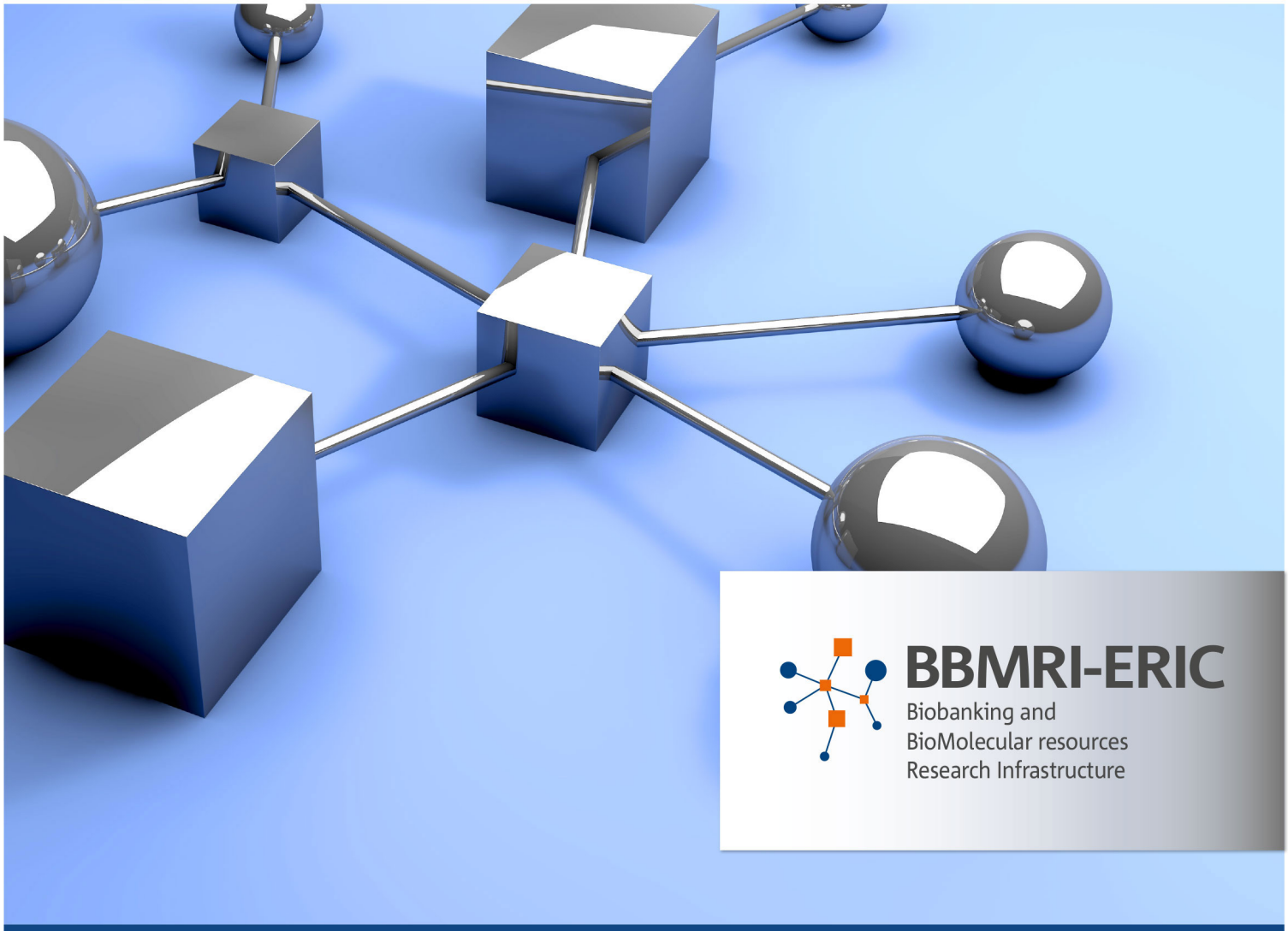


BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

WORK PROGRAMME 2014

v3.1

2014-06-05

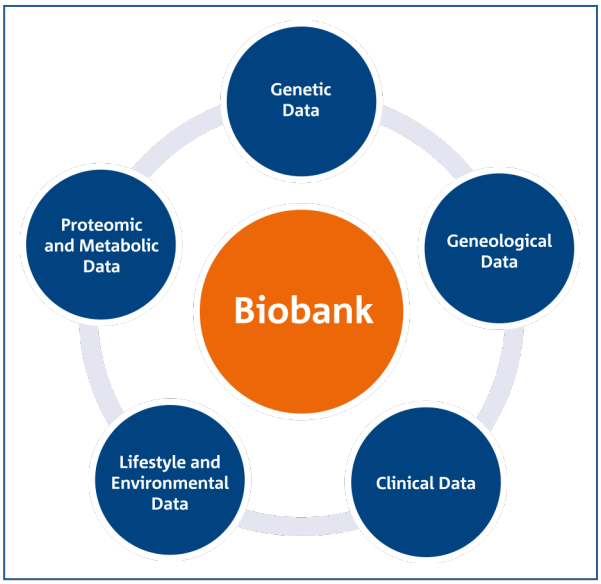
INTRODUCTION

One of the challenges in the post-genomics era is the research of common complex diseases, such as cancer, diabetes and Alzheimer's. Such disorders are caused by a large number of small, often additive effects, representing the outcome of the interplay of genes, lifestyle and the environment, at various levels. The complexity of the molecular patterns of diseases provides multiple opportunities for targeted therapeutic intervention, tailored to suit the particular characteristics of each patient.

Revealing these complex interactions will depend critically on the study of human biological *samples* and corresponding up-to-date epidemiological, clinical, biological, genealogical and molecular *information* from large numbers of patients and healthy individuals. The EU's aging population is resulting in an increase in many of those diseases and consequently, in heightened health care expenditure for people with old age, which in turn places pressure on the sustainability and viability of the EU's healthcare systems.

Human biological material – both samples and information – stored in biobanks and suitable for modern molecular analysis is the most critical resource for translation of advances in molecular biology and technologies towards improved human health. Biobanks enable the unraveling of the genetic and environmental factors that cause and influence the outcome of diseases, including new possibilities for disease prevention, early and/or improved diagnosis, prediction of optimal treatment alternatives and identification of new therapeutic drug targets (see Figure 1).

Figure 1: The Context of Biobanks



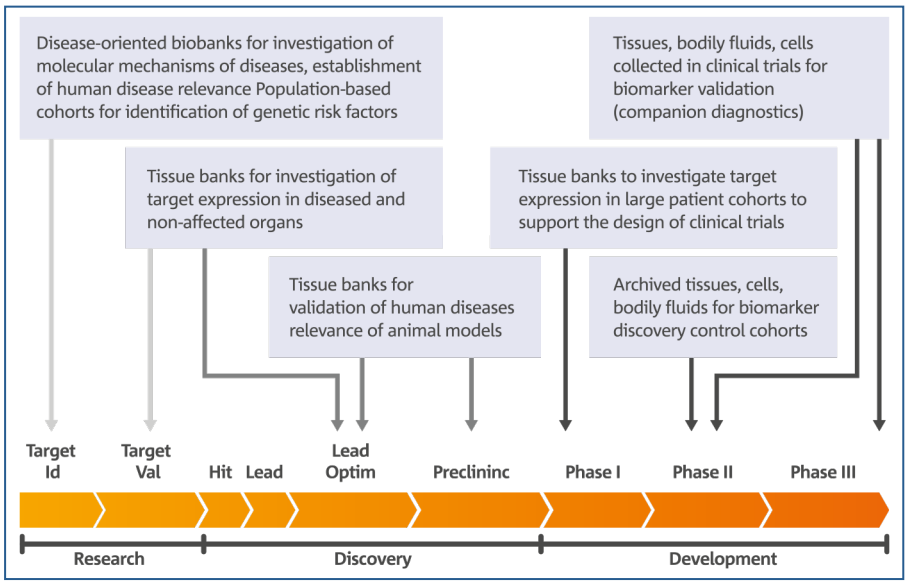
Biobank research involves the correlation of millions of data points – Big Data, by correlating molecular measurements of thousands of genes, proteins and metabolites, with all sorts of clinical, life-style, environmental and genealogical data. Many important and interesting scientific findings can be found in a combination of the variables under study.

By design, this data-driven, multi-purpose and multi-disciplinary research will constantly yield new biobank data. Specifically, the research is expected to identify risk factors related to more than one disease (common denominators) and the occurrence of various diseases within one individual. As the research findings and updated data are fed back into the biobank and the data is continuously updated, biobanks will become *"revolving data facilities".*

The whole process from early research up to preclinical research and further clinical development can be covered with samples provided by BBMRI-ERIC (Zatloukal and Hainaut, 2010, see Figure 2). BBMRI-ERIC is set up to become an important source for partners in academic and scientific institutions as well as in the pharmaceutical and life science

industries, thereby contributing directly to the Innovation Union concept.

Figure 2: BBMRI-ERIC: covering whole drug discovery and development process



However, biobank collections often suffer from fragmentation and underutilisation due to lack of commonly applied standards and limited access by investigators. As a result, merely retrieving high quality data on clinically annotated human samples is a time-consuming bottleneck for biomedical research in Europe as well as globally. Not having a proper infrastructure that connects biobanks across the EU, new discoveries, research on rare diseases identification of new targets for therapy and drug discovery and development continue to suffer from attrition and may be delayed, frustrated or even blocked from happening. Compounding the problem is the fact that biobanks contain sensitive data from human donors, of sometimes-vulnerable patient groups. To protect their interests, the use of biobanks, both internal and external use, is subject to laws and regulations which have proliferated into a patchwork of EU, national, institutional and data subject requirements and restrictions on access and exchange of information.

The ESFRI Roadmap leading to the BBMRI Preparatory Phase

The ESFRI roadmap addresses all scientific disciplines that require a large-scale Research Infrastructure with a joint effort on the European or international scale. In some cases, 'single sited' Research Infrastructures provide the best solution for the necessary research. In other cases, a 'distributed' Research Infrastructure is best suited from the scientific viewpoint as well as for the sustainability and optimisation of partially existing resources. BBMRI-ERIC will be a distributed infrastructure.

At the European level, BBMRI was one of the first ESFRI (The European Strategy Forum on Research Infrastructures) priorities. During the 3 years (2008-2011) of its Preparatory Phase BBMRI (BBMRI-PP) grew into a 54-member consortium with over 250 associated organisations from more than 30 countries in the Pan-European area. During BBMRI-PP, the concept of a functional, decentralised pan-European biobank research infrastructure was formulated and has been presented to Member States of the European Union and for associated states for approval and funding.
Table 1 shows the Work Package leader and governance structure under the Preparatory Phase.

Table 1: Governance Structure of BBMRI-PP

Work Packages (WP)	Leaders
WP1: Management and Coordination	K. Zatloukal (AT), E. Vuorio (FI)
WP2: Population-based Biobanks	L. Peltonen (FI,UK) + A.Metspalu (EE)
WP3: Diseases-oriented Biobanks	E. Wichmann (DE), T. Meitinger (DE)
WP4: Biomolecular Resources and Molecular Tools	U. Landegren (SE), M. Taussig (UK)
WP5: Database harmonization and IT-infrastructure	J-E. Litton (SE), M. Fransson (SE)
WP6: Ethical, Legal and Societal Issues	A. Cambon-Thomsen (FR)
WP7: Funding and Financing	G. Dagher (FR), J. Ridder (NL), C. Brechot (FR)
Governance Council Chair	L.Peltonen+ (FI/UK)
Advisory Board Chair	G-J van Ommen (NL)
Coordination Board Chair	K. Zatloukal (AT)
Stakeholder Forum Chair	M. Griffith (IR)

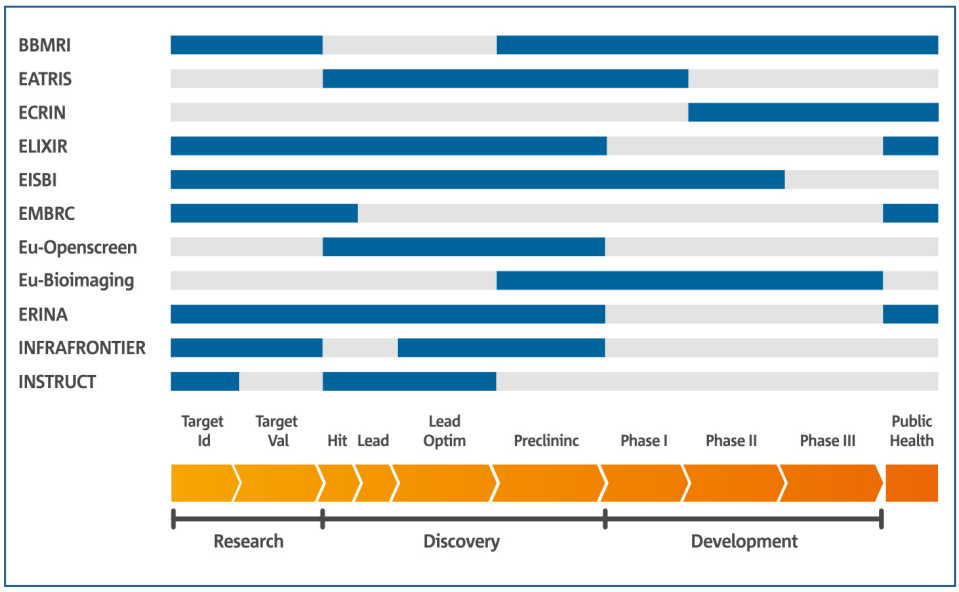
On December 3rd, 2013, BBMRI was officially awarded the Community legal framework for a European Research Infrastructure Consortium (ERIC). BBMRI-ERIC will provide access to the collections of partner biobanks and biomolecular resources, their expertise and services on a non-economic basis. Within the platform, research groups can develop functional standards for technical, legal and ethical purposes, set up criteria for biobanks, and so on. The ERIC also creates a platform for the involved researchers to communicate with policymakers in the EU and the Member States. A key challenge for BBMRI-ERIC is to provide access to biological samples and data that properly represent the diversity of European populations and diseases. This can only be achieved by a distributed research infrastructure with operational units in most, if not all, European Member States.

Supporting Research and Biobanking-activities for all BMS Research Infrastructures

Europe made a big leap forward in the last decade with the ESFRI process for establishing urgently required large-scale research infrastructures to support frontier research and innovation. There are currently 13 different biological and medical sciences (BMS) research infrastructures, from biobanks to structural biology, in the ESFRI Strategy Report and Roadmap 2010. These research infrastructures should work together to support the process from research up to clinical development for the benefit of the patients and the improvement of health care for European citizens, generating value for society through collaboration. (Zatloukal, Hainault 2010, see Figure 3).

Most of these infrastructures either require access to human biological samples or rely on biobanking expertise developed within BBMRI-ERIC. Consequently, BBMRI-ERIC will provide direct support of biobanking-related activities for all BMS research infrastructures. At the same time BBMRI-ERIC will benefit from technologies, know-how, and services developed by other infrastructures. For example, BBMRI- ERIC will work closely with ELIXIR to establish high-capacity computing and data storage solutions required for dealing with massive genomics, transcriptomics, metabolomics and with EURO-BIOIMAGING for imaging data. A Memorandum of Understanding has also been signed between EATRIS and BBMRI-ERIC. The main objectives of this collaboration will be to advance the development of biobanking and translational research infrastructures, and to improve quality and access to biobanking and biomarker development resources and expertise throughout Europe, thereby essentially contributing to the advancement of personalised medicine and to improve the efficacy in drug development.

Figure 3: Synergies of BMS Research Infrastructures



Furthermore, joint grant applications for improving interoperability of data management between BMS research infrastructures is ongoing. Under H2020, support will be provided for the implementation and operation of the research infrastructures listed on the ESFRI Roadmap, recognising the remarkable progress in recent years underpinning the European Research Area. BBMRI-ERIC will coordinate and partner in H2020 projects and will furthermore seek public-private partnerships within frameworks such as the Innovative Medicines Initiatives (IMI). The development of coordinated strategies for education and training in the life sciences is already a joint activity of all BMS research infrastructure.

BBMRI-ERIC: a Pan-European Research Infrastructure in Health Research

With 17 members, BBMRI-ERIC is one of the largest research infrastructures in health research today. Founding Member States of BBMRI-ERIC are: Austria, Belgium, Czech Republic, Estonia, Finland, France, Germany, Greece, Italy, Malta, The Netherlands and Sweden. Official Observers of BBMRI-ERIC are: Norway, Poland, Switzerland, Turkey and IARC. IARC is the International Agency for Research on Cancer, a World Health Organisation (WHO) agency and the first international organisation to join BBMRI-ERIC. Today, 24 countries are members of IARC.

