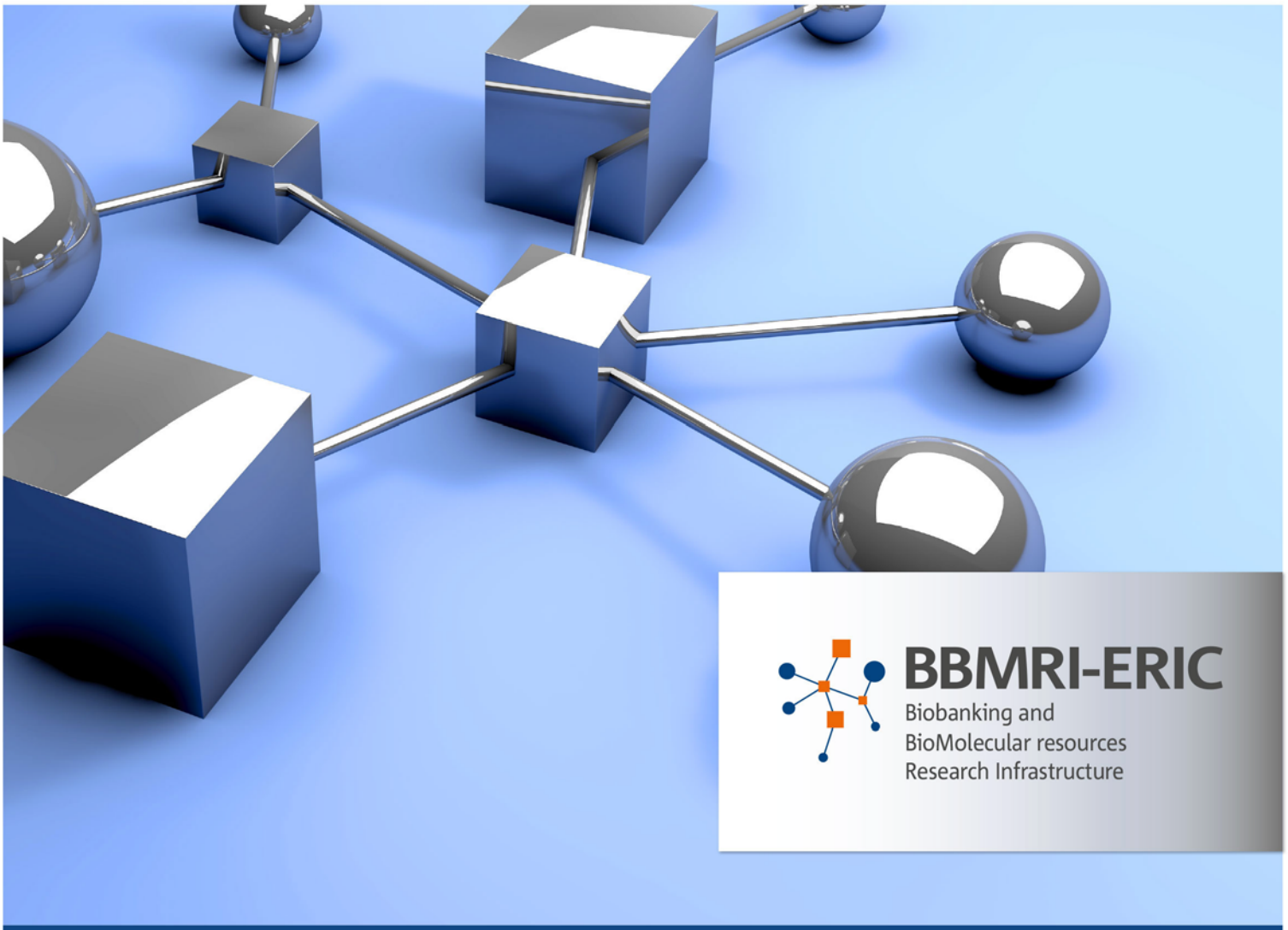


BBMRI-ERIC
Biobanking and
BioMolecular resources
Research Infrastructure

WORK PROGRAMME 2015

CORE WORK PROGRAMME 2015

AMENDMENT 2015/1

INTRODUCTION

Seventeen Member States and one International Organisation have joined forces in establishing BBMRI-ERIC, making it one of the largest Research Infrastructures in Europe today and a promising *gateway for health* to many more countries, which are currently preparing the application to become Members or Observers of the BBMRI-ERIC family.

The BBMRI Business Plan envisioned a start-up phase of two years for setting up all key infrastructure elements that are required for both operation and provision of access to human biological samples and associated data. This start-up phase began in reality with the approval of the Work Programme 2014 and Budget 2014 in the 2nd session of the BBMRI-ERIC Assembly of Members on 29 April 2014. This allowed us to strengthen community-building and to regain the momentum lost after the end of the Preparatory Phase. The community-building has been crucial due to the fact that new countries, with both new (types of) biobanks and personnel have joined, many of which were not part of the BBMRI Preparatory Phase.

Figure 1: Fereniki Ioakeimidou at the Reception Desk at the BBMRI-ERIC Headquarters in Graz

Hence, the Work Programme 2014 had a sharp focus on community-building and contained the tasks and activities (presented in 22 Work Streams divided into 8 Work Plans and 11 Working Groups) specified in accordance with Article 3.1 of the BBMRI-ERIC Statutes emerging from ample but necessary discussions within various bodies of BBMRI-ERIC. The main deliverables for 2014 were defined in the Work Programme 2014 (therein page 8).

Objective of the Work Programme 2015

The Work Programme for 2015 has its major focus on access to samples and data. Hence, its key priority will be the establishment of the *new Catalogue of European Biobanks*, including a search tool on the BBMRI-ERIC website. Thus, there is agreement that gaining fair access to samples with 'quality fit for purpose' is the most important element. This should be done through an updated/new Catalogue of biobanks for BBMRI-ERIC by creating an access gateway. The 1st BBMRI-ERIC Scientific Retreat in Tartu, Estonia highlighted that two frameworks for sample collection, are required: one prospective and one retrospective. Also, with the new ISO standards on the way, we will soon have ideal tools at hand to better describe the pre-analytical phase for many samples.

In order to further specify the usage of these resources, the following Work Streams will be included in the Work Programme 2015: Population-based biobanks; Clinical biobanks; Biomolecular resources. These Work Streams are to be supplemented by the e-infrastructure supporting activity, which has already been a part of the Work Programme 2014. Along these lines, BBMRI-ERIC has intensified its cooperation with the BMS Research Infrastructures. BBMRI-ERIC is also an official member of the World EXPO 2015 in Milan where next year's version of HandsOn: Biobanks will take place. Ultimately, the tasks are carried out by BBMRI-ERIC's 12 Working Groups (overview, see page 50) as agreed in the respective Management Committee Meetings. Their work represents a corner stone for the establishment of BBMRI-ERIC. The distributed leadership throughout Europe reflects the scientific excellence and expertise of BBMRI-ERIC Members.

To capitalise further on community-building during the 1st BBMRI-ERIC Scientific Retreat, a number of key factors for the success of BBMRI-ERIC were defined and expressed in an internal White Paper.

The two key services to ensure fair access will be the Common Service ELSI and the Common Service IT. To further specify the particular needs and requirements of the user groups (including researchers and business actors) – which vary from country to country – a close interaction with the National Nodes and their Directors is a key requirement for success. That said, governance and management activities are different responsibilities and need to be better differentiated in 2015.

