance with laws and regulations applicable in Austria and Austrian Standards on Auditing. Those standards require that we comply with professional guidelines and that we plan and perform the audit to obtain reasonable assurance whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the financial statements. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the Company's preparation and fair presentation of the financial statements 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. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

Opinion

Our audit did not give rise to any objections. In our opinion, which is based on the results of our audit, the financial statements comply with legal requirements and give a true and fair view of the financial position of the Company as of December 31, 2015 and of its financial performance for the fiscal year from January 1, 2015 to December 31, 2015 in accordance with Austrian Generally Accepted Accounting Principles.

Comments on the Management Report

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

Vienna, April 26, 2016

Ernst & Young
Wirtschaftsprüfungsgesellschaft m.b.H.

Katharina Schrenk
Wirtschaftsprüferin/Certified Auditor

ppa Gerald Steckbauer
Wirtschaftsprüfer/Certified Auditor

*) Disclosure, publication and duplication of the financial statements together with the auditor's report according to Section 281 (2) UGB in a form not in accordance with statutory requirements and differing from the version audited by us is not permitted. Reference to our audit may not be made without prior written permission from us.

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