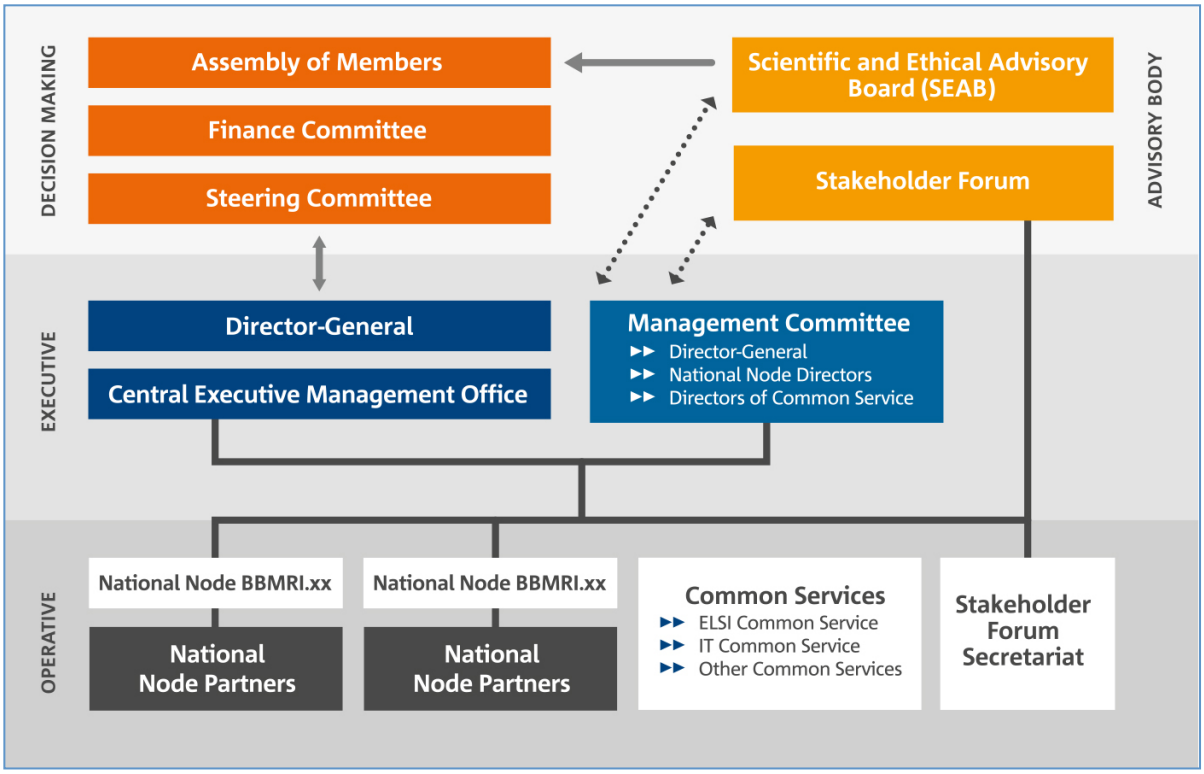
BBMRI-ERIC already shows good geographic and regional coverage all over Europe involving countries from South, East, West, North and Central Europe. BBMRI-ERIC has developed a funding model that allows both large member states such as Germany and France as well as very small member states like Malta and Estonia to participate as equal members.

Governance Structure

The principles of governance and management rules required for operation of BBMRI-ERIC are defined in BBMRI-ERIC Statutes and in the Rules of Procedure adopted by the Assembly of Members in its first session.

Figure 4 illustrates graphically the Governance and Management Structure of BBMRI-ERIC. The Members of BBMRI-ERIC are the countries and intergovernmental organisations that have signed the BBMRI-ERIC Statutes. The Assembly of Members consists of officially appointed delegates of participating Members.

Figure 4: Governance Structure of BBMRI-ERIC



Assembly of Members is the means by which the Members will make collective decisions on matters relating to BBMRI-ERIC, which will then be implemented by the Director General together with the staff of the Central Executive Management Office and the BBMRI-ERIC Management Committee. The Director-General acts as the Chief Executive Officer and legal representative of BBMRI-ERIC following the guidance given by the Assembly of Members, the Steering Committee and the Finance Committee.

In Table 2 the National Node Directors are presented by first listing the founding members and then the observers.

Table 2: National Node Directors

National Node	Director	National Node	Director
Austria	Prof. Kurt Zatloukal	Malta	Prof. Alex Felice
Belgium	Dr. Vincent Grégoire	The Netherlands	Prof. Gert-Jan van Ommen
Czech Republic	Prof. Dalibor Valíc	Sweden	Prof. Joakim Dillner
Estonia	Prof. Andres Metspalu		
Finland	Prof. Anu Jalanko	**Observer**	**Director**
France	Dr. Georges Dagher	Norway	Prof. Kristian Hveem
Germany	Prof. Michael Hummel	Poland	Dr. Lukasz Kozera
Greece	Dr. Sissy Kolyva	Switzerland	Dr. Stéphanie Wyss
Italy	Prof. Marialuisa Lavitrano	Turkey	Dr. Kemal Baysal
		IARC	Dr. Maimuna Mendy

A National Node is designated by a Member State that coordinates the national Biobanks and Biomolecular Resources Centres, and links national activities with the pan-European and international activities of BBMRI-ERIC. Each National Node has a Director appointed by an appropriate authority of the Member State. Each Member shall establish one National Node.

BBMRI-ERIC Common Services form a key element of the infrastructure as they provide top-level expertise, services and tools in specific areas of biobanking to the biobanking community and biobank users. Common Services are placed under the responsibility of the Director General and managed by a Director jointly appointed by the Director-General and the host Member State where the Common Service is located (see more under Work Plan 3).

Objective

The objective of BBMRI-ERIC is to create a world leading research infrastructure for bio-medical research in Europe. BBMRI-ERIC will increase efficacy and excellence of European bio-medical research:

- By facilitating access to quality-defined human health/disease-relevant biological resources, including associated data in an efficient and ethically and legally compliant manner
- By reducing the fragmentation of the bio-medical research landscape through harmonisation, of procedures, implementation of common standards and fostering high-level collaboration
- By capacity building in countries with less developed biobanking communities there by contributing to Europe's cohesion policy and strengthening the ERA

The Work Programme is the tool for fulfilling these objectives.

The Work Programme 2014 will establish basic operation and interoperability; overall efficacy will also be enhanced (2015-2016). In order to facilitate access the searchable catalogue of available samples and data will be updated and improved in data quality and granularity for BBMRI-ERIC partner biobanks. Common standards will be implemented and a quality management system established including performance indicators.

After the establishment of basic operation will follow by the full implementation for 2015-2016. Full implementation is characterised by capacity building as well as extending the operation and functionality of BBMRI-ERIC and work done by BBMRI-LPC and other projects mention in Work Programme 2014. This will comprise improved data management capacities and services including the establishment of web-based applications to improve searches on available samples and data, thereby increasing speed and efficacy for access. Research services will be implemented. Furthermore, the global integration and positioning of BBMRI-ERIC will become a strategic priority.

The **main deliverables 2014** include:

- Launch Central Executive Management Office in Graz
- Updated Catalogue of European Biobanks
- Launch Common Service ELSI
- Launch Common Service IT
- Planning for the Stakeholder’s Forum Secretariat
- Participation in H2020 calls as partner and/or coordinator
- Approval of Partner Charter
- Self-Evaluation of BBMRI-ERIC biobanks
- Hold HandsOn Biobanks in Helsinki, Finland
- Finish the Communication Platform of BBMRI-ERIC
- Engage with BBMRI-ERIC Stakeholders in building Pan-European Relationships
- Start to build a European Curricula on Education & Training for Biobankers
- Have the Scientific Retreat in Tartu, Estonia

- BBMRI-ERIC Webinar
- Publish Newsletter ”Biobank Europé”
- Publish the Minimum Information about Biobank data Sharing (MIABIS)
- Update Biobank Lexicon

Structure of the Work Programme

The Work Programme includes the description of the strategy, planned activities, staffing and funding of BBMRI-ERIC for a certain period of time. Over time, the Work Programmes will replace the Business Plan (v 21.1 from 2014/03/01).

The Statutes of BBMRI-ERIC foresee the annual Work Programme and preliminary Work Programmes for the two following years. The Director General, in collaboration with the National Coordinators via the BBMRI-ERIC Management Committee (MC), will develop the final Work Programme, therewith also including the input of the Directors of the Common Services. The budget of the Work Programme will be discussed in the Finance Committee and finally adapted by the Assembly of Members (AoM).

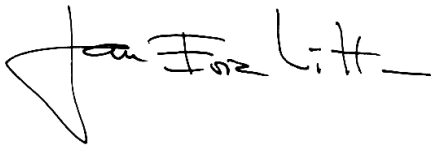
The Work Programme is divided into several Work Plans (Tasks), each of them consisting of different Work Streams. Every Work Stream is usually divided into 7 sections: Background, Mission, Goals and Deliverables, Time Plan, Priority, Project Group and Resources. Each Work Stream also has a priority 1-4 (1=high).

In Table 3, the priorities for the Work Streams - as prepared by the Management Committee - are summarised.

In preparation for the Work Programme 2014, 22 Work Streams have been identified and categorised into 8 Work Plans (for an overview of priorities see Annex, Table 7: Overview of Goals and Deliverables of Work Streams). These Work Plans are:

1. Foundation of the Central Executive Management Office in Graz
2. Biobank outreach
3. Setup of the BBMRI-ERIC Common Services
4. Start Pan-European and international fundraising efforts for BBMRI-ERIC
5. Quality assurance
6. Implementation of Expert Centres
7. Set-up of e-infrastructure
8. Finish work from BBMRI-PP

Graz 2014/06/05



Prof. Jan-Eric Litton
BBMRI-ERIC Director General

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ABBREVIATIONS

AD	Administrative Director
AoM	Assembly of Members
BBMRI	Biobanking and BioMolecular resources Research Infrastructure
BMS	Biological and Medical Sciences
BRC	Biological Resource Centre
BRIF	Bioresource Research Impact Factor
BSL	Biosafety level
CD	Corporate Design
CS	Common Service
DG	Director General
E&T	Education and Training
EATRIS	European Advanced Translational Research Infrastructure in Medicine
ECRIN	European Clinical Research Infrastructures Network
EFNA	European Federation of Neurological
EGAN	European Genetic Alliance Network
ELIXIR	Europeal life science infrastructure for biological information
ELSI	Ethical, Legal and Social Issues
ENRAH	European Network for Research on Alternating Hemiplegia
epSOS	European Patients Smart Open Services
ERC	European Research Council
ERIC	European Research Infrastructure Consortium
ESFRI	European Strategy Forum on Research Infrastructures
EU	European Union
EUOPENSCREEN	European Infrastructure of Open Screening Platforms for Chemical Biology
Europa Donna	The European Breast Cancer Coalition
EURORDIS	European Organisation for Rare Diseases
FC	Financial Committee
FP	Framework Programme
GWAS	Genome-wide association study
HQ	Headquarter
IAPO	International Alliance of Patient Organisations
IARC	International Agency for Research on Cancer
ICD	International Statistical Classification
IMI	Innovative Medicines Initiative
INSERM	Institut national de la santé et de la recherche médicale
ISBER	International Society for Biological and Environmental Repositories
ISO	International Organisation for Standardisation
ITM	IT Manager
LAW	Lawyer
MC	Management Committee

MIABIS	Minimum Information About BIobank data Sharing
P³G	Public Population Project in Genomics
PA	Project Assistant
PaaS	Platform-as-a-service
PP	Preparatory Phase
PR	Public Relations
Q	Quarter
QA	Quality assurance
QC	Quality control
QMS	Quality Management System
QUM	Quality Manager
R&D	Research & Development
RD	Rare Diseases
RI	Research Infrastructure
SEAB	Scientific and Ethical Advisory Board
SEC	Secretary/Receptionist
SF	Stakeholder Forum
SOP	Standard Operating Procedure
SPM	Senior Project Manager
VSOP	Dutch Genetic Alliance (VSOP)
WP	Work Programme
WHO	World Health Organisation
ZWT	Centre for Knowledge and Technology Transfer in Medicine

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WS 2.1 HandsOn			3	
WS 2.2 Communication			3	
WS 2.3 Stakeholder			3	
WS 2.4 E&T WP			3	
WS 2.5 Retreat				4
WS 2.6 Webinars				4
WS 2.7 Newsletter				4
WS 3.1 CS ELSI		2		
WS 3.2 CS IT		2		
WS 3.3 CS RD		2		
WS 3.4 CS SFS		2		
WS 3.5 EVA		2		
WS 4.1 Fundraising		2		
WS 5.1 QMS		2		
WS 5.2 Partner Charter		2		
WS 5.3 Self Evaluation		2		
WS 6.1 Expert Centre		2		
WS 7.1 Biobank Catalogue	1			
WS 7.2 BioBank Cloud			3	
WS 7.3 CoBiBa			3	
WS 8.1 MIABIS				4
WS 8.2 Lexicon				4

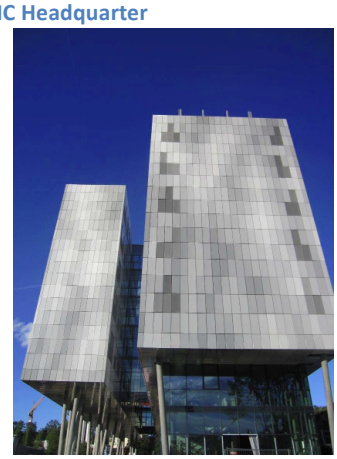
1 WORK PLAN: Central Executive Management Office in Graz

1.1 Work Stream Set-up of the Central Executive Management Office - HQ

1.1.1 Background

Image 1: BBMRI-ERIC Headquarter

BBMRI-ERIC, Neue Stiftingtalstrasse 2/B/6, 8010 Graz, AUSTRIA



The Founding Members of BBMRI-ERIC have jointly agreed to accept the Austrian Government's offer to host the Headquarter in Graz, Austria. Graz is the city with the country's biggest biobank. Biobank Graz is a facility of the Medical University of Graz, which was coordinating the BBMRI Preparatory Phase Project (BBMRI-PP, GA 212111), led by Prof. Kurt Zatloukal. The Federal Ministry of Science and Research has provided office space in a new building (ZWT) at the Campus of the Medical University of Graz. The ZWT will also host the office of the Austrian National Node of BBMRI-ERIC (see Image 1: BBMRI-ERIC Headquarter).

1.1.2 Mission

The Director General (DG) will serve as the Chief Executive Officer of BBMRI-ERIC, as such being responsible for the Executive Management of BBMRI-ERIC. The Central Executive Management Office (HQ) will assist him in his managerial functions. An Administrative Director (AD), responsible for all non-scientific issues like general administration, HQ, accounting and finance will support the DG. In fulfilling the objectives of the Work Programme and ensuring the future excellence of the organisation, BBMRI-ERIC relies on internationally competent staff. This requires attracting an internationally experienced team. The new premises of the HQ in A-8010 Graz, Neue Stiftingtalstrasse 2, ZWT will be ready in May 2014.

1.1.3 Goals and Deliverables

This Work Stream has the following goals:

- Recruiting the staff needed for the delivery of the Work Programme
- Equipping the office in Graz, IT infrastructure included
- Explore subletting free office space
- Implementation of internal rules and processes for the HQ, accounting and communication
- Support of the Assembly of Members (AoM), the Finance Committee (FC), the Management Committee (MC), Common Services and the Scientific and Ethical

Advisory Board (SEAB)
- Provide back office support to the other Work Streams and Working Groups[1]
- Coordinate reporting and evaluation activities
- Developing the Work Programme 2015 and preliminary Work Programme 2016-2017
- Support the tender process for the Common Services ELSI, IT, planning of the Stakeholder Forum Secretariat

The deliverables of this Work Stream are:

- the signed staff contracts
- a fully functioning and furnished office
- exploring subletting during the first months
- an Operations Handbook
- bank account and working consulting contract for general accounting and payroll accounting
- Project Management support system for the Working Groups, Holding Sessions of the AoM and FC, Management Committee Meetings and Common Services Meetings
- a constitutive SEAB meeting
- development of an archive system, the preliminary Annual Report 2014 and the Work Programme 2015 and provisional WP 2016-2017
- successful start of 2 Common Services into ERIC structures, and
- a plan for Stakeholder Forum Secretariat.

1.1.4 Time Plan

Some of the deliverables are continuous work; others have fixed or planned delivery dates. The following table summarises deliverables and timeline:

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Fully functioning and furnished office												
Operations Handbook												
Bank account and consulting contract for general accounting and payroll accounting												
Project Management support system for the Working Groups												
AoM Sessions	1			2						3		
FC Sessions	1			2					3			
MC Meetings	1	2	3		4	5			6		7	
SEAB Meeting											1	
Development of an archive system												
Preliminary Annual Report 2014												
Work Programme 2015 and provisional WP 2016-2017												
Recruit Senior Staff, DG and AD												
Recruit Support Staff, Secretary and Project Assistant												
Recruit Senior Project Manager												
Recruit IT Manager												

[1] Once the Working Groups are formed, interested parties to join should contact the respective Chair. New Working Groups can be formed any time when needed. See overview in the Annex.

Recruit Lawyer												
Recruit Quality Manager												
Tender for Common Service ELSI												
Tender for Common Service IT												
Plan for Common Service Stakeholder Forum Secretariat												
Plan for Common Service Rare Diseases												

1.1.5 Priority

1.

1.1.6 Project Group

AD, DG, SPM, ITM, LAW, QUM, PA, SEC of HQ

1.1.7 Resources

The Human Resources necessary for this Work Stream are as following:

Staff Function	Full Time Equivalent in Person Month
DG	**0.5**
AD	**4**
PA	**7**
SEC	**7**
SPM	**1**
ITM	**0.5**
LAW	**1**
QUM	**0.5**
total	**21.5**

Other Resources:

Office rent; running costs; insurances; fringe benefits and travel expenses; consulting fees for general accounting and payroll accounting; consulting fees for legal support; IT infrastructure, phone and Internet backbone; furniture of the HQ; recurrent expenses for mailing and consumables; marketing material; expenses to host the AoM and FC Sessions, the MC Meetings, Common Services Meetings and SEAB meeting; other outsourcing expenses (e.g. IT, Corporate Design, printing costs, etc.).