As for financial issues, we have started a process to affiliate the National Nodes with BBMRI-ERIC through a Framework Agreement allowing the inclusion of National Nodes as third-party beneficiaries of H2020. The full Business Model includes specifications on how biobanks in Member and Observer Countries will be able to participate.

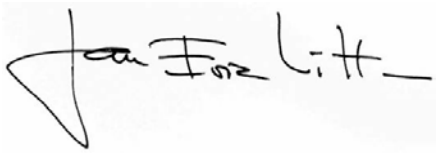
Structure of the Work Programme 2015

The present document consists of the Core Work Programme 2015 and its first Amendment.

The overall structure of the Core Work Programme 2015 is the same as for the Work Programme 2014 (background – mission – goals and deliverables – time plan – priority – project group – resources). The Work Streams are prioritised from 1 (highest priority) to 3 (lowest priority) within a given Work Plan. Moreover, the Core Work Programme 2015 has 6 distinct Work Plans and 15 Work Streams. In every Work Stream cross-references are made under the section priority to highlight the differences (if any) between the Work Programme 2014 and 2015.

Continuous Work Streams, such as administrative activities of the Central Executive Management Office (WS 1.1 in the Work Programme 2014), have not been included in the text of the Core Work Programme 2015 since the described activities include largely routine activities such as updating websites, scrutinising contracts etc. Personnel for those activities, however, are required and are explicitly indicated in the table on distribution of Person Months (page 51).

The Assembly of Members has approved the Core Work Programme in its 3rd session on 11 November 2014. Additionally, the Assembly of Members approved the first Amendment of the Core Work Programme in its 4th session on 27 April 2015, especially outlining the involvement of BBMRI-ERIC in research collaborations.



Prof. Jan-Eric Litton

BBMRI-ERIC Director General

28 April 2015

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AMENDMENT 2015/1

ABBREVIATIONS

AD	Administrative Director
AoM	Assembly of Members
BARCdb	The Biobanking Analysis Resource Catalogue
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
COM	Communication Assistant
CORBEL	COordinated Research infrastructures Building Enduring Life-science services (H2020 call application)
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	European Life Science Infrastructure for Biological Information
ELSI	Ethical, Legal and Social Issues
EMTRAIN	European Medicines research TRAINing network (IMI project)
ENRAH	European Network for Research on Alternating Hemiplegia
epSOS	European Patients Smart Open Services
ERC	European Research Council
ERIC	European Research Infrastructure Consortium
ESBB	European, Middle Eastern & African Society for Biopreservation & Biobanking
ESFRI	European Strategy Forum on Research Infrastructure
EU	European Union
EUOPENSCREEN	European Infrastructure of Open Screening Platforms for Chemical Biology
Europa Donna	The European Breast Cancer Coalition
EURORDIS	European Organization for Rare Diseases
FC	Financial Committee
FP	Framework Programme
GWAS	Genome-wide Association Study
HQ	Headquarters

IAPO	International Alliance of Patient Organizations
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 Organization for Standardization
ITM	IT/ Data Protection Manager
LAW	Lawyer
LIMS	Lab Information Management System
MC	Management Committee
MIABIS	Minimum Information About BIobank data Sharing
MoU	Memorandum of Understanding
P^3G	Public Population Project in Genomics
F/PA	Finance/Project Assistant
PM	Person Month
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
RItrain	Research Infrastructures training programme
SEAB	Scientific and Ethical Advisory Board
SEC	Secretary/Receptionist
SF	Stakeholder Forum
SOP	Standard Operating Procedure
SPM	Senior Project Manager
VSOP	Dutch Genetic Alliance
WP	Work Programme
WS	Work Stream
WHO	World Health Organisation

FIGURES, IMAGES AND TABLES

CORE WORK PROGRAMME 2015

1. WORK PLAN: E-INFRASTRUCTURE

The move towards a European e-infrastructure for biobanks is directly connected to issues of semantic interoperability through standardised message formats and controlled terminologies. In spite of several large scale projects and global achievements in standardisation, there are still largely isolated niche areas of informatics, with limited mutual awareness of the problems being tackled, the progress made, and of the possible solutions that each niche could offer to the others in support of common goals.

1.1 Work Stream: A New Gateway to European Biobanks

1.1.1 Background

Biobanks are resources comprising biological samples and associated data that are accessible to scientific investigation. They have become a key element for research involving human genetic or genomic and proteomic information in conjunction with other personal or health data. There is consensus in the scientific community that progress in understanding disease will depend on the establishment, harmonization and broad use of this information.

At present, it is difficult to access and integrate information from biobanks on demand, as there is no common terminology. This makes the Catalogue of European Biobanks (http://bbmri.eu/catalog-of-european-biobanks) difficult to update and maintain.

MIABIS (Minimum Information About Biobank data Sharing) is a standard that has been developed in response to the need of harmonisation and standardisation of Biobank information in Europe. Though MIABIS is accepted as the standard of minimum information for biobank data exchange, most of the information from biobanks is not regularly accessible in the MIABIS format because biobanks in Europe implemented their pipelines, database schemas and LIMS (Lab Information Management System) before the MIABIS standard was published (http://www.ncbi.nlm.nih.gov/pubmed/24849882). Consequently, although the wide adoption of MIABIS would be highly beneficial for the research community, the necessary changes in the existing data model of individual biobanks would require a lot of effort. At present there are four national biobank catalogues and three other projects following the MIABIS standard.

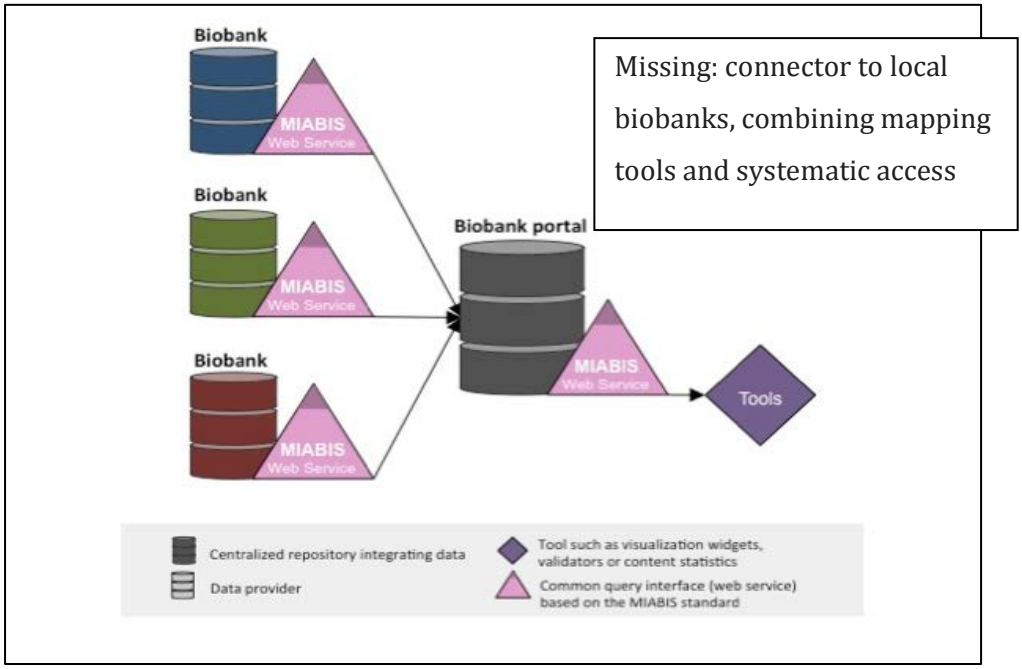

Figure 2: BBMRI-ERIC Information Federation through MIABIS

1.1.2 Mission

To build a common query interface for computational access to biobank information based on mapping existing biobank data to the new MIABIS standard. This will lead to a sustainable bridge between the biobanking community and services developed within BioMedBridges and will create a common query interface for accessing biobank data using the MIABIS standard. A layer will be built, promoting biobank data sharing without the need to change specific data models in the information management systems of individual biobanks.