2 WORK PLAN: Biobank Outreach (Central Executive Management Office)

2.1 Work Stream: HandsOn: Biobanks

2.1.1 Background

HandsOn: Biobanks will be a yearly event by BBMRI-ERIC hosted by a National Node(s). For the event, we have created an interactive biobank exhibition –THE ROUTE (Figure 5: Introducing the THE ROUTE Format: An Interactive Biobank Exhibition) – where you follow the research process and discuss the value of biobank research for society as well as for current and future patients.

The conference also offers keynote lectures, educational sessions and a knowledge-sharing programme. This conference gives a great opportunity to meet experts from all around the world in the biobanking field and to discuss future issues for biobanking.

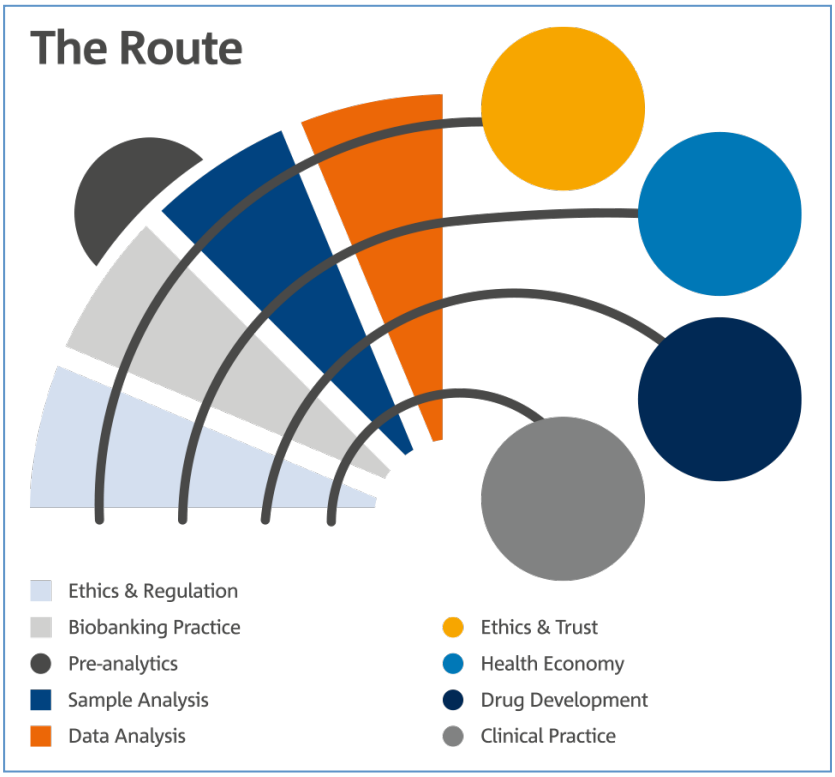


Figure 5: Introducing the THE ROUTE Format: An Interactive Biobank Exhibition

The steps of the Route:

The research process:

- Ethics & Regulation: ethics and law as regulations and prerequisites for biobank research
- Biobanking practice & Pre-analytics: the whole process around collection, distribution and storage (freezers, robotics, sample tracking systems, etc.). After samples have been collected and sent to a biobank, samples are registered in a system before processing and storage. This pre-analytical step includes aliquotation into barcoded storage tubes and DNA/RNA extraction
- Sample Analysis: the step to show how instruments for genomics, proteomics, metabolomics and transcriptomics are used to analyse the samples
- Data Analysis: statistical analysis
- Dissemination: suitable media, open access *vs*. privacy, nano-publications, high

throughput data, and biobank research impact factor

The value of biobanking:

- Ethics & Trust (Science Cafe)
- Health Economy
- Drug Development
- Clinical Practice

The first *HandsOn: Biobanks* conference was hosted by BBMRI.se, 2012/09/20-21 in Uppsala, Sweden and was a success with 400 delegates from 27 countries. Before the *HandsOn: Biobanks*, 2012/09/19, a pre-conference was arranged: *The International Biobanking Summit: Future Directions*, arranged by P^3G, ISBER, BioSHaRE.EU, ENGAGE and ESBB, and hosted by BBMRI.se. Following the great success of the 2012 conference, BBMRI-ERIC decided to make this conference an annual event. The second *HandsOn: Biobanks 2013: Communities Connected*, 2013/11/21-22, was held in The Hague, The Netherlands. The conference welcomed 331 participants from all strata of the life sciences from 17 countries.

2.1.2 Mission

Part of the conference programme is an interactive sequence of displays where participants can go through the biobanking process step by step. From filling out and signing an informed consent form, via sample collection and storage to analysis and dissemination of results, the samples and data in the Route will travel through a chain of different activities and processes.

There are Idea Labs, Hands-On Exhibitions, poster presentations and knowledge sharing to present, discuss and develop ideas for getting the best out of biobanking. Invited are academia, industry, doctors, patient groups, policy makers, public representatives and legislators to contribute and to share knowledge and concerns.

The inspiration for the Idea Labs format stems from the World Economic Forum meeting, where it is used to create an interactive discussion between the session participants that can come from very different backgrounds. At each Idea Lab at the World Economic Forum, leading thinkers from the world's top academic institutions present their current thinking, and the audience and their colleagues interact on their ideas.

2.1.3 Goals and Deliverables

A special invitation is directed to all EU- and IMI-funded consortia working with human tissue samples and registries. The aim of this conference is to share visions, knowledge and solutions, and BBMRI-ERIC will offer knowledge sharing platforms (posters and/or oral presentations) to both sponsors and participants.

2.1.4 Priority

3.

2.1.5 Time Plan

BBMRI.fi will be the next organiser responsible for the *HandsOn: Biobanks* Conference, which will be held on September 24-25, 2014 at the Marina Congress Center in Helsinki, Finland**.** The *International Biobank Summit* III (IBS III), arranged by ISBER, P^{3}G, BioSHaRE.EU, BBMRI-LPC and ESBB, and will be hosted by BBMRI.fi and is integrated in the HandsOn conference programme. For a full list of partners and organisers see http://www.handsonbiobanks.org/2014/.

The *HandsOn: Biobanks 2015* will be hosted by BBMRI.it and will be a part of Expo 2015 in Milan, Italy. The Expo is a non-commercial Universal Exposition organised by the nation that wins the candidature, with other countries participating through the diplomatic channels of the hosting nation. The first Expo was held in London in 1851 and was such a success that other nations were encouraged to organise similar events like the Paris Expo in 1889, for which the Eiffel Tower was designed and built.

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Planning of the conference												
Decision *HandsOn 2015* Italy, part of EXPO and first preparations												
Publishing of the *HandsOn* website												
Hold the conference *HandsOn 2014*												
Prepare for the conference *HandsOn 2015 (e.g. safe-the-date)*												
Post-production of *HandsOn 2014* (e.g. report, slides, update website)												

2.1.6 Project Group

DG and SPM of HQ

Organising Committee - HandsOn: Biobanks - Helsinki 2014:

Prof. Anu Jalanko, National Institute for Health and Welfare THL (BBMRI.fi National Coordinator) Anu.Jalanko@thl.fi
Prof. Jan-Eric Litton, BBMRI-ERIC Director General, Jan-Eric.Litton@bbmri-eric.eu
Dr. Outi Törnwall, THL, HandsOn 2014 project coordinator, Outi.Tornwall@thl.fi
Prof. Markus Perola, THL (BBMRI-LPC Coordinator) BBMRI.fi, Markus.Perola@thl.fi
Prof. Tarja Laitinen, University of Turku and Hospital District of Southwestern Finland, BBMRI.fi, Tarja-Helena.Laitinen@tyks.fi
Prof. Olli Carpen, University of Turku, BBMRI.fi, Olli.Carpen@utu.fi
Adjunct Prof. Heli Salminen, Auria Biobank, BBMRI.fi, hejsalm@utu.fi
M.Sc. Perttu Terho, Auria biobank, BBMRI.fi, pterho@utu.fi
Dr. Tuomas Mirtti, HUS, BBMRI.fi, Tuomas.Mirtti@hus.fi
Dr. Kimmo Pitkänen, Institute for Molecular Medicine Finland, FIMM, BBMRI.fi, Kimmo.Pitkanen@helsinki.fi

Dr. Helena Kääriäinen, THL, BBMRI.fi, Helena.Kaariainen@thl.fi
Dr. Tuija Koski, BBMRI.fi secretary, Tuija.Koski@thl.fi

Besides BBMRI-ERIC, BBMRI.fi, P^{3}G, ISBER, IRDiRC, ICGD, Inserm, Global Alliance and BioShare will be partners and organisers to *HandsOn 2014 and IBS III.*

2.1.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.25
SPM	0.25
total	0.5

BBMRI.fi (*HandsOn 2014*)

BBMRI.it (*HandsOn 2015*)

2.2 Work Stream: A Communication Platform for BBMRI-ERIC

2.2.1 Background

In recent years, biobanks have been identified globally as crucial research infrastructures significant to the progress in medicine and public health. To ensure that biobanks reach their full potential, better engagement with the various public players (biobankers, policy makers, patient groups, lay people, stakeholders, the industry, other BMS RIs, etc.) is needed.

The communication platform build up for BBMR-ERIC will first service BBMRI-ERIC and the National Nodes. Consequently, the communication platform should be built up as a mechanism to share information within BBMRI-ERIC. It should allow smooth communication among the National Nodes, Working Groups and BBMRI-ERIC bodies by providing updated information on ongoing and submitted research proposals, archiving draft and final minutes, etc.

Simultaneously, it should be set up to provide basic information on biobanking to the public and its peers. As for the European public, most of them have not heard of their nation's repositories of human blood and tissue samples and biobanking is still an unfamiliar concept to many, as is its European and international scope. Acknowledging the unfamiliarity of the general public with biobanks and the various sensitivities in European countries when it comes to biomedical and genetic research (Eurobarometer 2010), any media and PR-campaign has to be not only carefully drafted and tested before being launched but also coordinated among the National Nodes. Sharing experiences and coordinating PR and public engagement activities would not only increase efficacy, but also strengthen the recognition of biobanks all over Europe.

Moreover, the presentation of BBMRI-ERIC on the Web contributes greatly to the creation of an ever-increasing global information database and has to address issues of public fears as well as technical solutions on data protection. Thus, its importance cannot be overemphasised. Considering the connections within with the biobanking community (e.g. to coordinate and to advertise events among the National Nodes, HQ and with ISBER; P^3G et al.) and the dissemination of information on many different channels and computing platforms, including traditional mailing lists but also mobiles and the new media (e.g. twitter), the mechanisms of the Web insulates us from needing to know or dealing with this - it takes care of getting, moving and presenting the information we need. A stratified database containing the contact details of over 2000 individuals and organisations associated with BBMRI-PP (participants, associated organisations, peers, policy makers, etc.) from Coordination activities has been assembled. This contact database, together with the SF contact database, is a key asset for public relations. Also other communication tools are described in this Work Programme, e.g. Webinar (see 2.6) and the Newsletter “Biobank Europe” (see 2.7).

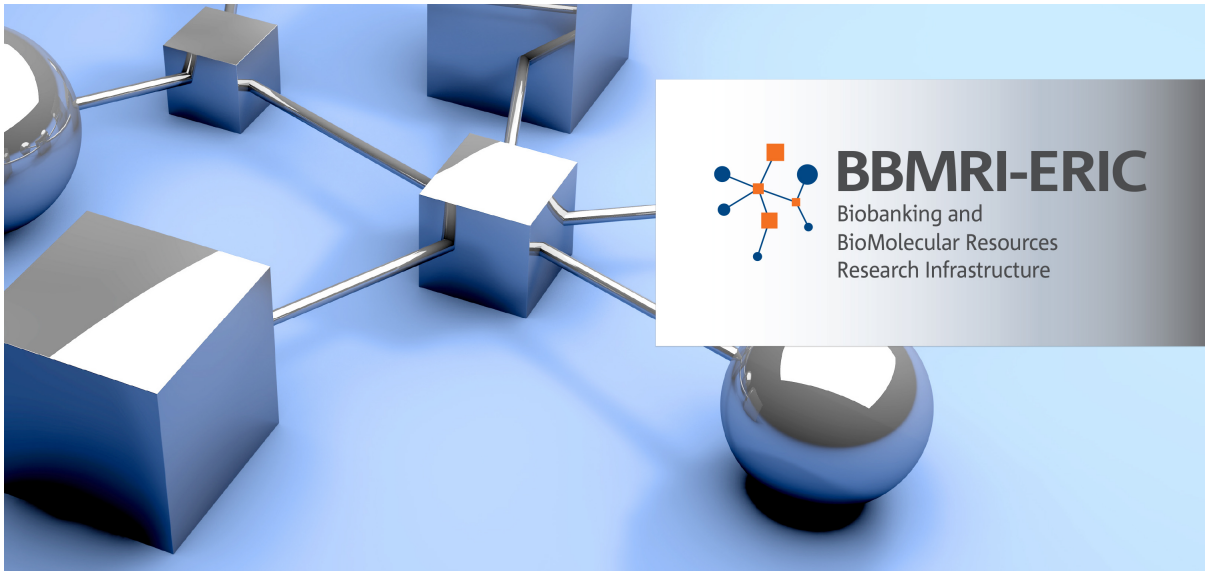
The graphic profile stems from the Hub-and-Spoke network (first described during the FP5 project GenomEUTwin in 2002), which was used as the central element for the logo design since the start of BBMRI in 2008. Meanwhile, the logo has become a recognised trademark in the field and will remain central to BBMRI-ERIC’s Corporate Design (see Image 2: Building

on the BBMRI-PP Logo for the Corporate Design (CD)).

2.2.2 Mission

A new CD and website (intranet and public), http://www.bbmri-eric.eu will be presented during Q2 2014. The website will be set up to address lay people and experts alike, such as patients, the general public, policy makers, stakeholders, experts, biobankers, etc. Moreover, this website will integrate or relink all existing websites of the BBMRI Preparatory Phase, such as the different wikis, catalogues, etc. It will also serve as the first contact point for individuals looking for biobanking resources in Europe. Most importantly, it will serve as an exchange platform for and within BBMRI-ERIC, the National Nodes (e.g. templates, images, etc.) and Working Groups (e.g., Horizon 2020).

Image 2: Building on the BBMRI-PP Logo for the Corporate Design (CD)



2.2.3 Goals and Deliverables

This Work Stream has the following goals:

- Creating a consistent, modern and memorable CD by building on the BBMRI Preparatory Phase logo
- Creating templates for Word, Powerpoint, scientific posters, etc. for BBMRI-ERIC and National Nodes
- Customising business cards, letter paper, notepads, etc.
- Conceptualising information material such as brochures and flyers
- Setting up the website with the new design and updated content for both the general public and the biobanking community
- Integrating or relinking all existing websites of the BBMRI Preparatory Phase to the new website
- Setting up an intranet website to exchange documents and information
- Creating a shared pool of images, graphs, etc. for presenting BBMRI-ERIC and the

National Nodes

- Engaging with the public via new (social) media, etc.
- Liaising with the biobanking community and stakeholders via the website, mailing lists, newsletter, information material and new (social) media
- Liaising with others on communication (e.g. other RIs or ISBER; P^3G etc.)
- Coordinating public engagement and PR activities among HQ and the National Nodes

2.2.4 Priority

3.

2.2.5 Time Plan

The work started unofficially in Q4 2013 in the course of the BBMRI-ERIC Inauguration Conference, including a new graphic design and a new outline for www.bbmri-eric.eu. This design will also be used for all printed material. The first phase of this project will end in Q2 2014, including the launch of the new website (public and intranet) and templates (word, ppt, etc.). The second phase includes various means of communication such as brochures and posters as well as new (social) media.

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Creating a consistent, modern and memorable Corporate Design (CD) for web and print	■	■	■	■								
Creating templates for Word, Powerpoint, scientific posters, etc. for BBMRI-ERIC and National Nodes	■	■	■	■								
Customising business cards, letter paper, note pads, etc.	■	■	■	■								
Conceptualising information material					■	■	■					
Setting up the website with the new design			■	■	■							
Finalising posters, brochures, etc. (content + print) for conferences, etc.								■	■	■	■	■
Setting up an intranet website to exchange documents and information				■	■							
Creating a shared pool of images, graphs etc.			■	■								
Starting engaging with the public via website and other means					■	■	■	■	■	■	■	■
Liaise with others on communication			■	■	■	■	■	■	■	■	■	■
Content management (intranet and old/new public website, contact database)	■	■	■	■	■	■	■	■	■	■	■	■

2.2.6 Project Group

DG, SPM, AD, ITM

2.2.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
SPM	2
DG	0.5
AD	0.5
ITM	0,25

total	3,25

The Company Ganzgustav, http://www.ganzgustav.at/ is responsible for the CD of BBMRI-ERIC and was also responsible for the graphic design of the BBMRI-ERIC Inauguration Conference. For BBMRI-ERIC, it is supported by 3D-Graphics Design through Elias Freiberger http://eliasfreiberger.prosite.com/. The BBMRI-ERIC website (intranet and public) will run with liferay 6.2 CE and is provided by HMMC KG. Options on secure and efficient server hosting will be explored.

2.3 Work Stream: Start Building Effective Pan-European Relationship with a Broad Range of Stakeholders

2.3.1 Background

The cooperation within international biobank networks in the pooling of samples and data has been ongoing since several decades. This collaboration is expected to further expand in the future with the objective of addressing common important public health issues. The collaboration will even go beyond the biobanking world and will include Learned Societies, Patient Organisations, Regional and National Governments.