The work will deliver a pluggable interface to the existing structures of biobanks. A web service will facilitate computational access to biobank information. All biobanks using the mapper component and its common query interface will be able to be queried in the exact same way presenting the information in the MIABIS format. The adoption of the common query interface will facilitate integration as well as automatic updates of registries such as the Catalogue of European Biobanks.

In addition, the biobank portal will be used as a broker service/gateway to register access points to MIABIS-compliant biobanks. This technical infrastructure following the Service Oriented Architecture will facilitate construction of a modular federated ecosystem of biobank information, which will improve access, discoverability and data exchange. It will facilitate sharing of Biobank data and tools, and open up possibilities to jointly develop new functionality.

The mapping work will have synergies with WP5.4, where a MIABIS-compatible layer is being built for the EU catalogue. Existing data will be mapped to MIABIS. This will add additional insights into the mapping needs, and it will lead to a version of the catalogue that will already contain data on the biobank and sample collection level.

The work will build on previous efforts within BioMedBridges and extend them to enable access to necessary levels of biobank information. It will be written up in a request for amendment to the grant agreement as an extension to Deliverable 10.3 in BioMedBridges. Moreover, to ensure an e-infrastructure providing knowledge about and access to European biobanks, it will be a key asset within the upcoming H2020 (INFRADEV-3) application of January 2015.

1.1.3 Goals and Deliverables

1. **Biobank common query interface implementation**
   a. Define technical requirements and design of the common query interface
      i. Web service (Methods, Query language)
      ii. MIABIS adaptors
   b. Implementation of the common query interface

2. **Adoption of the common query interface**
   a. Select at least 3 biobanks willing to adopt the common query interface
   b. Map biobank data to MIABIS
   c. Deploy common query interface

- BBMRI-ERIC HQ will lead the main development with unused funds from BioMedBridges. A developer will be hired to carry out the work
- EBI will collaborate with BBMRI.xx in the development of the project, especially in the first development step of the roadmap
- The proposed work will be open to the collaboration of other BioMedBridges partners

1.1.4 Time Plan

Deliverable \ month of 2015	01	02	03	04	05	06	07	08	09	10	11	12
Mapping												
Define technical requirements and design of common query interface												
Implementation of the common query interface												
Select BBMRI-ERIC Biobanks to adopt the common query interface												

Step (2) Q1 2015.

1.1.5 Priority

1. (This Work Stream was included in the Work Programme 2014, 7.1).

1.1.6 Project Group

DG, BBMRI.xx, Klaus Kuhn, ITM

1.1.7 Resources

Staff Function	Full Time Equivalent in Person Months
DG	5
AD	2,5
SPM	2
ITM	8
QUM	1

PA	1
Total	19,5

2. WORK PLAN: QUALITY

2.1 Work Stream: Quality Management System (QMS)

2.1.1 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. Currently, 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 in developing their quality management systems and assessing their own competence can use ISO 15189:2012. Laboratory customers, regulating authorities and accreditation bodies can also use it for confirming or recognizing the competence of medical laboratories. The scope of the 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), covers the standardization of biobanks, among other issues. Currently 18 countries are participating: Austria (ASI), Belgium (NBN), Canada (SCC), China (SAC), Finland (SFS), France (AFNOR), Germany (DIN), Japan (JISC), the Republic of Korea (KATS), Luxembourg (ILNAS), the Netherlands (NEN), Nigeria (SON), Spain (AENOR), Sri Lanka (SLSI), Sweden (SIS), the United Republic of Tanzania (TBS), the United Kingdom (BSI) and the United States (ANSI), 7 of which are Member Countries of 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 for biobanks to have similar quality systems. Currently, there are several international efforts to standardize quality systems for biobanks. These must be evaluated and practical administrative applications must be proposed and communicated within BBMRI-ERIC.

2.1.2 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 realized by setting up Quality Management Services (QMS).

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 them accordingly.

2.1.3 Goals and Deliverables

The following goals should be envisaged:

- Defining the quality management criteria for biobanks, in close coordination with the ISO/TC 276 Technical Committee
- Seeking to harmonize and standardize SOPs should be completed, if possible, in collaboration with other organizations that already have worked on this topic to avoid unnecessary and overlapping work
- Advising the biobanks of the quality requirements of industry is a crucial requirement for BBMRI-ERIC to meet its aims
- Setting up training in quality control for biobanks may be realized by providing on-site training and organizing events on quality control-related issues
- Advising in certification of biobanks may be realized 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

2.1.4 Time Plan

The start of this activity has been shifted from Q3 2014 to Q1 2015.

Deliverable \ month of 2015	01	02	03	04	05	06	07	08	09	10	11	12
Define quality management criteria												
Harmonization and standardization of SOPs												
Document quality requirements of the industry												
Map current training courses for Quality Managers												

2.1.5 Priority

1. (This Work Stream was included in the Work Programme 2014, 5.1. It included the BRIF, which has been given a separate Work Stream in 2015).

2.1.6 Project Group

DG, AD, QUM of HQ

2.1.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.5
AD	0.5
QUM	4

total	5

2.2 Work Stream: Self-Evaluation

2.2.1 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.

In order to identify quality-oriented European biobanks, able to provide to the European and international research community high quality samples and related information and to comply with the BBMRI-ERIC principles, an on-line 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 this kind of evaluation are available and will be analysed and taken into account in this work stream: in particular the BRIF initiative, BBMRI-LPC ("*Biobanking Article of the Week*"; http://www.bbmri-lpc.org/node/46) and the ESBB "*Biobank of the Year*".

2.2.2 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 to develop 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 standards, compatible with signing the Partner Charter of BBMRI-ERIC
- Collaborate with international initiatives

2.2.3 Goals and Deliverables

- To build a self-evaluation questionnaire, taking into account all parameters relevant to the quality management of biobanks
- To define a standardized 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

2.2.4 Time Plan

The start of this activity has been shifted from Q4 2014 to Q1 2015.

Deliverable \ month of 2015	01	02	03	04	05	06	07	08	09	10	11	12
Self-evaluation questionnaire												
Define a standardized method of evaluation												
Provide the self-evaluation tool to the National Nodes												
Assess the efficacy of this evaluation system												

2.2.5 Priority

1. (This Work Stream was included in the Work Programme 2014, 5.3)

2.2.6 Project Group

QUM of HQ

Prof. Marialuisa Lavitrano, BBMRI.it

2.2.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
QUM	1
total	1

BBMRI.it

2.3 Work Stream: Implementation of BRIF (The Bioresource Research Impact Factor)

2.3.1 Background

The BRIF initiative was set up to construct an adequate framework and provide a set of tools for objective measurement of the actual research utilisation of bioresources[1], as a significant component for establishing their impact on research. BRIF was introduced in 2003. After further improvement of the concept, an international Working Group was established in 2010 to initiate its development consisting of 134 members from 22 countries, most of which are either European (86) or North American (31). This group was further structured into five relevant thematic sub-groups: i) BRIF and digital identifiers, ii) BRIF parameters, iii) BRIF in sharing policies, iv) BRIF and journal editors and v) BRIF dissemination (http://www.gen2phen.org/groups/brif-bio-resource-impact-factor), following a first workshop in 2011. A second workshop held in 2012 was used to detail the objectives and milestones of each sub-group (see http://www.gigasciencejournal.com/content/2/1/7). Significant progress has been made, notably with standards for citing bioresources in scientific journal articles (http://www.equator-network.org/library/reporting-guidelines-under-development/#19). In addition, a pilot questionnaire for identifying parameters taking into account BRIF calculations has been circulated in two BBMRI-ERIC Member Countries (France and Italy). It is now essential that the biobank community at large and BBMRI-ERIC specifically, which was the first concerned with BRIF issues, should identify with BRIF and take responsibility for its further development.

2.3.2 Mission

Within BBMRI-ERIC, the BRIF initiative will develop mainly four axes in 2015:

(1) promotion of future standards for citation of bioresources towards all relevant communities

(2) promotion of the visibility of BBMRI-ERIC bioresources through publication of marker papers

(3) collective adoption of an identification (ID) scheme for bioresources and the creation of a necessary bioresource ID database/registry that will centralize all identified bioresources and their relevant metadata

(4) an initial phase involving the IT service to create a tool for calculating research impact of bioresources. This tool will require adequate metrics and algorithms to fuel it with relevant metadata (including a unique digital resource identifier).

[1]Bioresources (BR) are defined as biological samples with associated data (medical/epidemiological, social),
databases independent of physical samples, or other collections of biomolecular and bioinformatics research tools. Biobanks are the main bioresources.

2.3.3 Goals and Deliverables

To achieve **Mission 1**: transfer of the current BRIF website (hosted currently by the Gen2Phen Knowledge Centre) to the BBMRI-ERIC website; BBMRI workshop (WS1) for promoting the standards for BR citation in academic literature.

To achieve **Mission 2**: ensure that all BBMRI-ERIC resources have a marker paper with sufficient description, and if not yet available, through publication in the Open Journal of Bioresources or any other journal, preferably one with open access.

To achieve **Mission 3**: Two workshops (WS1, WS2) with BBMRI-ERIC leader team and relevant persons (IT) about the ID schemes and the ID database.

To achieve **Mission 4**: One workshop (WS3) with the IT persons focused on the metadata required for the implementation of the BRIF metrics (formula and algorithm).

2.3.4 Time Plan

Milestone (ML) / Deliverable (DL)	01	02	03	04	05	06	07	08	09	10	11	12
ML1 Mission 1: dissemination actions decided (BRIF website, relation to EQUATOR network…) DL1: Guidelines for BR citation in BBMRI-ERIC website												
ML2 Mission 2: Requirement of a marker paper specified on website DL2: Reference of marker paper included in metadata of each BBMRI-ERIC bioresource (database)												
ML 3 Mission 3: WS1, ID scheme decided (e.g. DOI DataCite related) DL3: Report, procedure implemented ML4 Mission 3: WS2, Database / registry scheme DL4: Database designed												
ML5 Mission 2: Session BRIF in HandsOn Biobanks, Milano, IT DL5: Report on session												
ML6 Mission 4: WS3, design of metrics / algorithm DL6: Report + action plan												

2.3.5 Priority

2. (This was part of the Work Stream 5.1. in the Work Programme 2014 and has been made a specific Work Stream in 2015).

2.3.6 Project Group

QUM

ITM

Anne Cambon-Thomsen, Inserm-Université Toulouse III, FR

Laurence Mabile, Inserm-Université Toulouse III, FR

Emmanuelle Rial-Sebbag, Inserm-Université Toulouse III, FR

Elena Bravo, Istituto Superiore di Sanita, IT

Pierre Antoine Gourraud, University of California SF, USA

Barbara Parodi, Istituto Nazionale per la Ricerca sul Cancro, IT

2.3.7 Resources

Staff Function	Full Time Equivalent in Person Month
AD	0,5
QUM	2
PA	0,25
total	2,75

2.4 Work Stream: Development of a BBMRI-ERIC Approval Process

2.4.1 Background

Within organisations that are developing standards, guidelines and reports of best practices, it is necessary to lay out a framework of how such documents should be written and what management processes need to be followed for their approval. One of the tasks of BBMRI-ERIC is to implement quality management including standardised procedures, best practices and appropriate tools to increase the quality of the resources collected and their associated data (Statutes, Article 3, para 2.c). It will be important to develop a management process on how to develop such guidelines, best practises and standardisation tools.

One good example is provided by the WHO Guidelines:

http://whqlibdoc.who.int/hq/2003/eip_gpe_eqc_2003_1.pdf.

2.4.2 Mission

Guidelines are systematically developed evidence-based statements, which assist providers, recipients and other stakeholders to make informed decisions about appropriate research undertakings. Guidelines are formal advisory statements which should be robust enough to meet the unique circumstances and constraints of the specific situation to which they are being applied. The basic nature and intent of guidelines have also been expressed under other formats variously labelled as protocols, best practice, algorithms, consensus statements, expert committee recommendations, and integrated care pathways.

A standard is a document that provides requirements, specifications, guidelines or characteristics that can be used consistently to ensure that materials, products, processes and

services are fit for their purpose. A panel of experts within a technical committee, for example, develops an ISO standard. Once the need for a standard has been established, these experts meet to discuss and negotiate a draft standard. As soon as a draft has been developed, it is shared with ISO's members, who are asked to comment and vote on it. If a consensus is reached the draft becomes an ISO standard. If no consensus is reached, it goes back to the technical committee for further amendment.

The mission of this Work Stream is to define jointly with the MC how to develop and approve guidelines and standards in BBMRI-ERIC.

2.4.3 Goals and Deliverables

The goal for 2015 is to agree on a framework document that describes the processes for developing guidelines and standards within BBMRI-ERIC. This needs to be done together with the MC and potentially also with outside experts. The HQ will draft a first version background document that will be further discussed and amended in a drafting group. The resulting draft will be opened for review. The HQ will revise the draft based on the input from review and a final document will be put before the Assembly in the second half of 2015 for formal approval. Once approved, these processes will be binding for future BBMRI-ERIC standards and guidelines.

2.4.4 Time Plan

Start Q1 2015, final document in Q3 2015 to the AoM for consideration.

Deliverable \ month of 2015	01	02	03	04	05	06	07	08	09	10	11	12
Establish task force												
Preparation of a draft version												
Seeking approval of the AoM												

2.4.5 Priority

2. (This is a new Work Stream).

2.4.6 Project Group

MC members will nominate one representative per country for the drafting group. From HQ, this will be organised under the supervision of the AD and contribution of the QUM.

2.4.7 Resources

HQ AD and QUM

Staff Function	Full Time Equivalent in Person Month
AD	2
QUM	0,25
total	2,25

2.5 Work Stream: Biobank Lexicon

2.5.1 Background

With the domestic and international proliferation of biobanks and their associated data a common language for biobanks is essential. Today, however, we have different meanings for the same terminology in both the field of law and the biobanking community. This causes serious misinterpretations among biobankers as well as users.

Already during the Preparatory Phase the goal was to provide a Biobank Lexicon for the usage of not only the European but also the global biobank community. To improve and update the Biobank Lexicon was henceforth a goal in the Work Programme 2014 (4Q). The work, however, requires further resources in 2015, and potentially 2016.

2.5.2 Mission

To overcome the language barrier (both legal and cultural) that comes with crossing borders when conducting research, the Lexicon will be translated into multiple languages to support a common understanding within the community.