2.3.2 Mission

The mission of this Work Stream is:

- To present BBMRI-ERIC at international events
- To identify the national and international success stories where biobanks/epidemiology has been used for major discoveries of significant public health impact in Europe and internationally
- To identify new areas for specific public health interventions
- Coordinate with National Nodes and Member States to raise awareness on stakeholder and policy maker levels
- Explore BBMRI-ERIC membership with China

Building on existing engagement activities:

Working Group 3 led by Prof. Alex Felice (BBMRI.mt) is set up to strengthen the Euro–Mediterranean engagement. Additionally, the Working Group 5 on China (led by Dr. Georges Dagher) and Working Group 6 on Sub-Saharan-Africa (led by Prof. Kurt Zatloukal) have been set up to connect to important initiatives such as PAERIP.

Furthermore, BBMRI-ERIC is a collaborator of BCNet – The Low-and Middle-Income Countries Biobank and Cohort Network. BCNet is an initiative from IARC. The BCNet catalogue will be built with MAIBIS (see 8.1) as the base. Details can be found at: http://www.iarc.fr/en/media-centre/iarcnews/pdf/BCNetLaunch.pdf

A consulting agreement will be explored with a Brussels-based company to get better access to political opinion leaders in the EU and beyond. In addition to raising awareness with its user community and stakeholders, BBMRI-ERIC will require the support of policy and decision makers to create a favourable legal, regulatory and funding environment. This includes:

- Reducing the fragmentation of the bio-medical research landscape through harmonisation
- Contributing of procedures, implementation of common standards and fostering high-level collaboration
- By building in countries with less developed biobanking communities

BBMRI-ERIC will need to raise awareness about these issues with European policy- and decision makers to increase efficacy and excellence of European bio-medical research. Furthermore, these areas will be crucial in order to further Europe's cohesion policy and strengthening the European Research Area.

2.3.3 Goals and Deliverables

Engage with stakeholders on all levels and policy makers, well coordinated with the National Node activities.

Present BBMRI-ERIC activities during 2014 in international events and invite new countries to join BBMRI-ERIC. Presenting BBMRI-ERIC during Q1, Q2 in the following international events:

- *Cancer Biobanking – Establishing the 1st Cancer Biobank in Jordan*, Amman, Jordan, 2014/04/10-11, BBMRI-ERIC a new governance tool for Biobanking, Prof Jan-Eric Litton, The BBMRI Biobank lexicon, Prof Jan-Eric Litton
- *ELIXIR EU-meeting*, Sandhamn, Sweden, 2014/05/06-08, BBMRI-ERIC a new governance tool for Biobanking, Prof Jan-Eric Litton
- *P3G, Ethics at the Crossroads: Where Public Health, Genomics, Data and Translational Science Meet*, Indianapolis, USA, 2014/05/07, Robin Round, introducing BBMRI-ERIC, Dr. Michaela Th. Mayrhofer
- *ISBER 2014*, Annual Meeting & Exhibits, Orlando, Florida, 2014/05/20-24, Invited speaker Prof Jan-Eric Litton; Important Biobanking development in Europe; BBMRI-ERIC.
- *International Symposium on clinical and translational Medicine*, Shanghai, China, 2014/05/28-29. BBMRI-ERIC, Prof Jan-Eric Litton
- *Biobank in Poland and Europe – technical, legal and ethical aspects*, 2014/06/17-18. Hosted by the Ministry of Science and Higher Education, Warsaw, Poland. Why biobanks should cooperate. The initiative of BBMRI-ERIC, Prof Jan-Eric Litton

BBMRI-ERIC is aware of the increasing importance of imaging for detailed analysis and interoperability of samples collected in biobanks. In a European context, Euro-BioImaging is set to become the infrastructure that will provide access and training in biological and medical imaging technologies. BBMRI-ERIC is collaborating with Euro-BioImaging in BioMedBridges, working towards interoperability of human, mouse and cellular image data sets in order to facilitate discovery of potential biomarkers. We will work together towards development of the joint Memorandum of Understanding, driving our collaboration even further.

Correspondence 1: News Release: BBRMI-ERIC & EATRIS signed MoU

The importance of the role of biobanking within biomedical research is recognised through the collaboration between EATRIS-ERIC and BBMRI-ERIC.

EATRIS-ERIC (the European Infrastructure for Translational Medicine) and BBMRI-ERIC (the Biobanking and BioMolecular Resources Research Infrastructure) have normalised their collaboration through the signing of a Memorandum of Understadning (MoU) 16 March 2014.

The purpose of this MoU is to set up a collaboration between the two Research Infrastructures (RI) EATRIS-ERIC and BBMRI-ERIC. The main objectives of this collaboration will be to advance the development of biobanking and translational research infrastructures, and to improve quality and access to biobanking and biomarker development resources and expertise throughout Europe.

The governance of the collaboration will be dealt with as part of the structuring of a joint project and will be stipulated in a Collaboration Agreement. Partners and stakeholders that will be involved in the development and implementation of the collaboration are other ESFRI BMS RI's or RI preparatory projects required for the R&D pathway and other relevant international organisations.

By combining the significant resources and expertise residing in these two permanent international infrastructures, Europe is better positioned to tackle the significant challenges of innovation in the age of personalised medicine.

Giovanni Migliaccio, Scientific Director, Amsterdam, The Netherlands

http://www.eatris.eu

Jan-Eric Litton, Director General, Graz, Austria
http://bbmri-eric.eu

2.3.4 Time Plan

Started Q1 2014

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Introducing BBMRI-ERIC at national and international meetings												
MoU EATRIS-BBMRI												
MoU EuroBioImaging												
Involve Mediterranean countries												
Collaborate with other continents and existing initiatives												
Meetings with European political opinion leaders												

2.3.5 Priority

3.

2.3.6 Project Group

DG, AD, SPM of HQ

Prof. Alex Felice	BBMRI.mt (chair)
Prof. Marialuisa Lavitrano	BBMRI.it
Dr. Suzanne Kolyva	BBMRI.gr
Dr. Georges Dagher	BBMRI.fr
Dr. Maimuna Medny	IARC
Dr. Kemal Baysal	BBMRI.tr

Working Group 3: Euro-Mediterranean Engagement / Chair: Alex Felice, BBMRI.mt

Working Group 5: China Engagement / Chair: Georges Dagher, BBMRI.fr

Working Group 6: Sub-Saharan Africa Engagement / Chair: Kurt Zatloukal, BBMRI.at

EATRIS

Euro-BioImaging

2.3.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	1
AD	0.5
SPM	0.5
LAW	0.5
total	2.5

Prof. Alex Felice BBMRI.mt

Prof. Kurt Zatloukal BBMRI.at

Dr. Georges Dagher BBMRI.fr

2.4 Work Stream: Set-up a Working Party to Develop an European Biobanking Education and Training Strategy

2.4.1 Background

Education and Training (E&T) is the backbone of a knowledge-based society. Every scientific field or technological sector has developed over time a policy framework that describes the necessary skills and training needs of its employees. No such policy framework exists for Europe or even a single country in the field of biobanking. There is a great need to structure E&T activities in this growing field, taking into account the existing courses and providers.

2.4.2 Mission

The Mission of this Work Stream is to jointly develop a policy framework for Europe and beyond in the field of E&T for Biobank Employees and the user community, deliver a European curricula, sustainability, access and training.

2.4.3 Goals and Deliverables

This Mission can only be achieved once a full landscape of existing activities is available, the needs for E&T are collected and skill sets are defined. These are the goals of this Work Stream. BBMRI-ERIC will set up a Working Party with membership of all interested countries and Institutions to:

- Map the existing E&T landscape of Europe in field of Biobanking
- Define the skill sets of Biobanking employees incl. Manager, Operator, Quality Manager, IT systems operator, ethicists, project nurses etc.
- Develop European Curricula with interested Universities for the different levels
- If requested, coordinate providers of short courses in the field for Continuous Professional Training

Not all of these goals will be reached in 2014. During this year, the Working Party will be set up and a first meeting will be organised to define the mission and objectives of the Working Party; agree on Rules of Procedures; define milestones and deliverables for 2014 and the following years; start with the mapping exercise; start defining skill sets.

2.4.4 Time Plan

The Work Party should start In Q3 2014. The time from approval of this Work Programme to the summer break will be used to identify and invite people to this WP. The WP will then decide on the detailed timetable and milestones.

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Map existing E&T landscape												
Start defining skill sets												
Identify interested Universities												

2.4.5 Priority

3.

2.4.6 Project Group

AD of HQ

All National Node Directors; other experts

2.4.7 Resources

The resources for this Work Stream are mainly Person Month of staff of BBMRI-ERIC and National Nodes plus expenses for hosting a constitutive meeting during Q3. BBMRI-ERIC will also apply for EU funding to complement these tasks (H2020 Infrasupp-3 2014).

Staff Function	Full Time Equivalent in Person Month
AD	2
total	2

2.5 Work Stream: Scientific Retreat with the BBMRI-ERIC National Nodes

2.5.1 Background

Retreat [Retriever: t] is an English expression used in religious contexts. The implication (as a verb) is to retreat into silence, for one or more days. Can also as a noun to mean place or premises for such withdrawal.

Many well-known Universities and Institutes use scientific retreats. For BBMRI-ERIC, this should become a yearly event and could be hosted by a Member State. One of the aims of the meeting is to engage the entire community in how BBMRI-ERIC is viewed upon today and what issues the organisation is facing for the years to come.

2.5.2 Mission

The two-day BBMRI-ERIC Retreat will feature short talks, breakout sessions, and the opportunity to meet and exchange information with your BBMRI colleagues away from the pressures of labs, offices and regular meeting schedules. One of the missions is to discuss the upcoming Work Programme.

2.5.3 Goals and Deliverable

BBMRI-ERIC Retreat #1; discuss the preliminary Work Programme of the following years; identify new fields of action for the community; re-evaluate the priorities for the coming years.

2.5.4 Priority

3.

2.5.5 Time Plan

The first Scientific will be in September 8-9, 2014 in Tartu, Estonia. The second scientific retreat is set to take place in Turkey.

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Organise Retreat #1												
Incorporate outcome of meeting into WP 2015												

2.5.6 Project Group

DG, SPM of HQ

2.5.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.25
SPM	0.25
total	0.5

BBMRI.ee

2.6 Work Stream: BBMRI-ERIC Webinars

2.6.1 Background

One of the important communication tools for BBMRI-ERIC will be regular biobank webinars. Webinar is a short web-based seminar, a presentation, lecture or workshop that is transmitted over the Web. Key features of a Webinar are its interactive elements and the ability to give, receive and discuss information.

2.6.2 Mission

- Visualise activities and disseminate information around the Europe in an easy way for BBMRI-ERIC
- Attracts new groups to share BBMRI-ERIC resources and tools
- Initially a broad impact on topic – collaboration with health care, collaboration with industry
- Storytelling around BBMRI-ERIC tools: users in focus

2.6.3 Goals and Deliverables

There is a three-stage procedure for 2014:

1. A few test webinars during autumn 2014 with personal test invitations
2. Send html invitation to all our contacts, writing newsletters and marketing in print
3. Enlist the help of partner organisations: our peers, financiers, etc.

After this, we plan to hold an evaluation and possible continuation.

The proposed test Biobank webinar is entitled *"From collection of biobank samples to usage in –omics analyses",* which will discuss how millions of human biosamples currently in cold storage in older biobanks were collected before the advent of omics technologies, and how useful these samples are for studies of gene expression and disease aetiology. BBMRI-ERIC will stress the importance of pre-analytical factors in collection and usage of biobank samples during this Webinar.

2.6.4 Time Plan

Test webinars during the Q4 of 2014 and regular webinars during 2015 are planned. During 2014, decision will be taken on which platform will work best for the entire Members' countries in BBMRI-ERIC.

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Test webinars												
Sent invitations												
Enlist the help of partners												

2.6.5 Priority

4.

2.6.6 Project Group

SPM, ITM of HQ

2.6.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0
SPM	0,25
ITM	0,25
total	0,5

BBMRI.se

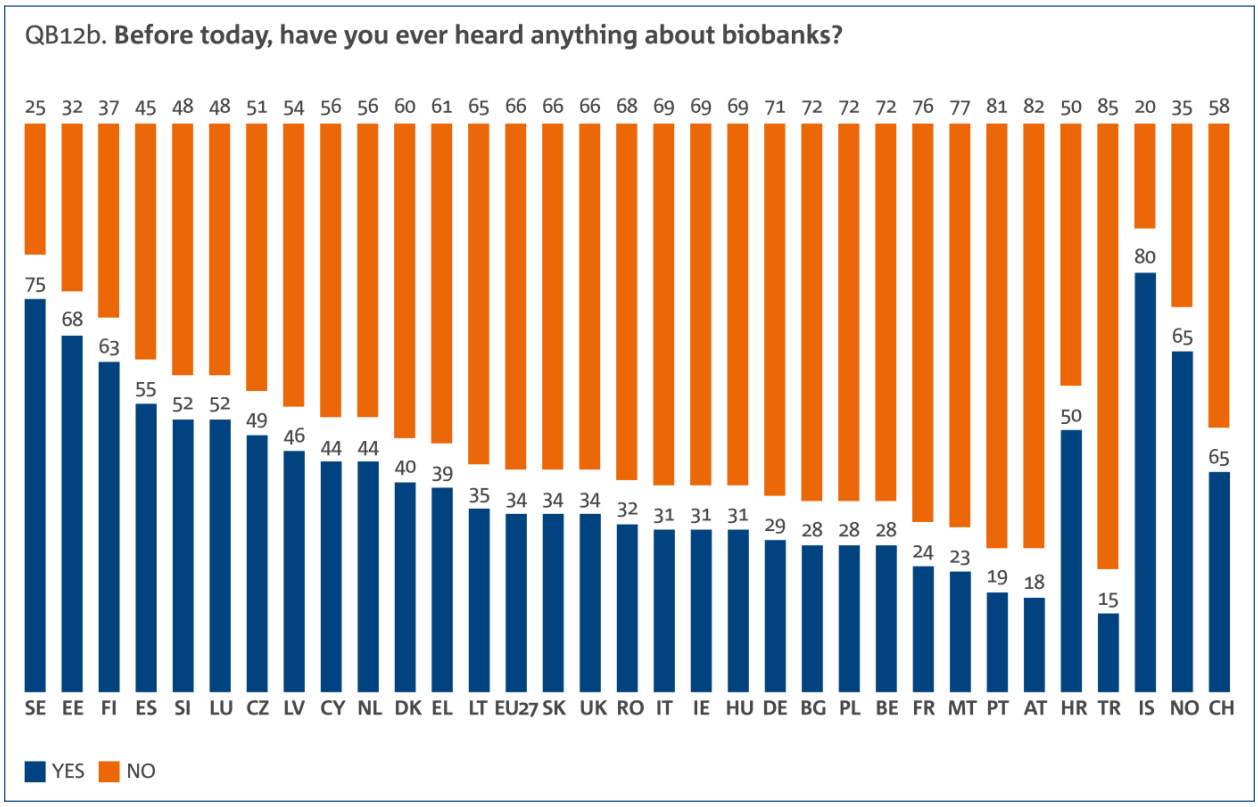
2.7 Work Stream: Newsletter "Biobank Europe"

2.7.1 Background

According to the Special EUROBAROMETER on Biotechnology, October 2010 a survey shows that around a third of Europeans has heard of biobanks.

The chart below shows that awareness varies greatly between countries. It is highest in Iceland (80%) and Sweden (75%), whereas less than one respondent in five in Turkey (15%), Austria (18%) and Portugal (19%) had heard of biobanks prior to the survey (see Figure 6: Have You Ever Heard Anything About Biobanks?)

Figure 6: Have You Ever Heard Anything About Biobanks?



This preparatory work, including the efforts of the Stakeholder Forum of BBMRI Preparatory Phase, highlighted the importance for a regular informative newsletter to interested groups, especially stakeholders, biobankers, policy makers and interested lay people.

2.7.2 Mission

In Q4 2014, the HQ will launch the first issue of its newsletter called "Biobank Europe". It will be both in electronic form and in paper format. The main objective for the publication is to inform all stakeholders and the public about different BBMRI-ERIC activities and the National Nodes, as well as the progress of the Common Services and other biobank-related activities.

It will also highlight excellent biobank research in Europe.

2.7.3 Goals and Deliverables

The newsletter, Biobank Europe, for which visitors of our website can sign up for, can help us gather the email addresses or mailing addresses of potential users of BBMRI-ERIC services. The content should focus on BBMRI-ERIC and National Nodes, but topics of common interest should be explored with P^3G and IBSER as well as other Research Infrastructures (e.g. advertising conferences, topics of shared priority, etc.).

Four newsletters per year will be published, starting Q4 2014 for the first newsletter.

2.7.4 Priority

4.

2.7.5 Project Group

SPM of HQ

2.7.6 Time Plan

Start the layout and work with the first newsletter in Q4 2014.

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Graphic layout of the newsletter*												
Preparing the content												
Final layout, editing and printing**												
Published newsletter												

*The graphic layout is part of the Corporate Design (see 2.2).

**The printing costs etc. are part of the Central Executive Management Office.

2.7.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
SPM	1.5
DG	0.25
total	1,75

3 WORK PLAN: Common Services for BBMRI-ERIC

BBMRI-ERIC Common Services form a key element of the infrastructure as they provide the biobanking community and biobank users top-level expertise, services and tools in specific areas of biobanking. Common Services are placed under the responsibility of the Director General and managed by a Director jointly appointed by the Director General and the host Member State where the Common Service is located.