2.5.3 Goals and Deliverables

Its current version is translated into 10 EU languages (http://bbmri-wiki.wikidot.com/lexicon-list). The interest for this lexicon has also been raised outside the EU, such as Arabic countries as well as China, the US and Canada.

A new global Working Group including lawyers will be set up.

2.5.4 Time Plan

Deliverable \ month of 2015	01	02	03	04	05	06	07	08	09	10	11	12
International Working Group Meeting												
Update the existing version												
Report												

2.5.5 Priority

3. (This Work Stream is an effort continued from the Preparatory Phase and was included already in the Work Programme 2014, Work Stream 8.2. It was delayed because of the late recruitment of the QUM.)

2.5.6 Project Group

DG, ITM, QUM of HQ.

ISBER, ESBB and P³G.

M.Sc. Roxana Martinez BBMRI.se

2.5.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.25
ITM	0.5
SPM	0.25
QUM	0,5
total	1,5

3. WORK PLAN: CLINICAL BIOBANKS

A task was set up for clinical biobanks and was defined as an outcome of the Work Group meeting in Berlin on 16-17 September 2014. During that meeting it was decided to convert the Working Group for Clinical Biobanking to a Work Plan for Clinical Biobanking. Biobanks are playing an increasingly important role in transferring knowledge to health systems and many countries envision that their biobanks will become integral parts of their health care structures.

3.1 Work Stream: Clin Bio

3.1.1 Background

Biobanking in the background of patient care differs significantly in almost all aspects from others types of biobanking. Thus different rules and frameworks have to be considered. This includes quality measurements of the samples (liquid and tissue) and data (diagnostic, treatment and follow-up), patient information and consent, IT management and dissemination of the samples.

3.1.2 Mission

In order to identify the needs of clinical biobanking on the European scale, a pilot study will be set up involving one or a few national biobanks from each member country (total number of maximum 15 biobanks). A use case comprising one disease (e.g. infiltrative ductal T2 breast cancer diagnosed in year 2000 and 2010) will be defined with a limited number of cases designed to challenge the existing interoperability of the respective biobanks. This includes the availability of certain cases and data (diagnostic and treatment), the electronic exchange of data (ontology), the definition of the quality of the samples as well as follow-up.

3.1.3 Goals and Deliverables

The goal of the first phase of the working group is to lay out the basis for collaboration between patient care biobanks within BBMRI-ERIC. To this end, the project aims to select randomly 5-10 cases fulfilling the defined criteria (e.g. infiltrative ductal T2 breast cancer diagnosed in the years 2000 and 2010 including treatment, outcome, follow-up and quality data) from each of the identified biobanks in different European countries. From each of the selected cases, 5 fresh slides are prepared, followed by histological review and new analysis of biomarkers (ER, PR, Her2) followed by a scan of the new slides. A joint review of the cases (pathologist from each identified biobank) is conducted for diagnosis, prognostic factors and the new biomarkers (joint meeting or web-based evaluation). Finally, DNA from the selected cases will be extracted and used for quality-control PCR to evaluate the sample quality of FFPE samples.

Deliverables:

1. Survey and compilation of the clinical biobanks from each member country which will join the pilot phase of this working group
2. Definition of one use case (e.g., Infiltrative ductal T2 breast cancer diagnosed in year 2000 and 2010 including treatment, outcome, follow-up and quality data)
3. Application of the use case(s) to the respective biobank
4. Aggregation of the results from each biobank
5. Transfer of the sample and clinical data in a comparable format
6. Collection of the data

7. Selection of up to 5 cases per biobank
8. Production of tissue section for histology and biomarker assessment
9. DNA extraction and quality-control PCR
10. Definition of the quality of the samples/evaluation of the available quality features
11. Identification of problems in interoperability
12. Definition of solutions

3.1.4 Time Plan

Deliverable	01	02	03	04	05	06	07	08	09	10	11	12
Identification of participating biobanks and definition of use cases												
Application of use cases, aggregation of results, collection of data												
New analysis (histology, prognostic factors, biomarkers)												
Evaluation of sample quality/identification of problems/ definition of solutions												

3.1.5 Priority

1. (This is a new Work Stream)

3.1.6 Project Group

Prof. Michael Hummel, Prof. Tuomas Mirtti, Prof. Giorgio Stanta, Prof. Gerhard Zielhuis, Prof. Olli Carpen (defined during ClinBio Meeting in Berlin, Germany on 16-17 September 2014), Working Group 4: Clinical Biobanks

3.1.7 Resources

Staff Function	Full Time Equivalent in Person Months
SPM	0.25
ITM	0,5
QUM	1,5
PA	0,25
total	2,5

Other resources: BBMRI.de, BBMRI.nl, BBMRI.fi, BBMRI.it

4. WORK PLAN: POPULATION-BASED COHORTS

Central to the research into human biological variation that is underpinning the drive towards personalized medicine is the collection of biological, clinical and other data from large numbers of individuals with shared characteristics (cohorts). Large prospective cohort studies are considered the most reliable study design to elucidate causes of human disease, as the design minimizes several major sources of errors in etiological studies and is the only study design that can follow how genes and environment interact over time in the development of human diseases. The recent rapid development of high throughput genotyping and phenotyping techniques, including genomics, transcriptomics, proteomics, metabolomics, epigenetics and imaging techniques have vastly expanded our ability to obtain large amounts of data on etiology of diseases and/or biomarkers for prediction and early diagnosis of diseases.

Longitudinal research over a long period of time – generations – demands appropriate coordination, infrastructure, methodology and systems to handle the gathering, storage and utilisation of samples and information. These biobanks bring to the fore the need for a standardisation of research materials and data and a long-term computing and storage strategy.

The overall long-term aim of this Work Plan is to create a European Cohort Consortium. The European Cohort Consortium will be essential for the European research community as it introduces new methods and gives new value to existing cohorts and infrastructures. It will work to harmonise data in cohorts, but also to lower thresholds for cohort collaboration by harmonising application forms, data, biomaterial transfer agreements, etc.

4.1 Work Stream: BBMRI-LPC

4.1.1 Background

The Biobanking and Biomolecular Resources Research Infrastructure – Large Prospective Cohorts (BBMRI-LPC) is one of the largest biobanking networks in Europe. The BBMRI-LPC infrastructure project is funded by the European Commission under the Seventh Framework Programme (FP7), and specifically aims to facilitate transnational access to prospective cohort studies across Europe. This will be achieved through a number of activities, for instance the cataloguing of existing cohort resources and support for access through open scientific calls. Currently there are 22 cohorts from all participating countries involved in the BBMRI-LPC-project.

BBMRI-LPC aims to help overcome barriers to multinational research projects, which are often complicated by sample and data sharing difficulties due to limited resources, as well as by country specific legal and ethical procedures. In particular, BBMRI-LPC will:

- Unite the large prospective study sets in Europe, and tune them up for ground-breaking science by improving the harmonization of collected samples and data
- Facilitate collaborative transnational research by providing access to biobanked samples and data for researchers working in academia and industry
- And provide a networking platform that connects the already established and new emerging biobanks

4.1.2 Mission

BBMRI-LPC was launched for "support to existing research infrastructure (Call N° 10 - FP7-INFRASTRUCTURES-2012-1). The project will end in 2017. The results of BBMRI-LPC will be implemented through BBMRI-ERIC concurrently as they are delivered.

4.1.3 Goals and Deliverables

BBMRI-ERIC is a full partner of BBMRI-LPC and is responsible for:

- Communicating the results to the biobanking community at large
- Providing a Forum for new European biobank initiatives, particularly from Eastern Europe
- Preventing overlapping activities, which can be provided by BBMRI-ERIC, especially using the service of the Common Service ELSI, assist to harmonise biobanking technologies and quality management

4.1.4 Time Plan

Some of the deliverables are continuous work; others have fixed or envisaged delivery dates. The following table summarizes deliverables and time line:

Deliverable \ month of 2015	01	02	03	04	05	06	07	08	09	10	11	12
Communicate the results												
Provide a Forum for Biobank initiatives (esp. Eastern Europe)												
Prevent overlapping activities												

4.1.5 Priority

2. (This is a new Work Stream.)

4.1.6 Project Group

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

BBMRI-LPC

4.1.7 Resources

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

Staff Function	Full Time Equivalent in Person Month
DG	0.25
AD	1
total	1,25

5. WORK PLAN: BIOBANK OUTREACH (CENTRAL EXECUTIVE MANAGEMENT OFFICE)

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

5.1.1 Background

Many well-known universities and institutes use scientific retreats. For BBMRI-ERIC, this yearly event should ideally be hosted by a member state. One of the aims of the retreat is to allow thinking and exchanging new ideas without being distracted by daily duties.

The first retreat has proven the importance and added value of the retreat for the success of BBMRI-ERIC.

5.1.2 Mission

The two-day BBMRI-ERIC Scientific Retreat features short talks, breakout sessions, and the opportunity for BBMRI-ERIC colleagues to meet and exchange information away from the pressures of labs, offices and regular meeting schedules.

5.1.3 Goals and Deliverables

BBMRI-ERIC Retreat#2: 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.

5.1.4 Time Plan

The second Scientific Retreat will be held before the summer vacations 2015.

Deliverable \ month of 2015	01	02	03	04	05	06	07	08	09	10	11	12
Planning												
Date for Scientific Retreat #2 (exact date to be determined doodle)												
Incorporate outcome of meeting into WP 2016												

5.1.5 Priority

1. (This Work Stream has already been included in the Work Programme 2014, 5.3)

5.1.6 Project Group

DG, SPM of HQ

BBMRI.xx

5.1.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Months
DG	0.25
SPM	0.5
PA	0,25
total	1

BBMRI.xx

5.2 Work Stream: HandsOn: Biobanks

5.2.1 Background

HandsOn: Biobanks will be a yearly event by BBMRI-ERIC hosted by a National Node(s). The *HandsOn: Biobanks 2015* will be hosted by BBMRI.it and will be part of Expo 2015 in Milan, Italy. The Expo is a non-commercial Universal Exposition organized 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 organize similar events like the Paris Expo in 1889 for which the Eiffel Tower was designed and built.

5.2.2 Mission

For the event, we have created an interactive biobank and industry exhibition called THE ROUTE, where conference participants can follow the sample collection, processing and research process as well as discuss the value of biobank research for society. Part of the conference programme is an interactive sequence of displays where participants can go through the biobanking process step by step.

The conference concept furthermore includes thematic idea labs, exhibitions, poster presentations and knowledge sharing to present, discuss and develop ideas for improving and sharing the practice of biobanking. BBMRI-ERIC is inviting academics, representatives of industry, physicians and healthcare professionals, patient groups, policy makers, public representatives and legislators to sharing both knowledge and concerns, and contribute their thoughts.

5.2.3 Goals and Deliverables

The aim of this conference is to share visions, knowledge and solutions. BBMRI-ERIC conceptualises this knowledge-sharing platform for the benefit of both sponsors and participants.

5.2.4 Time Plan

Deliverable \ month of 2015	01	02	03	04	05	06	07	08	09	10	11	12
Prepare for the conference *HandsOn 2015 (e.g. catering, finalise programme, etc.)*												
Decision on *HandsOn 2016* with ESBB												
Hold the conference *HandsOn 2014*												
Prepare for BBMRI-ERIC specific EXPO events												
Post-production of *HandsOn 2015* (e.g. report, slides, update website)												

5.2.5 Priority

2. (This is a continued Work Stream from the Work Programme 2014, 2.1.).

5.2.6 Project Group

DG, SPM, PA of HQ

BBMRI-ERIC Organising Committee HOBB 2015:

Jan-Eric Litton jan-eric.litton@bbmri-eric.eu (Chair)

Marialuisa Lavitrano marialuisa.lavitrano@unimib.it (Vice Chair)

Michaela Theresia Mayrhofer michaela.th.mayrhofer@bbmri-eric.eu (Liaison Officer)

Anu Jalanko anu.jalanko@thl.fi

Törnwall Outi outi.tornwall@thl.fi

Markus Pasterk markus.pasterk@bbmri-eric.eu

Gert-Jan van Ommen gjvo@lumc.nl

Local Organising Committee HOBB 2015:

Marialuisa Lavitrano marialuisa.lavitrano@unimib.it (Chair)

E. Bravo, Bravo Elena elena.bravo@iss.it

MG Daidone, tbc

Rita Lawlor rita.lawlor@arc-net.it

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Barbara Parodi, barbara.parodi@hsanmartino.it

D. Pistillo, tbc

Giorgio Stanta, stanta@icgeb.org

Scientific Committee HOBB 2015:

see http://handsonbiobanks.org/

5.2.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Months
DG	0.25
SPM	1
PA	0,5
total	1.75

BBMRI.it (HandsOn 2015)

BBMRI.fi (HandsOn 2014)

5.3 Work Stream: Working Party on a European Biobanking Education and Training Strategy

5.3.1 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 biobanking in Europe. There is a great need to structure E&T activities in this growing field taking into account the existing courses and providers.

5.3.2 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 curriculum, sustainability, access and training.

5.3.3 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 has 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 with interested Universities European Curricula for the different levels
- Coordinate if requested providers of short courses in the field for Continuous Professional Training

Towards the end of 2014, 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 2015 and the following years; next steps will be to start with the mapping exercise; start defining skill sets. Within the first wave of H2020 project applications BBMRI-ERIC is – in relation to E&T – the co-leader of the Coordinated Research Infrastructures

Building Enduring Life-science services (CORBEL) project and the Coordinator of the Research Infrastructures Training Programme (RItrain). For both applications, the role of BBMRI-ERIC is to be the gateway to the envisioned goals. Hence, the applications have been developed to define the competencies of both operators (CORBEL) and managers (RItrain) of RIs. If one or both applications are funded, a substantial part of this Work Stream will be co-funded. It is planned to start at the level of the HQs, then National Nodes and then at the level of individual biobanks. Together with the European, Middle Eastern & African Society for Biopreservation & Biobanking (ESBB), with which BBMRI-ERIC is currently fine-tuning an MoU, we are planning to map all current relevant short term training activities and provide them for users through the IMI project European Medicines Research Training Network (EMTRAIN). The information will be gathered using questionnaires. Additionally, it is planned to identify those European Universities interested in the development of a modular curriculum and bring them around one table.

5.3.4 Time Plan

The Work Party should start during the second half of 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 2015	01	02	03	04	05	06	07	08	09	10	11	12
Map existing E&T landscape												
Start defining skill sets												
Identify Universities interested												
Drafting of the first E&T Policy Document												

5.3.5 Priority

3. (This Work Stream has already been part of the Work Programme 2014, 2.4)

5.3.6 Project Group

AD of HQ

All National Node Directors; other experts

5.3.7 Resources

The resources for this Work Stream are mainly Person Month of staff of BBMRI-ERIC and National Nodes.