It is planned that Common Services are jointly funded by BBMRI-ERIC and the Member State hosting the facility. On behalf of BBMRI-ERIC, such funding decisions are made by the Assembly of Members on the basis of scientific excellence and cost efficacy as part of the Work Programme jointly funded by the Members.

3.1 Work Stream: Common Services for ELSI

3.1.1 Background

One formidable challenge for the establishment of the pan-European BBMRI-ERIC is how to navigate the complex set of laws and regulations governing biobanking in general and cross-border biobanking specifically. Consequently, it is vital that the broad and unified access to be provided to the data and sample collections of BBMRI-ERIC partners and Members is compliant with both the national laws and the content of the consent forms. This legal challenge is entangled with the need to acknowledge and consider the variety of ethical questions related to biobanking activities.

3.1.2 Mission

In order to manage ELSI-issues in BBMRI-ERIC as a Common Service to stakeholders, e.g. biobankers, researchers, authorities, legislators, patient organisations, industry and the general public, it is essential that there is broad participation from the European countries and that the work is deeply rooted within the different national socio-cultural and legal contexts. There are common regulatory frameworks in the EU to take into consideration, but each country has its own legislations with many national laws, which also need to be considered. The interpretations of these laws require close acquaintance with socio-cultural characteristics of each country, monitoring of ongoing legislation, the role and work of different national authorities, ethical committees, as well as facing public debate.

Establishing a common ethical and legal service that will drive harmonisation and provide advice is an agreed cornerstone of the structure of BBMRI-ERIC and has been intensively discussed during the preparatory phase with the Commission and Member States and is a basis of the approval of the ERIC status and Member State participation.

In order to meet the criteria of scientific excellence, a proposed research project seeking access to samples and data should seek advice from the BBMRI-ERIC Ethical Review Board. The review process is obligatory for all project proposals seeking access. **The review process does not replace the requirement for local and/or national ethics committees nor does it overrule their authority**. It is not mandatory to have an additional ethical review by the ELSI Common Service but projects might request review (as high level expert opinion) to facilitate

decision making of local research ethics committees. The ELSI Common Service should facilitate and monitor this process. It should support the decision-making process of local and/or national ethics committees and thereby contribute to European harmonisation by improving the efficacy of national/local processes. The aim is to establish BBMRI-ERIC ethical review approval as a sign of excellence.

3.1.3 Goals and Deliverables

We need to establish an ELSI-Infrastructure for the Common Service with a node in every European country as far as it is possible. In order to attain credibility on ethical and legal analyses, as well as conclusions and advice, each National Node should have a scientific/academic basis with publications in scientific/academic peer-reviewed journals at hand.

- Intervention to address joint matters for the biobanking community on the European level;
- Build conclusions and advise on a sound scientific/academic basis and experience in ethical reviews of European/international projects;
- Provide updated background information and practical guidance to biobankers to respond to ELSI issues, especially in relation to the exchange of human samples and data for research use in Europe ('help-desk' format);
- Ensure the dissemination of results of relevant surveys and studies to towards the various audiences;
- Organise tools and services to address ELSI issues related to biobanks and biobanking by building on already available tools and generating new ones if necessary;
- Organise experience sharing and exchanges regarding ELSI aspects between BBMRI-ERIC members;
- Set up training and education on ELSI issues related to biobanks and biobanking;
- Provide an ethics check of compliance for research proposals submitted to BBMRI-ERIC in compliance with the BBMRI Business Plan and Statutes and with the European Commission research ethics framework.

3.1.4 Time Plan

The first ELSI Common Service identification meeting was held in Toulouse, France on 4 March 2014. After that meeting, on 30 April 2014, a tender process until 14 June 2014 to identify participating countries and hosts was started. Upon request, on 5 June 2014, the deadline was extended until 28 June 2014. Taking into account that no single Member State has the expertise to serve all tasks, the Directorate of BBMRI-ERIC encourages applicants to submit one joint application integrating the remarkable and internationally acknowledged excellence in ELSI of European academics and research centres for the ELSI Common Service. The HQ will by taking into account applications evaluated by external experts. The results will be reported to the FC and brought forward to the AoM for approval. The plan is to launch the ELSI Common Service, by 2014/11 at the latest. (see Minutes of the ELSI Toulouse meeting and the tender text at www.bbmri-eric.eu).

Deliverable \ month of 201	01	02	03	04	05	06	07	08	09	10	11	12
Identify ELSI experts in Members												
Tender for ELSI services												
Evaluate the application(s)												
Prepare decision												
AoM decides on the proposal												
Contract negotiation with legal partners												
Start setting up services												
CS ELSI inaugurated												

3.1.5 Priority

2.

3.1.6 Project Group

Image 3: ELSI Planing Group (meeting in Toulouse, France on 4 March 2014

Participants:

DG, AD, SPM of HQ

Including ELSI experts, National Node/Observer representatives:

Prof. Alex Felice, MT (AF); Dr. Alexandra Soulier, SE (AS); Prof. Anna-Sara Lind, SE (ASL); Prof. Anne Cambon-Thomsen, FR (ACT); Dr. Araceli Diez-Fraile, BE (ADF); Prof. Barbara Parodi, IT (BP); Dr. Carole Goutorbe, IARC (CG); Dr. Deborah Mascalzoni, SE (DM); Dr. Dominic Allen; LUX (DA); Dr. Elena Bravo, IT (EB); Dr. Emmanuelle Rial-Sebbag, FR (ERS); MsC Gauthier Chassang, FR (GC); Dr. Georges Dagher, FR (GD); Dr. Helene Alavere, EE (HA); Jane Reichel, SE (JR); Jasper Bovenberg, NL (JB); Kemal Baysal, TR (KB); Dr. Maimuna Mendy, IARC (MM); Marialuisa Lavitrano, IT (MLL); Prof. Mats G Hansson, SE (MGH); Dr Mattias Johansson, IARC (MJ); Dr. Roland Jahns, DE (RJ); Dr. Sirpa Soini, FI (SS); Dr. Stéphanie Wyss, CH (SW).

3.1.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.5
AD	0.5
SPM	1
LAW	1
total	3

BBMRI-ERIC ELSI Common Service

3.2 Work Stream: Common Services for IT

3.2.1 Background

Biobanks are the biological backend of data-driven medicine but lack generic solutions for database interoperability and information harmonisation. So far, most biobank infrastructure initiatives have developed as organisational networking, pure harmonisation efforts in terms of specific data sets, or standardising operational procedures for material collection. While this is important, the full potential of a biobank infrastructure will only be realised if a biobank e-infrastructure is constructed. As a result, merely retrieving high quality data on clinically annotated human samples is a time-consuming bottleneck for biomedical research.

As biobank data become more abundant, the main problem is no longer finding the information as such. At the national level in Europe, in the wake of the BBMRI Preparatory Phase, a number of Member States are in the process of establishing national hubs. The move toward a universal information infrastructure is directly connected to the issues of semantic interoperability through standardised message formats and controlled terminologies. The biobanks bring to the fore the problems concerning the need for standardised research data and a long-term storage strategy.

Key components of BBMRI-ERIC are comprehensive collections of biological samples from different (sub-)populations in Europe, which are being stored together with continuously updated data on the health status, lifestyle and environmental exposure of the sample donors, resulting in a significant number of repositories with annotated biospecimens distributed across Europe.

The lack of standardisation is a general problem, which restricts the utilisation of many biological samples. Inspite of several large-scale projects and global achievements in standardisation, there are still niche areas of informatics that are largely isolated. The awareness of the problems being tackled, the progress being made, and the possible solutions that each niche could offer to one another in support of common goals is limited. Specific key issues include proteomic profiles, sampling procedures, and storage conditions of samples, etc. Standard protocols for different types of samples, so that these can be utilised also in the future, as well as making the protocols public are essential. The same is true for lifestyle factors where standard protocols will make comparisons of results from different cohorts simpler.

3.2.2 Mission

During the BBMRI-PP, the project's Work Package 5 planned and coordinated the interoperability of the existing biological databases of biobanks. Based on the planning work done during the PP, the IT-infrastructure of BBMRI-ERIC will be created and will consist of a network using the hub-and-spoke topology to connect the different nodes, which are geographically spread through Europe. Major nodes act as hubs, and may for instance comprise a specific region or an entire nation. Local biobanks constituting the end-nodes will be connected via the National or Regional Nodes. Information harmonisation will primarily

be utilised by a minimum set of data attributes, which are assumed to be achievable from all biobank collections. Use of the system for data discovery will be the first step towards complete data federation. Initially, exchange of source data may be possible by providing appropriate contact information to responsible authorities.

3.2.3 Goals and Deliverables

Based on the results of BBMRI-PP, the IT structure for the Implementation Phase of BBMRI can be finalised through the following goals:

- Assure confidentiality of donors
- Use state-of-the-art open-source frameworks and web technologies,
- Use state-of-the-art concepts for semantic integration, integrating the terminologies/ ontologies to be further developed by the ConceptWiki project,
- Use an agile and user-centred development process, providing maximum support for researchers,
- Grant flexibility in terms of biobank content and schema handling,
- Grant extensibility in terms of additional participants and new data and information,
- Grant efficiency in terms of a priori and a posteriori data harmonisation and query processing, and
- Keep efforts low for biobanks willing to participate in the federation.

BBMRI-PP has collaborated with other biobanking/health infrastructure initiatives (such as IMI, epSOS and HEALTH.2010.1.1-1: Harmonisation of phenotyping and biosampling for human large-scale research biobanks), the Gen2Phen EU- project and the DataShaper project to reach interoperability of biobanks, both at the concept- and at the sample character (comparability) level. BBMRI-ERIC will continue to collaborate closely with these initiatives and others.

The most significant outcome of the BBMRI-PP WP5 has been the development and deployment of a portal system and the development of an integration prototype. The portal system already comprises services for authentication and management of user accounts for identification of biobanks, and for the management of metadata. The integration prototype is already connected to test-instances of existing biobank management systems and provides a service interface for the creation, update, and querying of a materialised view. These developments can be used as a nucleus for a service-oriented integration architecture, which supports high adaptability and agile development of components. Core services have been designed and implemented and can be further elaborated into a comprehensive integration architecture. Additional services will comprise connection and registration services for the component systems, services for schema integration and terminology mapping, integration services for virtual and secure access of component systems in order to build and query materialised views with regard to semantic integration, as well as services for caching and indexing. The topology of the solution is hubs and spokes. Hubs collect and integrate data, but can also provide a data connection service. This results in cascading hubs and spokes, connecting biobanks to regional networks, then further to national hubs, and finally, to a pan-European BBMRI-ERIC hub. Thus, key requirements and key concepts, together with a successful prototypical solution, are available as a starting

point for implementing BBMRI-ERIC's IT-infrastructure.

One of the most important tasks for this Common Service is to finalise the Biobank Catalogue – an updated version from the Preparatory Phase (see 7.1). That catalogue has been established for the collection and presentation of data describing a few of the European biobanks. It is based on a format originally provided by the Public Population Project in Genomics (P^3G) observatory. BBMRI-PP developed a core questionnaire to collect essential information from European biobanks, such as objectives, number and type of samples, and specific strengths. By March 2011, the catalogue included data from 63 population-based and 219 clinical biobanks located in 27 countries, together representing more than 20 million samples.

The goal is to set up an infrastructure at the HQ for the catalogue as well as a system for updating the information on a regular basis.

3.2.4 Time Plan

On 2-3 June 2014, a first meeting with all responsible people for informatics and IT met to set up a procedure for this Common Service. In a subsequent meeting, a priority list will also be done for IT-tools that had been developed during the Preparatory Phase and in projects like BioSHaRE, BBMRI-LPC, BioMedBridges and others. The tender process will be launched during Q3 with a 10-week deadline in early September. The commencement of the Common Service IT is planned for Q1 2014.

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Identify IT experts in Member countries												
Preparatory Meeting for Common Service IT												
Tender for Common Services IT												
Evaluate the application(s)												
Prepare decision												
AoM decides on the proposal												
Contract negotiation with legal partners												
Start setting up services (2015)												
CS IT inaugurated (2015)												

Concurrently, a Working Group in BBMRI-LPC is updating the Biobank Catalogue (preparatory work for BBMRI-ERIC).

Another Working Group has already had two meetings in Copenhagen, Denmark on 2013/03/30 and The Hague, The Netherlands on 2013/11/20.

The efforts of the two Working Groups will be joined for the benefit of the relaunch of the BBMRI-ERIC Catalogue.

3.2.5 Priority

2.

3.2.6 Project Group

DG, ITM of HQ

M.Sc. Linda Mook, Dr. Morris Swertz, Dr. David van Enckevort	BBMRI.nl
Prof. Erich Wichmann, Prof. Klaus Kuhn	BBMRI.de
M. Sc. Jon Hegglan	BBMRI.no
M. S. Nicolas Malservet	BBMRI.fr
Dr. Linda Zaharenko	BBMRI.lv
M.Sc. Loreana Norlin, M. Sc. Roxana Merino Martinez	BBMRI.se
Dr. Kaisa Silander, D r. Niina Eklund, Dr. Juha Muilu	BBMRI.fi
Dr. Heimo Müller	BBMRI.at
M. Sc. Erkki Leggo	BBMRI.ee
Prof. Luciano Milanesi	BBMRI.it
Dr. Adam Faulconbridge	EBI

Pre-meetings were held in The Hague, during the HandsOn Biobanks Conference 2014 and in Copenhagen at the Statens Serum Institute on 2014/05/25.

3.2.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	1
ITM	1,25
total	2,25

3.3 Work Stream: Working Group for Rare Diseases

3.3.1 Background

BBMRI-ERIC improves the accessibility and interoperability of the existing comprehensive collections, either population-based or clinic-oriented, of biological samples, including associated information from different (sub-)populations of Europe. These collections include the attached data on factors such as health status, nutrition, lifestyle, and environmental exposure of the study subjects and are in part linked to disease registries, such as cancer or death registries. BBMRI-ERIC is designed to support research in all disease areas (common to rare diseases) as well as public health.

Furthermore, a concept for collaboration of different ESFRI BMS research infrastructures in certain disease areas have been agreed upon to enable vertical integration of different core expertise of research infrastructures to address needs of specific research communities. INNORARE is an already agreed upon collaboration between BBMRI-ERIC, EATRIS and ECRIN

to establish a joint research infrastructure platform for rare diseases.

3.3.2 Mission

During the BBMRI Preparatory Phase, specific attention was paid to user needs of different scientific fields. For rare diseases, expert panels defined user needs, participation of scientist from the rare disease community in work packages and involvement with funders for rare disease research. It became evident that rare diseases require specific solutions in the context of the operation of BBMRI-ERIC (e.g., data management, quality criteria, access rule, and ethical issues). In order to provide appropriate flexibility to address requirements of specific research communities, the Common Services for such fields were established in the BBMRI-ERIC governance structure and specified in the Statutes of BBMRI-ERIC. A Common Service for rare diseases could be, if needed, established under BBMRI-ERIC and will be placed under the responsibility of the Director General. A Director who will develop the scientific and operational concept for rare disease biobanks and data registries with his/her team, which will be implemented in the context of the annual Work Programme of BBMRI-ERIC, will manage the Common Services. Directors of Common Services participate in the operational management of BBMRI-ERIC as members of BBMRI-ERIC Management Committee. Common Services are financed through the common BBMRI-ERIC budget.

3.3.3 Goals

Rare diseases affect approximately 30 million Europeans and access to high quality human biological materials is a prerequisite for research. BBMRI-ERIC can serve this purpose and can become a key asset within the RD-Connect platform. A map of RD biobanks will be built starting with European biobank networks that are already established. During 2014, a plan will be put in place to participate in 2 RD specific calls and develop the necessary preparatory work for setting up Common Service during 2015 in case of funding through the EC.

3.3.4 Time Plan

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Prepare for submission to the deadline for the 2 INFRADEV calls												
Prepare structure and objectives of a CS RD (if agreed upon)												

To address the RD community, a letter dated 2014/03/02 has been written, defining the position of BBMRI, EATRIS, ECRIN, ELIXIR and EUOPENSCREEN.

Correspondence 2: Joint BMS Letter to RD Community

Dear all,

given the intense discussions and complexity surrounding the rare diseases proposals to be developed for the current infrastructure calls, the ESFRI research infrastructures involved in the discussions until now (BBMRI, EATRIS, ECRIN, ELIXIR, EUOPENSCREEN) would like to make clear our joint position:

In order to ensure that the proposals submitted to the INFRA-IA and Design Study calls have the optimal success chances, we think that it is essential that the rare disease research community is able to find consensus, and act together proactively. In other words, we think it would be extremely destructive if competing proposals were submitted, as the reviewers will not

support the funding of a fragmented, "immature" community.

Further, we have clear criteria dictated by our missions for the type of INFRA-IA proposal that we would be prepared to be involved in, in terms of objectives and content of the proposal. In order to reach our goal of offering sustainable and long term infrastructure services for R&D in the rare diseases field, the proposal should reflect closely the objectives of the INNORARE concept. This is a concept for a meta-infrastructure that provides services to R&D actors with the aim of improving rare disease patient outcomes, in the form of novel diagnostic, therapeutic and care approaches. In a nutshell, the services captured under the scope of the proposal should comprise quality assured (with respect to regulatory requirements) activities:

1) Pre-clinical research services, including biology, animal models, assay development, screening;

2) Clinical research services including access to -omics capabilities, biobanking resources, patient registries and cohorts, clinical trial capabilities, and translational research facilities including advanced imaging;

3) Impact activities involving close interaction with key stakeholders, including funders, regulators, industry and the patient.