Staff Function	Full Time Equivalent in Person Months
AD	2
PA	1
total	3

BBMRI.xx

6. WORK PLAN: COMMON SERVICES FOR BBMRI-ERIC

BBMRI-ERIC Common Services form a key element of the infrastructure as they provide to the biobanking community and biobank users top-levels 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 based. It is envisaged that Common Services will be 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.

6.1 Work Stream: Working Group for Rare Diseases

6.1.1 Background

During the BBMRI Preparatory Phase, specific attention was paid to user needs of different scientific fields. For rare diseases, expert panels have defined user needs, participation of scientists from the rare disease community in work packages and involvement with funders for rare disease research.

6.1.2 Mission

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). The involvement in H2020 applications, especially the outcome of the INNORARE and INFRADEV-3 proposal, will influence the goals and deliverables of this Working Group that will become fully operational in the event that the two H2020 proposals are funded.

6.1.3 Goals and Deliverables

In order to provide appropriate flexibility to address the requirements of the proposal mentioned above, we need to improve:

- The crosstalk with RD-oriented initiatives (like RD-Connect and EuroBioBank) in order to emphasise the utility of biobanks and registries along the translational pathway
- A “registry/biobank” support service/ helpdesk facility that will provide real time support to RD biobanks/registries in meeting requirements for inclusion in BBMRI (including the catalogue)
- Return-on-investment models or a sustainable public funding to guarantee long-term sustainability especially for Support Services
- Define the National Contact Point representatives and plan a meeting with RD CONNECT and EuroBioBank representatives
- And to support the European Reference Networks on RD for 2015 ERN call

6.1.4 Time Plan

Deliverable \ month of 2015	01	02	03	04	05	06	07	08	09	10	11	12
Standard catalogue **INNORARE**												
Standard access request procedure **INNORARE**												
Guidelines for High quality Biomaterials and data **INNORARE**												

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Support service/helpdesk **INFRADEV-3**												
Business plan for sustainability **INFRADEV 3**												

6.1.5 Priority

2. (This has been a Work Stream in the Work Programme 2014, 3.3.).

6.1.6 Project Group

Working Group 9: Rare Diseases.

6.1.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
AD	0,5
PA	0,25
total	0,75

6.2 Work Stream: Common Service for Biological Resources

6.2.1 Background

With rapidly expanding opportunities for extensive molecular analyses of biobank samples, there is an increasing demand for investigations of large sample collections in order to achieve statistical significance and ensure applicability of findings in different populations. This creates a need for broad agreement on methods to use, and to identify optimal techniques to use for a given purpose. It is therefore a central purpose for BBMRI-ERIC to ensure broad access to state-of-the-art – and beyond state-of-the-art - techniques and reagents for biospecimen analysis, and to promote interoperability of data across studies and biobanks across Europe. A continuously

updated network is being established, linking centres/platforms and facilities across Europe that provide access to relevant technologies for distinguishing, measuring and imaging nucleic acids, proteins, metabolites, etc. in large sample collections.

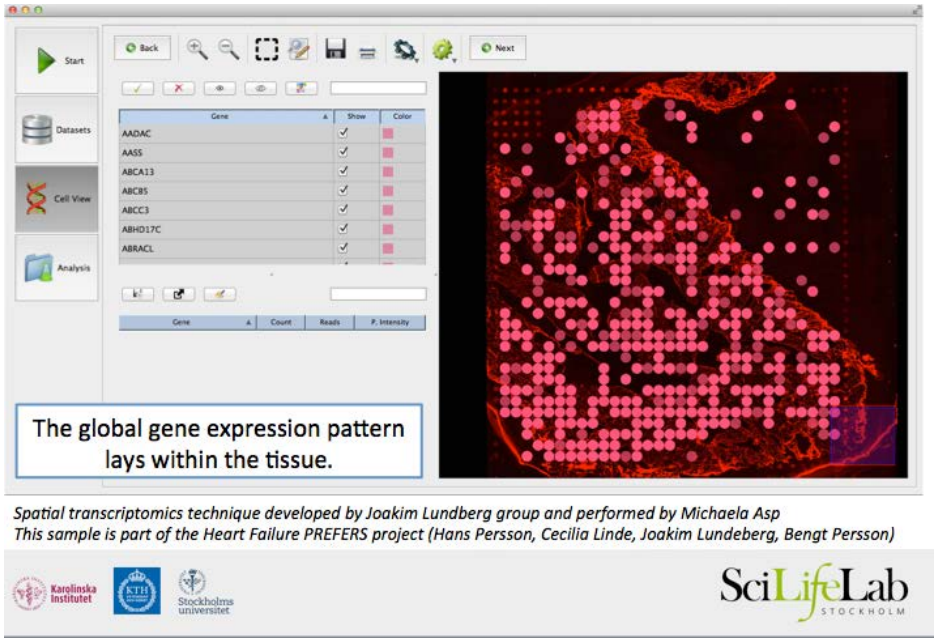

Figure 3: Global Gene Expression Pattern
To the right is the histological tissue section (myocardial biopsy) overlaid with information about gene expression in each tissue (pink dots). To the left is an interface where you can see which genes are expressed and also determine the colour. In this picture, all the genes the same colour to not disclose the results which are not yet published.

6.2.2 Mission

A first step will be to set up a catalogue of biological resources and workshops starting 1Q2015.

By ensuring broad access to advanced, and in some cases unique and emerging methods and valuable reagents for use with high-quality biobank samples, we aim to promote scientific progress in academia, commercial application by biotechnology, diagnostic and pharmaceutical industries, and ultimately patient benefit in health care. Expected medical and exploitable benefits include the discovery of new disease biomarkers and drug targets through large-scale and or novel molecular technologies, in addition to a generally enhanced understanding of disease mechanisms.

6.2.3 Goals and Deliverables

Biobanking Analysis Resource Catalogue (BARCdb)

BARCdb, www.barcdb.org, is a freely available web resource, listing expertise and molecular resource capabilities of research centres and biotechnology companies. The database is designed to offer researchers information on how to make best use of valuable biospecimens from biobanks and other sample collections, focusing on the choice of analytical techniques and the demands they make on the type of samples, pre-analytical sample preparation, and on amounts of a sample needed. Service provider information is presented in the form of resource cards that summarise the services available and the contact details for potential users. Currently there are about 150 cards online, mostly relating to Swedish providers, but the coverage is

being extended to the whole of Europe. The providers who have agreed to make their resources available regularly update the information. The value of the catalogue lies in providing the information about where services can be obtained in a simple and readily accessible form; information that is not always easy to find.

BARCdb can help match resource providers with potential users, stimulating transnational collaborations, and ensuring compatibility of results from different labs. The database can promote more optimal use of valuable European biobank samples, both with respect to standard and more experimental technologies.