The proposal that fulfils these criteria, and organises and collects patients data in a (regulatory compliant) format that would allow these targets to be reached, will receive the full support of the RI legal entities.

With respect to the Design Study, we feel that this is not a matter for us in which to intervene, but our opinion remains that this call is an excellent opportunity to seek a sustainable infrastructure approach for the patient information and data initiatives out there. In order to fit Europe's chosen approach to research infrastructures, this should be disease agnostic (cross-cutting) infrastructure, but naturally the proposal would have strong RD representation.

We hope that this helps in developing a path forward. Time is running short, thus we invite the community to act quickly and decisively.

Best regards,

on behalf of BBMRI, EATRIS, ECRIN, ELIXIR and EUOPENSCREEN

3.3.5 Priority

2.

3.3.6 Project Group

A planning group is set up incl. Dr. Luca Sangiorgi (Italian Delegate AoM), DG, AD and Prof. Gert-Jan van Ommen (BBMRI.nl), Prof. Alex Felice (BBMRI.mt). They will later be supported by ITM and LAW.

3.3.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.5
AD	0.5
ITM	0.25
LAW	0.5
total	1,75

BBMRI.at

BBMRI.it

3.4 Work Stream: Planning for a Stakeholder Forum Secretariat

3.4.1 Background

Close interaction with the Pan-European stakeholders as well as the public (see also 2.2 and 2.3) is essential for the success and acceptability of BBMRI-ERIC. Therefore, BBMRI launched a comprehensive consultation and engagement process with its broad stakeholder community, comprising patients, clinicians, funding organisations, associated project partners, industry, users, but also the general public, early on in its Preparatory Phase. Within BBMRI-ERIC, the Stakeholder's Forum (SF) will continue to play an important role in stimulating discussion and keeping the European public informed about the intentions and the progress of BBMRI-ERIC.

3.4.2 Mission

A stratified database containing the contact details of over 500 participants from SF activities has been assembled over the course of the BBMRI Preparatory Phase. SF meetings were designed to provide mechanisms for participants, practitioners and other stakeholders to ask questions, discuss their concerns, and provide feedback. Information was provided on the use of the BBMRI resource and on the value derived from participation, thus enabling stakeholders to formulate informed viewpoints on the BBMRI process as a whole as well as to encourage stakeholders towards active participation in this process.

The consultation document arising from the patient working group workshop was designed as a guideline for basic principles reflecting patient participation in both new and existing biobanks within BBMRI-ERIC. A draft document was distributed for consultation to European patient organisations as a mechanism by which they could indicate their general support for the BBMRI initiative and for appropriate patient representation in the infrastructure. The resultant document entitled "Basic Principles for Patient Participation in BBMRI" has been officially endorsed by the European and Member State patient organisations listed below. The document was presented to the Steering Committee of the BBMRI-PP at the BBMRI Stakeholders' Forum meeting on June 9th, 2010 to assist in the drafting of policies and procedures for the implementation of the research infrastructure.

Participating Patient Organisations during the Preparatory Phase were:

- European Organisation for Rare Diseases (EURORDIS)
- International Alliance of Patient Organisations (IAPO)
- European Genetic Alliance Network (EGAN)
- European Federation of Neurological (EFNA)
- Europa Donna – The European Breast Cancer Coalition
- European Network for Research on Alternating Hemiplegia (ENRAH)
- Dutch Genetic Alliance (VSOP)
- Genetic Alliance UK

3.4.3 Goals and Deliverables

Set up a strategy for starting up the planning of a Stakeholder Forum Secretariat.

3.4.4 Time Plan

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Planning												
Identify candidates												
Planning of content of the Stakeholder Forum Secretariat												

3.4.5 Priority

2.

3.4.6 Project Group

DG, AD, LAW, SPM of HQ

3.4.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.5
AD	0.5
LAW	0.5
SPM	0.25
total	1,75

3.5 Work Stream Biobanking of Infectious Materials

3.5.1 Background

Biobanking of human biological samples containing pathogens or isolated pathogens fall under the scope of BBMRI-ERIC and has been identified as a currently underdeveloped field in the report of the ESFRI strategic working group for biological and medical sciences. Biobanking of infectious materials require special procedures and has to meet requirements such as biosafety and biosecurity. Therefore, the feasibility of a common service for biobanking of infectious materials, which specifically deals with issue of biobanking of infectious materials, should be elaborated. The work should particularly explore synergies with other related infrastructures, such as the European research infrastructure for highly pathogenic agents (ERINHA) or the European virus archive (EVA). EVA and the European Commission indicated interest in exploring opportunities to integrate EVA into BBMRI-ERIC, thereby providing a sustainable framework for the operation of EVA. This could also be of great relevance for BBMRI-ERIC since EVA is fully operational and several aspects of providing access to biobanks are even more advanced than in other human biobanks (see below). A specific challenge in evaluating opportunities for integration of EVA into BBMRI-ERIC will be that EVA comprises in addition to European partners international partners like China, Russia, USA, South Africa. Therefore EVA could create the first concrete case for involving international participants in BBMRI-ERIC.

Short description of EVA: The network of EVA laboratories represents an extensive range of virological disciplines and currently holds approximately 50% of the 500 recognised species within the EVA collection. The ultimate aim of EVA is to coordinate these collections to produce the largest library of authenticated, quality-controlled and available viruses in the world. Partner laboratories have been selected according to the following criteria: extent and relevance of virus collections, capacity to isolate new viruses; recognised high calibre; high quality of associated research; record of achievement in meeting targets; experience of working within standard protocols. EVA as a quality-assured virus collection will have the important mission to provide this unique resource, resulting from the merging of well-established infrastructures existing in Europe, to service science, the environmental and public health authorities, the needs of the pharmaceutical industry in developing new technologies for disease control, and provide material for teaching and training purposes.

3.5.2 Mission

Dr. Sissy Kolyva will specify the Work Stream and identify National Node candidates for the Working Group.

3.5.3 Goals and Deliverables

Dr. Sissy Kolyva will specify the goals and deliverables.

3.5.4 Time Plan

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Specify the Work Stream												

3.5.5 Project Group

DG, AD, LAW, Kurt Zatloukal

tba

3.5.6 Priority

2.

3.5.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.25
AD	0.5
LAW	0.5
total	1.25

BBMRI.at

4 WORK PLAN: Start pan-European and International Fundraising Effort for BBMRI-ERIC

4.1 Work Stream Fundraising efforts

4.1.1 Background

To apply for research and coordination grants will be an ongoing activity for BBMRI-ERIC. During Q1 and Q2 2014, BBMRI-ERIC will involve itself both as partner and coordinator in several applications for Horizon 2020. This will be continued for the following calls for the years to come. Horizon 2020 is the largest EU Research and Innovation programme in history, with nearly €80 billion of funding available over 7 years (2014 to 2020). Research infrastructure will develop European research infrastructure for 2020 and beyond, foster their innovation potential and human capital, and complement this with the related Union policy and international cooperation.

Examples of currently running FP7-projects that are related to and important for BBMRI-ERIC are projects like BBMRI-LPC, BioSHaRE, BiobankCloud, BioMedBridges and RD-connect, ERINHA, etc. On 2014/03/13, a letter was sent to these projects requesting BBMRI-ERIC to become official partner:

BBMRI-LPC (Large Prospective Cohorts) is a biobanking network in Europe aiming to facilitate access to large prospective study sets on human health and disease. By improving harmonisation, providing solutions for transnational access and networking. Read more at http://www.bbmri-lpc.org.
Status: BBMRI-ERIC has been accepted as official partner to BBMRI-LPC during the Consortium Meeting in Lyon (2014/04/03-04). An official amendment will be launched.

BioSHaRE is a consortium of leading biobanks and international researchers from all domains of biobanking science. Read more at: https://www.bioshare.eu
Status: Discussions about official partnership are ongoing.

RD-connect. Individual efforts often have little interoperability and it can be almost impossible to connect the detailed clinical information held in one database with the genetic information held in another, or with information on whether a biomaterial sample or data from clinical research studies is available. Read more at: http://rd-connect.eu.
Status: BBMRI-ERIC will be granted associated partnership as of immediate effect. Official partnership explored with RD-Connect consortium partners.

Another ongoing activity is the BiobankCloud project. The amount of data we will have in BBMR-ERIC is Big Data. Big Data refers to data sets whose size is beyond the capabilities of today's database technology. The current data deluge is revolutionising the way research is carried out and also results in the emergence of a new fourth paradigm of science based on data-intensive computing. Science is a global undertaking and research data are more than ever national and global assets. Read more at http://www.biobankcloud.com.
Status: The Steering Group accepted the request for partnership. Amendment will be launched.

BioMedBridges; The concept and objective of this project are summed up in its mission: BioMedBridges will construct the e-infrastructure to allow interoperability between data and services in the biological, medical, translational and clinical domains. It will provide the computational "data and service" bridges between the individual biological and medical sciences (BMS) research infrastructures (RIs), clustering them together and linking the basic biological research and data to the clinical research and associated data. More information at: http://www.biomedbridges.eu
Status: Generally acceptable to BioMedBridges coordination.

ERINHA, is a project of building a pan-European research infrastructure aiming to reinforce the European coordination and capacities for the study and the surveillance of highly pathogenic micro-organisms. The ERINHA infrastructure will provide open access to state-of-the-art BSL-4 facilities for the European scientific community to enhance basic and finalised research activities. The infrastructure will promote the harmonisation of biosafety and biosecurity procedures will develop standards for the management of biological resources, diagnosis of group 4 pathogens, and training of BSL4 labs users. Read more at http://www.erinha.eu
Status: BBMRI-ERIC will sustain from partnership as the project is not prolonged for a second time and will end in April 2014.

4.1.2 Mission

Research infrastructures play an increasing role in the advancement of knowledge and technology and their exploitation. By offering high quality biobank services to users from different countries, by attracting young people to science and by networking facilities, research infrastructures help structure the scientific community and play a key role in the construction of an efficient research and innovation. A state-of-the-art research infrastructure becomes increasingly complex and costly, often requiring integration of different equipment, services and data sources, as well as extensive transnational collaboration. Due to the low budget during the start-up phase for BBMRI-ERIC. it is important to be involved and take the lead of the upcoming Horizon 2020 calls. Furthermore, BBMRI-ERIC will have an important role to play not only in the Horizon calls but also in many existing and upcoming infrastructures. The European Research Council (ERC) will provide attractive and flexible funding to enable talented and creative individual researchers and their teams to pursue the most promising avenues at the frontier of science, on the basis of Union-wide competition.

4.1.3 Goals and Deliverables

A Working Group has been set up for H2020, which is led by Prof. Marialuisa Lavitrano (BBMRI.it), to remain updated and coordinated on ongoing calls. It consists of the following members:

Dr. Georges Dagher	BBMRI.fr
Prof. Kurt Zatloukal	BBMRI.at
Prof. Kristian Hveem	BBMRI.no

Prof. Joakim Dillner BBMRI.se

Dr. Suzanne Kolyva BBMRI.gr

Prof. Anu Jalanko BBMRI.fi

Dr. Araceli Diez-Fraile BBMRI.be

An inventory will be made with help of the National Node Directors, coordinated by the HQ, of on-going FP7 projects, and to make it available to BBMRI-ERIC and National Nodes via the intranet site.

4.1.4 Priority

2.

4.1.5 Time Plan

Horizon 2020 starts Q1 2014.

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Setting up of the WG on H2020 Including on-going FP7 projects												
Exchange of ongoing participations & proposal writing (partner &/or coordinator)												
Deadlines for H2020 calls												

4.1.6 Project Group

All staff from HQ

Working Group for Horizon 2020, led by Prof. Marialuisa Lavitrano

4.1.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	1
AD	1
SPM	2
LAW	0.25
QUM	0.5
total	4,75

BBMRI.it

5 WORK PLAN: Quality

5.1 Work Stream: Quality Management System (QMS)

5.1.1 Background

The QMS defines the organisation's quality policy and objectives and ensures that these are achieved through quality assurance (QA) and quality control (QC). QA focuses on the processes through which the product is obtained whereas QC focuses on the product. The only existing national biobank-specific standard is the French standard, NF S 96-900 Quality of biological resource centres (BRC) – Management system of a BRC and quality of biological resources of human and microbial origin, published in July 2008.

The international standard ISO 9001:2008 sets out the requirements of a QMS and can be certified to. This standard is currently under revision and an updated version is expected for 2015. Medical laboratories can use ISO 15189:2012 in developing their quality management systems and assessing their own competence. Laboratory customers, regulating authorities and accreditation bodies can also use it for confirming or recognising the competence of medical laboratories. Technical Committee ISO/TC 276 Biotechnology, created in 2013 and under the secretarial guidance of DIN, Deutsches Institut für Normung e.V. (http://www.din.de), has the scope to standardise Biobanks, among other issues. Currently 18 countries participate: Austria (ASI), Belgium (NBN), Canada (SCC), China (SAC), Finland (SFS), France (AFNOR), Germany (DIN), Japan (JISC), Korea, Republic of (KATS), Luxembourg (ILNAS), Netherlands (NEN), Nigeria (SON), Spain (AENOR), Sri Lanka (SLSI), Sweden (SIS), Tanzania, United Republic of (TBS), United Kingdom (BSI) and the United States (ANSI), out of which 7 are Member Countries to BBMRI-ERIC; 14 countries have an observer status (BBMRI-ERIC relevant: CZ (UNMZ), Estonia (EVS), Italy (UNI), Norway (SN), Poland (PKN) and Switzerland (SNV).

Certification is the procedure by which a third party gives written assurance that a product, process or service conforms to specific requirements. Accreditation is the procedure by which an authoritative body gives formal recognition that a body or person is competent to carry out specific tasks.

It is important that biobanks have similar quality systems. Currently, there are several international efforts to standardise quality systems for biobanks. These must be evaluated and practical administrative applications must be proposed and communicated within BBMRI-ERIC.

5.1.2 Mission

One of the key elements of BBMRI-ERIC infrastructure is to provide top-level expertise, services and tools in the areas of biobanking to the biobanking community and biobank users. This can be realised by setting up Common Services from which Quality Management Services (QMS*)* will constitute one entity with several important duties.

Thus, the role of a Quality Manager (QUM) is to work in the middle grounds of BBMRI-ERIC partnering biobanks (national nodes), industrial operators, and BBMRI-ERIC's Expert Centres

to bring all currently running projects and expertise together and support those accordingly.

In addition to the above, the BRIF mission - to develop a Bioresource Research Impact Factor - needs to be implemented. The plan is to set up a Work Stream for implementation during 2015. The idea is to construct a quantitative parameter to describe the use of bioresources, modelled on the publication "Impact Factor". Such a BRIF would make it possible to document:

- The quantitative use of a bioresource
- The quality and the importance of research results involving it
- The scientific and management efforts of those who set up and made a valid bioresource and their institution available

During 2014, BBMRI-ERIC will setup a Working Group to discuss the prerequisites to be able to continue the successful work done by the Toulouse INSERM group in this field in 2015. The QUM will serve as a Project Manager for the BRIF processes and will therefore sustain the work started in Toulouse and help implement the results in the future.

5.1.3 Goals and Deliverables

The following goals should be planned:

- defining the quality management criteria for biobanks in close cooperation with the work done in the ISO/TC 276, Technical Committee
- Seeking to harmonise and standardise, SOPs should be completed, if possible, in collaboration with other organisations that have already worked on this topic to avoid unnecessary and overlapping work
- Advising the biobanks of the quality requirements of the industry is a crucial requirement for BBMRI-ERIC to meet its aims
- Setting up training in quality control for biobanks may be realised by providing on-site training and organising events on quality control linked issues
- Advising in certification of biobanks may be realised by offering expertise for the development of international biobank certification programmes
- Auditing quality management upon request should be offered by QMS
- Performing accreditation of Expert Centres requires an internationally applicable accreditation programme suitable particularly for the Expert Centres
- Prepare for take over the coordination of the 5 BRIF working groups on (1) identifiers, (2) parameters, (3) sharing policies, (4) journal editors and (5) dissemination

5.1.4 Time Plan

Start of this activity is envisaged during Q3 2014 after hiring of a Quality Manager for the HQ.

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Define quality management criteria												
Harmonisation and standardisation of SOPs												
Document quality requirements of the industry												
Map current training courses for Quality Managers												
Prepare to take over all 5 BRIF Working Groups*												

*http://precedings.nature.com/collections/brif-workshops

5.1.5 Priority

2.

5.1.6 Project Group

DG, AD, QUM of HQ

5.1.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.5
AD	0.5
QUM	3.5
total	4.5

5.2 Work Stream: Partner Charter

5.2.1 Background

The BBMRI-ERIC Partner Charter should define the most important cornerstones for the participation of biobanks or biological resource centres (Partner) that are associated with BBMRI-ERIC to foster scientific excellence, guarantee interoperability, and compliance with ethical and legal requirements. The Partner Charter is binding for any Partner of the BBMRI-ERIC and shall be agreed upon between national BBMRI-ERIC nodes and the Partners. Participation of a Partner in BBMRI-ERIC is non-exclusive and has no effect on any activity of a Partner outside of BBMRI-ERIC.

5.2.2 Mission

Samples and data need to be accessible through a clear access procedure compliant with the general access procedures and conditions of BBMRI-ERIC. BBMRI-ERIC will foster the establishment of scientific collaborations between authenticated scientific users and Partners. Special access policies can be established for industrial users.

Access to samples and data will honour commitments to donors and follow the principles of “fair access” and scientific excellence. Access in the context of research projects performed within BBMRI- ERIC will only be provided for specified research projects, in accordance with the terms of the consent given by the participant and after approval of the research proposal by the competent national ethics committees. Access has to be compliant with regulations of BBMRI-ERIC Partner biobanks, and Partner biobanks have to decide whether access can be granted for a specific project. This decision has to follow transparent and non-discriminating decision-making procedures. The establishment of high quality research collaboration is the preferred format for access.

5.2.3 Goals and Deliverables

The goal was to explore if the Partner Charter (draft version 5; 18.6.2012) had to be updated and a final version (including explanatory text) to be developed for approval of the AoM. For this purpose, a Working Group chaired by Prof. Anu Jalanko was established and it was concluded that the draft Partner Charter should be brought forth to the AoM without any changes. The MC unanimously accepted this suggestion.

5.2.4 Time Plan

Start Q1 2014, final document in Q3 2014 to the AoM for consideration.

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Preparation of a final draft version												
Seeking approval of the AoM												

5.2.5 Project Group

A Working Group 2 Partner Charter is set up with Chair; Prof. Anu Jalanko BBMRI.fi

Prof. Kurt Zatloukal	BBMRI.at
Dr. Georges Dagher	BBMRI.fr
Dr. Suzanne Kolyva	BBMRI.gr
Prof. Marialuisa Lavitrano	BBMRI.it
Dr. Maimuna Mendy	IARC
AD	HQ

5.2.6 Priority

2.

5.2.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
AD	0*
total	0

* The estimated time for this Work Stream is below the lowest Person Month unit of 0,25. Hence, it is stated as 0.

5.3 Self-Evaluation

5.3.1 Background

BBMRI-ERIC aims at facilitating access to quality-defined human health/disease-relevant biological resources including associated data, in an efficient, ethically and legally compliant manner. It also aims at reducing fragmentation in Europe through harmonisation of procedures and implementation of common standards. During the Preparatory Phase, BBMRI developed its own Standard Operating Procedures and best practices for the management of biobanks, and biobanks which will become partners of BBMRI-ERIC, will have to comply with the principles as defined by the BBMRI-ERIC Partner Charter.

In order to identify quality-oriented European biobanks able to provide high quality samples and related information to the European and international research community, and to comply with the BBMRI-ERIC principles, an online self-evaluation tool will be designed, taking into account all parameters for compliance with the Partner Charter (primacy, access policy, data protection and management policy, informed consent, infrastructure and management, quality management, charges).

Examples of such kinds of evaluations are available: the BRIF initiative, BBMRI-LPC ("*Biobanking Article of the Week*"; http://www.bbmri-lpc.org/node/46) and the ESBB "*Biobank of the Year"* that will be analysed and taken into account in this work stream.

5.3.2 Mission

To develop a tool to:

- Identify biobanks who give assurance of service to the scientific community, interoperability, compliance with ethical and legal standards, compliance with National and International best practices
- Help biobanks and their host institutions in identifying strengths and weaknesses in their Quality System
- Help National Nodes in developing services and tools for improving quality and efficiency of their networks
- Support the Member States in allocating financial resources to improve quality of biobanking
- Sustain the construction of a European biobank network working under common and agreed SOPs and standards, appropriate to sign the Charter Partner of BBMRI Europe

5.3.3 Goals and Deliverables

- To build a self-evaluation questionnaire, taking into account all parameters relevant to the quality management of biobanks
- To define a standardised method of evaluation, by giving a score to each parameter and by weighing the items under evaluation on the basis of their respective

importance

- To provide the self-evaluation tool to the National Nodes, in order to adapt it to specific requirements
- To assess the efficacy of this evaluation system through on-site audits of biobanks

5.3.4 Time Plan

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Self-evaluation questionnaire												
Define a standardised method of evaluation												
Provide the self-evaluation tool to the National Nodes												
Assess the efficacy of this evaluation system												

5.3.5 Project Group

QUM of HQ

Prof. Marialuisa Lavitrano, BBMRI.it

5.3.6 Priority

2.

5.3.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
QUM	0.5
total	0,5

BBMRI.it

6 WORK PLAN: Expert Centres

6.1 Work Stream: Planning for a Structure for BBMRI-ERIC Expert Centres

6.1.1 Background

Cutting edge research as well as further innovations in the life science industry will strongly depend on transnational access to high quality human biological samples and associated medical information for academia and the industry in an efficient and secure manner. Furthermore, human biological samples are a finite key resource underlying a series of ethical and legal restrictions thus requiring innovative solutions for efficient usage. By performing the primary analysis of biological samples under internationally standardised conditions in a pre-competitive environment, two major goals are addressed: 1) to provide access to primary data that can easily be shared in contrast to biological samples and 2) to provide high quality information from biological samples to industry for further product development. This should be achieved by so called "BBMRI-ERIC Expert Centres" (see Business Plan v.21.1, especially pages 29 to 30) that are associated with BBMRI-ERIC.

6.1.2 Mission

This work is highly important to allow use of valuable biobank material for many years to come, since the collection of methods should be adjusted to fit the emerging analysis technologies and needs.

6.1.3 Goals and Deliverables

The first goal of this Work Stream is to map the current activities in establishing Expert Centres in Europe. Within Austria and Italy, Sweden and Norway discussions are advanced to set up an Expert Centre on EXCEMET; an Expert Centre for metabolomics, SciLifeLab: Science for Life Laboratory and HUNT Biosciences AS. Furthermore, a guiding document needs to be developed on how to set up such Centres including a criteria list for certification.

6.1.4 Time Plan

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Map current activities (see BBMRI-LPC)												
Develop a guiding document in collaboration with BBMRI-LPC												

During Q2 a Working Group will be set up to map ongoing activities. Based on these experiences, the WG will propose a first draft-guiding document to the MC to be finalised by the Q4 2014.

6.1.5 Priority

2.

6.1.6 Project Group

DG, AD, SPM, LAW from HQ

Prof. Kurt Zatloukal	BBMRI.at
Prof. Gert-Jan van Ommen	BBMRI.nl
Dr. Georges Dagher	BBMRI.fr

6.1.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.5
AD	0.5
SPM	0,5
LAW	0.5
total	2

BBMRI.at

BBMRI.nl

BBMRI.fr

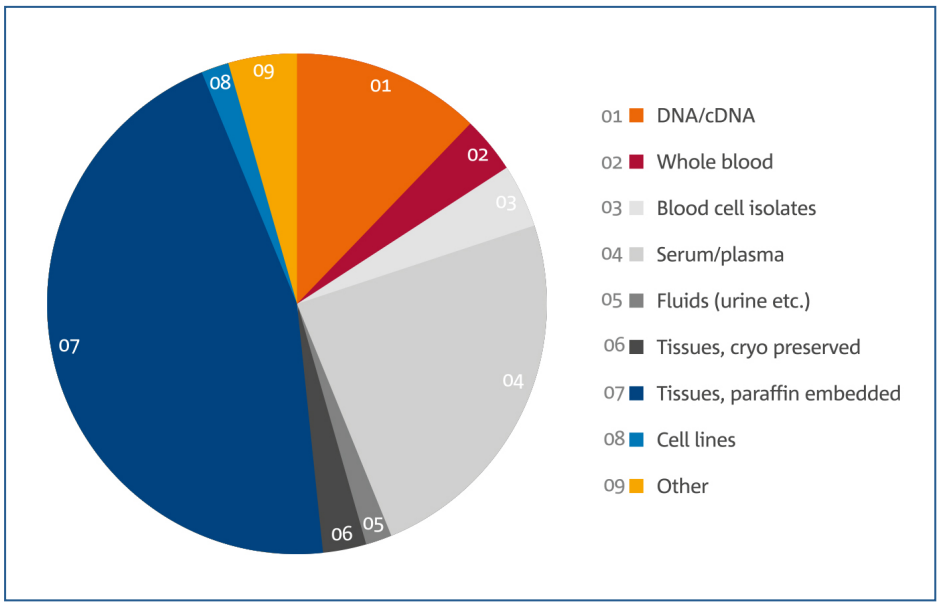
7 WORK PLAN: e-Infrastructure

7.1 Work Stream: Catalogue of European Biobanks

7.1.1 Background

During the BBMRI Preparatory Phase, an inventory was prepared for population-based and clinical (or disease-orientated) biobanks in Europe (Figure 7). Based on questionnaires designed in collaboration with the Public Population Project in Genomics (P^3G), information was collected on the type and quality of collected samples and data, standardisation of procedures, IT solutions as well as governance structure, funding, and legal and ethical issues. Detailed data obtained from the survey can be accessed through a searchable catalogue at the old BBMRI website (www.bbmri.eu).

Figure 7: Summary of the nature of the 20 million human biological samples in Europe (BBMRI-PP catalogue)



Based on the concepts of the BBMRI-PP deliverables, a flexible database scheme will be built for the new BBMRI-ERIC catalogue which allows for dynamic attribute specification and refined queries. Basically, the old use cases of the Preparatory Phase, which are similar to those developed later, should be supported.

7.1.2 Mission

To develop an up-to-date catalog of known biobanks samples in Europe. The BBMRI-ERIC catalogue of European Biobanks provides a high-level description of Europe's biobanks characteristics using a portal solution managing metadata and aggregating data of biobanks. The catalogue can be queried by country, by biobank, by ICD-groups, by specimen types, by specific strengths, by funding and more. A search function will be available for all data.

7.1.3 Goals and Deliverables

First release: The first release will be proof of a concept pilot that supports dynamic attribute management to the extent that the complete MIABIS data model can be instantiated.

Second release: The most important follow-up step will be the migration of data from the current catalogue, including a mapping of existing entries to MIABIS. It will be done step by step, i.e. to start with a core set of attributes and to extend this.

Subsequent development will incorporate further features:

- User and permission management
- Support of subcatalogues
- Enhanced web service functionality developed in the context of BioMedBridges WP4.

The final version will contain all the data from the current catalogue (and new data) and vastly increased functionality and flexibility. The design of the database scheme can be easily extended to support data on a finer level of granularity (e.g. individual samples or donors) if desired. Such an extension would then enable a user to search for (numbers of) entities satisfying a logical AND combination of specified attributes.

7.1.4 Time Plan

Step (1) by Q3 2014

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Planning on catalogue integration												
First release												
Second release												

Step (2) Q1 2015.

7.1.5 Priority

1.

7.1.6 Project Group

DG, SPM, ITM of HQ

C&P Working Group 7 from IT

7.1.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	1
SPM	1
ITM	1
total	3

In line with deliverables from Work Package 4 of BioMedBridges and BBMRI-LPC.

7.2 Work Stream: BiobankCloud

7.2.1 Background

BBMRI-ERIC is not only supposed to create a structure for samples and their data, but also a structure for analysing the samples. The amount of data we will have in Europe is Big Data. Big Data refers to data sets whose size is beyond the capabilities of today's database technology. The current data deluge is revolutionising the way research is carried out and resulting in the emergence of a new fourth paradigm of science based on data-intensive computing. Science is a global undertaking and research data are more than ever national and global assets.

Genomics research has high value to both society and industry. Biomedicine researchers, hospital diagnostics, food industries, agronomy, and pharmaceutical industries use it. A quantum shift is happening in the area of human genomics. A huge wave of big data is approaching, driven by the decreasing cost of sequencing genomic data, which has been halving every 4 months since 2004. Biobanks that are used to store and catalogue human biological material are not prepared to handle this wave of data - there is a biobank bottleneck: a lack of platform support for the storage, analysis and interconnection of the coming massive amounts of human genomic data. In this project, we will develop a cloud-computing platform-as-a-service (PaaS) for the storage, analysis and inter-connection of biobank data. The platform will provide security, storage, data-intensive tools and algorithms, and support for allowing biobanks to share data with one another, all within the existing regulatory frameworks for the storage and usage of biobank data.

7.2.2 Mission

BiobankCloud aims to build the first open and viable PaaS for storage and analysis of digitised genomic data. The project will provide solutions to the problems of secure storage and efficient analysis of massive amounts of biomedical data and also make inter-connection of biobanks possible.

The main research challenges we will address include:

- Definition of the regulatory framework and data model for biobank data sharing
- The development of a scalable, highly available storage infrastructure with support for strongly consistent data
- Data-intensive tools and workflows for aligning, clustering, aggregating, compressing and anonymising sequence data
- A cross-cutting security platform that ensures data confidentiality, data integrity, and data access auditing
- Inter-connection of biobanks, while also leveraging the storage and processing capacity of public clouds
- Validation of the system by evaluating real-world, parallelised analysis pipelines to facilitate the biological interpretation of genomic data
- Integration of these components as a PaaS

7.2.3 Goals and Deliverables

The project will require focused interdisciplinary research. We have assembled a project team containing complementary competencies from developers and users of biobanks, to systems researchers with deep expertise in building dependable and scalable software platforms. Our platform will be evaluated and disseminated at existing biobanks in Sweden and Germany. Our project goal is to have BiobankCloud remove the biobank bottleneck, enabling global leadership for European biobanks, with improved support for preventing diseases, spotting trends, and advancing our understanding of clinical and molecular pathology.

7.2.4 Time Plan

Late 2015 it will be an operating tool for BBMRI-ERIC partners.

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Beta version												
Operating version (2015)												

7.2.5 Priority

3.

7.2.6 Project Group

The platform will be designed together with the DG and ITM of HQ.

KTH - Royal Institute of Technology
Dr. Jim Dowling
Prof. Erwin Laure
M.Sc. Salman Niazi
M.Sc. Mahmoud Ismail
M.Sc. Kamal Hakimzadeh
M.Sc. Ali Gholami

University of Lisbon
Prof. Paulo Verissimo
Prof. Alysson Bessani
M.Sc. Vinicius Cogo, PhD Candidate

Karolinska Institute
Prof. Jan-Eric Litton
M.Sc. Roxana Martinez

Humboldt University
Prof. Ulf Leser
M.Sc. Jörgen Brandt

Dr. Karin Zimmermann
Dr. Sebastian Wandelt

Charité University Hospital
Prof. Michael Hummel

7.2.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.5
ITM	0.5
total	1

Co-funded by FP7 STREP, CT-2011.4.4 Intelligent Information Management, 2.6 M€.

7.3 Work Stream: Connecting BioBanks-CoBiBa

7.3.1 Background

The proposal “Connecting BioBanks”, in short CoBiBa, addresses a very important field of the research for Europe aiming at optimising the use of existing, emerging or future biobank-oriented infrastructures, and will ensure the access of research teams from across the EU to these infrastructures in a secure, ethical and controlled manner.

By itself, a biobank can be very useful for many types of studies. However, the power of biobank research will increase enormously if multiple biobanks are connected to enable sharing of information and samples. The move toward a universal information e-infrastructure for biobanking is directly connected to the issues of semantic interoperability through harmonised services and common ontologies. Specific consideration is given to the sensitive nature of biobank data, through the development of a disclosure filter that will promote transparency, trust and, hence, the sustainability of the proposed e-infrastructure of EU biobanks. CoBiBa’s ultimate objective is to facilitate the development of innovative, newly targeted diagnostics and therapeutics tools and will be a good example of how e-science can be an essential accelerator of research and health-related innovations.

7.3.2 Mission

The potential advantages of CoBiBa to strengthen the foundation of public health will be to:

- Enhance the effective sharing and synthesis of information and collections of biological material of high quality, thereby addressing the need for very large sample sizes and helping to promote collaborative European genetic, epidemiological, and clinical research
- Avoid the expensive mistakes and inefficiencies that can arise when individual initiatives repeatedly “reinvent the wheel,” thereby saving funders and researchers a lot of time and money and raise the benefit of investments in collections of high quality
- Significantly reduce the time and effort for collecting data and material for medical research projects (“Time to Lab”) and thus increase the competitiveness of medical research in Europe
- Promote communication within and between major European biobank initiatives in East and West, thereby helping to overcome existing fragmentation of health research

7.3.3 Goals and Deliverables

Apply for a Horizon 2020 call; Integrating and opening existing national and regional research infrastructures of pan-European interest.

7.3.4 Time Plan

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Prepare proposal												
Deadline INFRAIA call												

7.3.5 Project Group

DG, ITM of HQ

Prof. Johann Eder BBMRI.at

Prof. Klaus Kuhn BBMRI.de

7.3.6 Priority

3.

7.3.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.5
ITM	0.5
total	1

8 WORK PLAN: Finish Work from BBMRI-PP

Some of the work started during the Preparatory Phase of BBMRI still needs to be finished. This Work Plan is developed to fulfill this task.

8.1 Work Stream: MIABIS

8.1.1 Background

MIABIS (Minimum Information About, BIobank data Sharing) represents the minimum information required to initiate collaborations between biobanks and to enable the exchange of biological samples and data. MIABIS consists of three "core" components at present: Biobanks and Samples Collections and "additional" components including Study, Samples, OMICS, GWAS, participant and rare diseases.

8.1.2 Mission

Numerous successful scientific results have emerged from projects using shared biobanked samples and data. In order to facilitate the discovery of underutilised biobank samples, it would be helpful if a global biobank register containing descriptive information about the samples existed. But first, for shared data to be comparable, it needs to be harmonised. In compliance with the aim of BBMRI-ERIC to harmonise biobanking across Europe, and the conclusion that the move towards a universal information infrastructure for biobanking is directly connected to the issues of semantic interoperability through standardised message formats and controlled terminologies, we have developed an updated version of the minimum data set for biobanks and studies using human biospecimens. The data set called MIABIS consists of 52 attributes at present describing a biobank's content. The aim is to facilitate data discovery through harmonisation of data elements describing a biobank at the aggregate level. As many biobanks across Europe possess a tremendous amount of samples that are underutilised, this would help pave the way for biobank networking on a national and international level, resulting in time and cost savings and faster emergence of new scientific results.

8.1.3 Goals and Deliverables

Deliver BBMRI-ERIC's first informatics standard.

8.1.4 Time Plan

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Specifying document												
Publication												

8.1.5 Priority

3.

8.1.6 Project Group

DG, ITM of HQ

IT Preparatory Working Groups

8.1.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.5
ITM	0.5
total	1

8.2 Work Stream: Biobank Lexicon

8.2.1 Background

With the domestic and international proliferation of biobanks and their associated data, a common language for biobanks are essential.

8.2.2 Mission

This Wiki is intended to help establish a standard vocabulary within the European BBMRI to facilitate the definition and updating of new terms. The Wiki contains the present version of the BBMRI Biobank Lexicon. To overcome the language barrier that comes with crossing borders when conducting research, the Lexicon will be translated into multiple languages.

8.2.3 Goals and Deliverables

The goal is to update and finish a new Biobank Lexicon that the global biobank community will use. The current version is translated into 10 EU languages.

A new Working Group including lawyers will be set up.

8.2.4 Time Plan

Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Set up a new Working Group												
Update the existing version												
Publish the new version												

8.2.5 Priority

4.

8.2.6 Project Group

DG, ITM of HQ
M.Sc. Loreana Norlin BBMRI.se
M.Sc. Roxana Martinez BBMRI.se

8.2.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.25
ITM	0.25
LAW	0.25
total	0,75

9 Budget

The proposed Budget for 2014 is composed of **1,544,682 Euros,** revenues and equal expenditures. The full details of the budget will be described in document AoM/2/3/Rev1 (2014/05/27). For the purpose of the Work Programme, two tables are shown: first, the distribution of Person Month of all staff between the different Work Streams (Table 4) and second the overall expenses (Table 5). Member contribution consists of obligatory contribution as part of the budget of the HQs and hosting contributions for the HQ and the Common Services.

The overall amount is divided into expenditures for the Central Executive Management Office (HQ) and for two Common Services, namely for ELSI, and for Information Technology Services. The budgets for those two Common Services are not for detailed discussion during the 2nd Session of the AoM and will be put aside as a reserve until a final discussion and decision is taken after the call for tenders are evaluated and the results been put forward to the AoM. The originally planned Common Service Stakeholder Forum Secretariat will not be ready to start during 2014 and therefore was removed from the budget as originally foreseen in the preliminary budget. All three units' expenditures are further divided into nine categories, namely:

I. **salaries per year (**net salary, employer and employees contribution to social security and state pension, unemployment insurance)
II. **fringe benefits** (legal obligatory settlement for dismissal, relocation grant, additional health insurance, organizational pension fund, education grant, travel grant, starting aid)
III. **investment** (furniture, IT and phone infrastructure, electrical and other appliances)
IV. **rent** (contents and public liability insurance; directors and officers liability insurance; internet and phone expenses)
V. **consumables** (stationery, kitchen and social room utensils and other)
VI. **marketing material** (2 roll-up banners, website hosting, brochures, flyer and other material)
VII. **travel** (expenses for HQ staff to meetings, networking and scientific events)
VIII. **Assembly of Members** (hosting of Governance body meetings; AoM, FC, SC, MC)
IX. **Scientific Meetings** (hosting of the retreat and contribution to scientific meetings)
X. **Outsourcing Services** (accounting, contractual law, social security and HR law, domain expenses, corporate design, local IT support, travel agency and other consulting)
XI. **Reserve** (for unforeseen events and liquidity)

These categories are important to understand in the future deviations as well as to explain host country contributions for all 3 units as the revenues are composed of Member State contributions and host country contributions. In the future this section will also include income from other resources as grants, donations or fees. It is intended to keep for accounting reasons these financial streams separate.

Table 4: HQ Person Month Distribution

Work Stream / Function	DG	AD	SPM	LAW	ITM	QUM	PA	SEC	Sub-total
WS 1.1 CEMO	0,5	4	1	1	0,5	0,5	7	7	21,5
WS 2.1 HandsOn	0,25		0,25						0,5
WS 2.2 Communication	0,5	0,5	2		0,25				3,25
WS 2.3 Stakeholder	1	0,5	0,5	0,5					2,5
WS 2.4 Education		2							2
WS 2.5 Retreat	0.25		0,25						0,25
WS 2.6 Webinars	0		0,25		0,25				0,5
WS 2.7 Newsletter	0,25		1,5						1,75
WS 3.1 CS ELSI	0,5	0,5	1	1					3
WS 3.2 CS IT	1				1,25				2,25
WS 3.3 CS RD	0,5	0,5	0,25	0,5					1,75
WS 3.4 CS SFS	0,5	0,5	0,5	0,5					2
WS 3.5 EVA	0,25	0,5		0,5					1,25
WS 4.1 Fundraising	1	1	2	0,25		0,5			4,75
WS 5.1 QMS	0,5	0,5				3,5			4,5
WS 5.2 Partner Charter		0							0
WS 5.3 Self Evaluation						0,5			0,5
WS 6.1 Expert Centre	0,5	0,5	0,5	0,5					2
WS 7.1 Biobank Catalogue	1		1		1				3
WS 7.2 BioBankCloud	0,5				0,5				1
WS 7.3 CoBiBa	0,5				0,5				1
WS 8.1 MIABIS	0,5				0,5				1
WS 8.2 Lexicon	0,25			0,25	0,25				0,75
Total in 2014	10	11	11	5	5	5	7	7	

Explanatory note:

Using the Person Month (PM) model, this table shows how much time a full time employee should dedicate to a specific Work Stream.
The maximum that can be allocated by person/year is 12 PM. 12 PM equals 1.0 FTE (full time equivalent/year). Hence, 1 PM equals 1/12 or 0,0833 FTE.

Example

1 person working for 6 months at full time equals 0.5 FTE or 6 PM; 2 persons working at 50% of their time for 12 month equals 6PM or 0.5 FTE.

In 2014, all staff is hired in different months (e.g., DG resumes his work in March 2014, hence 10 person months of his time can be allocated accordingly).

Table 5: HQ Expenditures

		expenditures total	**€1,544,681.52**
draft expenditures for 2014 of HQ			
	I	salaries per year	€531,980.75
	II	fringe benefits	€58,242.87
	III	investment	€116,678.00
	IV	rent	€89,034.00
	V	consumables	€8,000.00
	VI	marketing material	€12,000.00
	VII	travel	€87,000.00
	VIII	Assembly of Members	€10,800.00
	IX	Scientific Meetings	€23,500.00
	X	Outsourcing Services	€130,000.00
	XI	Reserve	€273,242.87
			€1,340,478.48
draft expenditures for 2014 of CS Ethics			
	I	salaries per year	€116,522.41
	II	fringe benefits	€1,782.79
	III	investment	€20,000.00
	IV	rent	€6,720.00
	V	consumables	€1,750.00
	VI	marketing material	€1,000.00
	VII	travel	€0.00
	VIII	Miscellaneous	€3,000.00
	IX	Scientific Meetings	€0.00
	X	Outsourcing Services	€0.00
	XI	Reserve	€15,077.52
			€165,852.72
		total	**€1,544,681.52**

draft expenditures for 2014 of CS ITS			
	I	salaries per year	€5,693.48
	II	fringe benefits	€87.11
	III	investment	€9,583.33
	IV	rent	€9,000.00
	V	consumables	€3,000.00
	VI	marketing material	€2,000.00
	VII	travel	€0.00
	VIII	Miscellaneous	€5,500.00
	IX	Scientific Meetings	€0.00
	X	Outsourcing Services	€0.00
	XI	Reserve	€3,486.39
			€38,350.32

ANNEX

Table 6: Working Groups of BBMRI-ERIC

Working Group 1: H2020 / Chair: Prof. Maria Luisa Lavitrano, BBMRI.it
Working Group 2: Partner Charter / Chair: Prof. Anu Jalanko, BBMRI.fi
Working Group 3: Euro-Mediterranean Engagement / Chair: Prof. Alex Felice, BBMRI.mt
Working Group 4: Clinical Biobanks / Chair: Prof. Michael Hummel, BBMRI.de
Working Group 5: China Engagement / Chair: Dr. Georges Dagher, BBMRI.fr
Working Group 6: Sub-Saharan Africa Engagement / Chair: Prof. Kurt Zatloukal, BBMRI.at
Working Group 7: BBMRI-ERIC Catalogue / Chair: Prof. Jan-Eric Litton, BBMRI-ERIC.eu
Working Group 8: Financial Workflow / Chair: Mr. Markus Pasterk, BBMRI-ERIC.eu
Working Group 9: Rare Diseases / Chair: Dr. Luca Sangiorgi, Italian Delegate AoM

Explanatory Note:

Once the Working Groups are formed, interested parties to join should contact the respective Chair. When required, additional Working Groups can be formed at any time.

Table 7: Overview of Goals and Deliverables of Work Streams

WS 1.1 CEMO	01	02	03	04	05	06	07	08	09	10	11	12
Deliverable \ month of 2014												
Fully functioning and furnished office												
Operations Handbook												
Bank account and consulting contract for general accounting and payroll accounting												
Project Management support system for the Working Groups												
AoM Sessions	1			2						3		
FC Sessions	1			2					3			
MC Meetings	1	2	3		4	5			6		7	
SEAB Meeting											1	
Development of an archive system												
Preliminary Annual Report 2014												
Work Programme 2015 and provisional WP 2016-2017												
Recruit Senior Staff, DG and AD												
Recruit Support Staff, Secretary and Project Assistant												
Recruit Senior Project Manager												
Recruit IT Manager												
Recruit Lawyer												
Recruit Quality Manager												
Tender for Common Service ELSI												
Tender for Common Service IT												
Plan for Common Service Stakeholder Forum Secretariat												
Plan for Common Service Rare Diseases												
WS 2.1 HandsOn												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Planning of the conference												
Decision *HandsOn 2015* Italy, part of EXPO and first preparations												
Publishing of the *HandsOn* webseite												
Hold the conference *HandsOn 2014*												
Prepare for the conference *HandsOn 2015 (e.g. safe-the-date)*												
Post-production of *HandsOn 2014* (e.g. report, slides, update website)												
WS 2.2. Communication												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Creating a consistent, modern and memorable Corporate Design (CD) for web and print												
Creating templates for Word, Powerpoint, scientific posters, etc. for BBMRI-ERIC and National Nodes												
Customising business cards, letter paper, note pads, etc.												
Conceptualising information material												
Setting up the website with the new design												
Finalising posters, brochures, etc (content + print) for conferences etc.												
Setting up an intranet website to exchange documents and information												
Creating a shared pool of images, graphs etc.												
Starting engaging with the public via website and other means												
Liaise with others on communication												
Content management (intranet and old/new public website, contact database)												

WS 2.3 Stakeholder												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Introducing BBMRI-ERIC at national and international meetings												
MoU EATRIS-BBMRI												
MoU EuroBioImaging												
Involve Mediterranean countries												
Collaborate with other continents and existing initiatives												
Meetings with European political opinion leaders												
WS 2.4 E&T WP												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Map existing E&T landscape												
Start defining skill sets												
Identify interested Universities												
WS 2.5 Retreat												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Organise Retreat #1												
Incorporate outcome of meeting into WP 2015												
WS 2.6 Webinars												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Test webinars												
Sent invitations												
Enlist the help of partners												
WS 2.7 Newsletter												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Graphic layout of the newsletter*												
Preparing the content												
Final layout, editing and printing**												
Published newsletter												
WS 3.1 CS ELSI												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Identify ELSI experts in Members												
Tender for ELSI services												
Evaluate the application(s)												
Prepare decision												
AoM decides on the proposal												
Contract negotiation with legal partners												
Start setting up services												
CS ELSI inaugurated												
WS 3.2 CS IT												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Identify IT experts in Member countries												
Preparatory Meeting for Common Service IT												
Tender for Common Services IT												
Evaluate the application(s)												
Prepare decision												
AoM decides on the proposal												
Contract negotiation with legal partners												
Start setting up services (2015)												
CS IT inaugurated (2015)												
WS 3.3 CS RD												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Prepare for submission to the deadline for the 2 INFRADEV calls												
Prepare structure and objectives of a CS RD (if agreed upon)												

WS 3.4 CS SFS												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Planning												
Identify candidates												
Planning of content of the Stakeholder Forum Secretariat												
WS 3.5 EVA												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Specify the Workstream												
WS 4.1 Fundraising												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Setting up of the WG on H2020 Including on-going FP7 projects												
Exchange of on-going participations & proposal writing (partner &/or coordinator)												
Deadlines for H2020 calls												
WS 5.1 QUM												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Define quality management criteria												
Harmonisation and standardisation of SOPs												
Document quality requirements of the industry												
Map current training courses for Quality Managers												
Prepare to take over all 5 BRIF Working Groups*												
WS 5.2 Partner Charter												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Preparation of a final draft version												
Seeking approval of the AoM												
WS 5.3 Self-Evaluation												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Self-evaluation questionnaire												
Define a standardised method of evaluation												
Provide the self-evaluation tool to the National Nodes												
Assess the efficacy of this evaluation system												
WS 6.1 Expert Centre												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Map current activities (see BBMRI-LPC)												
Develop a guiding document in collaboration with BBMRI-LPC												
Develop a guiding document in collaboration with BBMRI-LPC												
WS 7.1 Biobank Catalogue												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Planning on catalogue integration												
First release												
Second release												
WS 7.2 Biobank Cloud												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Beta version												
Operating version (2015)												
WS 7.3 CoBiBa												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Prepare proposal												
Deadline INFRAIA call												
WS 8.1 MIABIS												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Specifying document												
Publication												

WS 8.2 Lexicon												
Deliverable \ month of 2014	01	02	03	04	05	06	07	08	09	10	11	12
Set up a new Working Group												
Update the existing version												
Publish the new version												

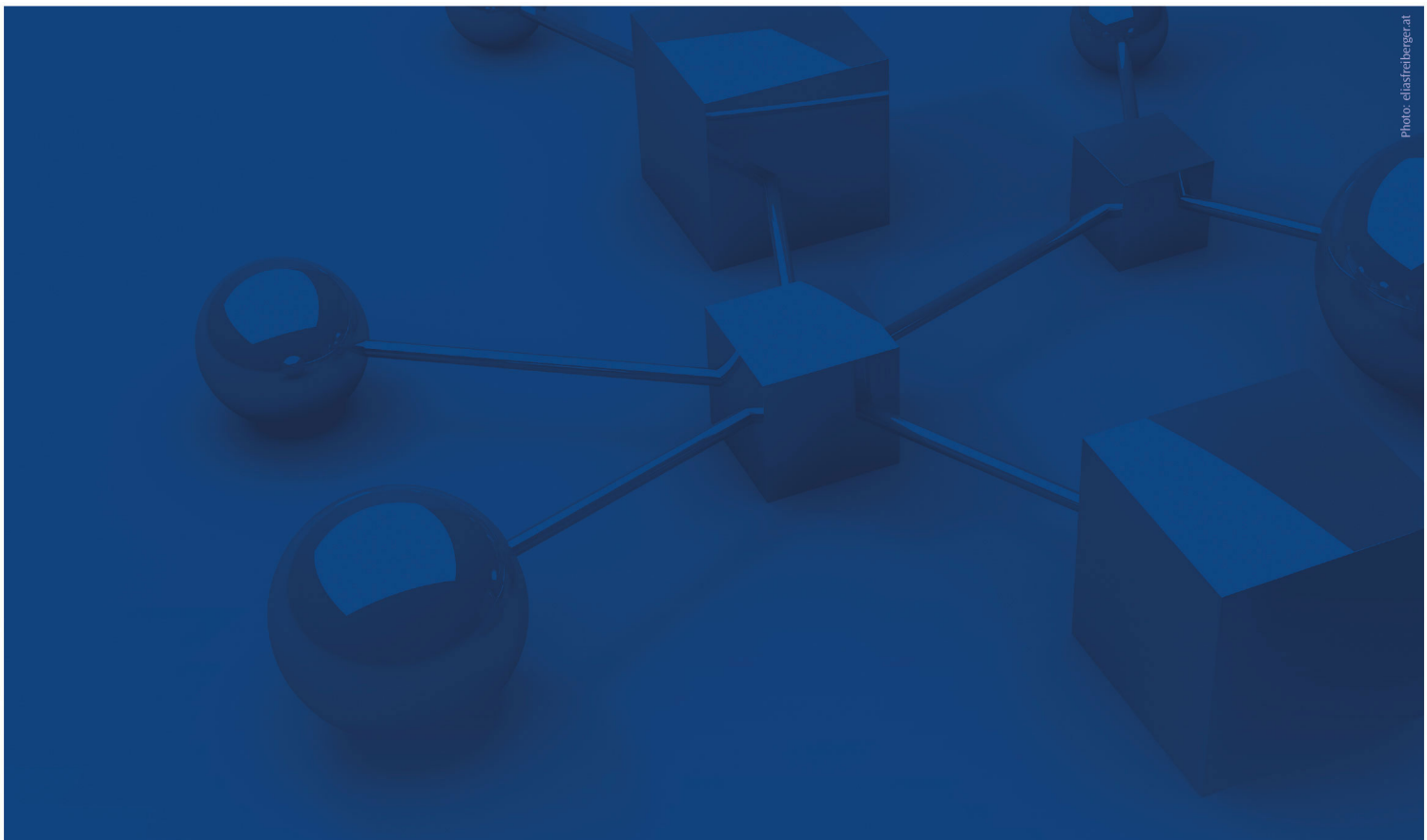


Photo: eliasfreiberger.at