Aims:

1. To optimise interactions between providers of analytical resources and researchers who use biobank samples.
2. To provide up-to-date information about molecular technologies, reagents, commercial products, service facilities and contacts to technical experts for users of biobank services.
3. To assist with advice about how researchers can best make use of valuable samples, from preanalytical handling and sample preparation to the choice of analysis techniques and their providers, and what the requirements for the techniques are.
4. To offer advice in the planning for new sample collections to meet analytical possibilities and requirements of emerging technologies

In a further development the BARCdb database will be further developed in a number of ways, including:

- An improved design of the database to simplify webpage navigation
- Continuous expansion by inclusion of additional company and academic resources providing technologies and products for analysis of biobank samples in Europe. Collaboration has been initiated with relevant partners in other European countries
- Identification of reagent collections of value for biobank analyses
- A news section on the front page, including short articles describing technology and instrument developments that are provided by the various platforms, facilities and companies. The section will also include information on relevant courses and conferences
- A discussion forum where users can request as-yet-unavailable techniques for biobank analyses, to promote the development of new approaches and as a stimulus to technology developers
- Technology watch, summarising new and emerging resources for analysis
- Providing benchmarking reports that compare technologies in the different omics fields, which will serve as a guide for researchers to find the optimal tools for their research

<u>The Molecular Methods (MolMeth) database</u>

The aim of MolMeth is to render protocols and SOPs for collecting and using biobank material readily available in an open-access database and to provide a digital infrastructure for harmonisation of biobanking practices.

The resource is a publicly accessible database for laboratory protocols, including standardised methods and data storage recommendations for analysis of DNA, RNA, proteins and metabolites, applicable to biobank samples. It is a structured database created with the aim of providing best practice-based protocols for molecular analyses of different types of samples. Specific entries may be deposited identifying specific variants of methods used on specific occasions for particular sets of samples and with links to the data generated. Even though MolMeth is functional and open to the public, it remains under continuous development and expansion of protocols. Relevant items provided include:

- Standardised protocols for biobank sample processing
- Standardised protocols for molecular analysis of samples
- SOPs for sample handling
- Versioning and history system for protocols
- Opportunity for collaboration and sharing of methods between labs through password protected areas

Further development:

- Make a greater number of high quality laboratory protocols available to researchers.
- Create groups dedicated to specific research topics and knowledge sharing.
- Collaborate with provider companies to make it easier for researchers to compare commercial protocols using standardised formats
- Simplify harmonisation of assay procedures at different sites, in different expert centres and countries, for collaborative projects with a distributed analysis pipeline
- Improve search functions such as taxonomy searching and similar protocols.
- Make connections to biomolecular resources such as BARCdb, Antibodypedia, IntAct and others
- Make connections to commercial vendors and scientific publications, including as a source or supplementary on-line information.
- Create stronger connections to minimum information, ISO- and GxP-standards for reporting methods, and simplifying methods reporting in scientific publications
- Establish collaborations with biobanks to provide comprehensive coverage of protocols for all aspects of the Biobank process.

Training and Dissemination

Provide expert advice and guidance on a national level to researchers of relevant technologies, covering all omics fields, for analysis of biobank samples, and guidance for pre-analytical steps, such as sample collection and storage, as required for the intended analyses.

We propose to organise regular technology workshops, giving researchers insights into the different omics technologies and available resource providers.

6.2.4 Time Plan

Deliverable	01	02	03	04	05	06	07	08	09	10	11	12
BARCdb version 2.0												
BARCdb coverage in Europe												
First Workshop												
Second Workshop												

6.2.5 Priority

3. (This is a new Work Stream for 2015).

6.2.6 Project Group

DG, SPM, QUM, BBMRI.se

6.2.7 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0.5
SPM	0.5
QUM	1
total	2

6.3 Work Stream: Biobanking of Infectious Materials

6.3.1 Background

Biobanking of human biological samples containing pathogens or isolated pathogens falls under the scope of BBMRI-ERIC and was 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 special requirements in areas 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 so as to provide 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 includes, in addition to European partners, international partners like China, Russia, the USA and South Africa. Therefore EVA could give rise to 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 recognized 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; recognized high calibre, high quality of associated research; record of achievement in meeting targets; experience of working to standard protocols. EVA as a quality assured virus collection will have the important mission of providing this unique resource, resulting from the merging of well-established infrastructures existing in Europe, to serve science, the environmental and public health authorities and the needs of the pharmaceutical industry in developing new technologies for disease control, and to provide material for teaching and training purposes. The EVA consortium has submitted an application for further development of the network during September 2014. BBMRI-ERIC was not included as a participant, but the involvement of BBMRI-ERIC is planned once the application is funded. To prepare this cooperation a MoU was drafted between BBMRI-ERIC and Aix-Marseille University, the legal home of the Coordinator of EVA and will be signed later this year.

Short description of ERINHA: it 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 shall 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 shall promote the harmonization of biosafety and biosecurity procedures and will develop standards for the management of biological resources, diagnosis of group 4 pathogens, and training of BSL4 labs users. The Medical University of Graz participated on behalf of BBMRI in this preparatory project and was responsible for a task to identify collection holders of BSL4 and BSL3 labs. This report consists of four major parts: (1) an Inventory report on existing collection centres; (2) a Survey of sample processing within the centres identified; (3) a Derivation of a strategy based on the identified collection centres and common sample processing (from 2); and (4) a plan for Upgrades and inclusion of new centres.

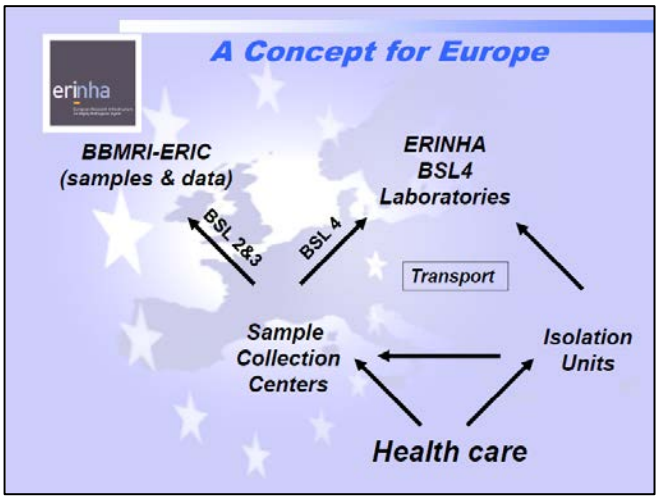

Figure 4: BBMRI-ERINHA: A Concept for Europe

6.3.2 Mission

The mission of this Work Stream is to develop, based on the contributions from working with ERINHA and EVA, a common strategy on how biobanks with infectious material shall be integrated into BBMRI-ERIC and how to make optimal use of such resources. One solution might be the establishment of a Common Service within this field.

Awaiting further specifications by Working Group 12: Infectious Diseases.

6.3.3 Goals and Deliverables

Awaiting further specifications by Working Group 12: Infectious Diseases.

6.3.4 Time Plan

Tentative time plan. To be further specified by the Working Group 12: Infectious Diseases.

Deliverable \ month of 2015	01	02	03	04	05	06	07	08	09	10	11	12
Working Group Meeting												
Specify interaction with ERINHA, EVA												
Define common strategy (esp. BSL-3)												

6.3.5 Priority

3. (This has been a part of Work Programme 2014, 3.5).

6.3.6 Project Group

SPM, PA

Working Group 12: Infectious Diseases.

6.3.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Months
SPM	0,5
PA	0,25
total	0,75

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7. WORK PLAN: EXPERT CENTRES

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

7.1.1 Background

Cutting-edge research as well as further innovations in the life science industry will strongly depend on implementing efficient and secure transnational access to high-quality human biological samples and associated medical information for academia and industry. Furthermore, human biological samples are a finite key resource subject to a series of ethical and legal restrictions thus requiring innovative solutions for efficient usage. Commercialisation of human biological sample and medical data is prohibited in the European Convention ETS164 and in national legislation of most Member States.

By performing the primary analysis of biological samples under internationally standardized 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 page 29f.) that are associated with BBMRI-ERIC.

7.1.2 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.

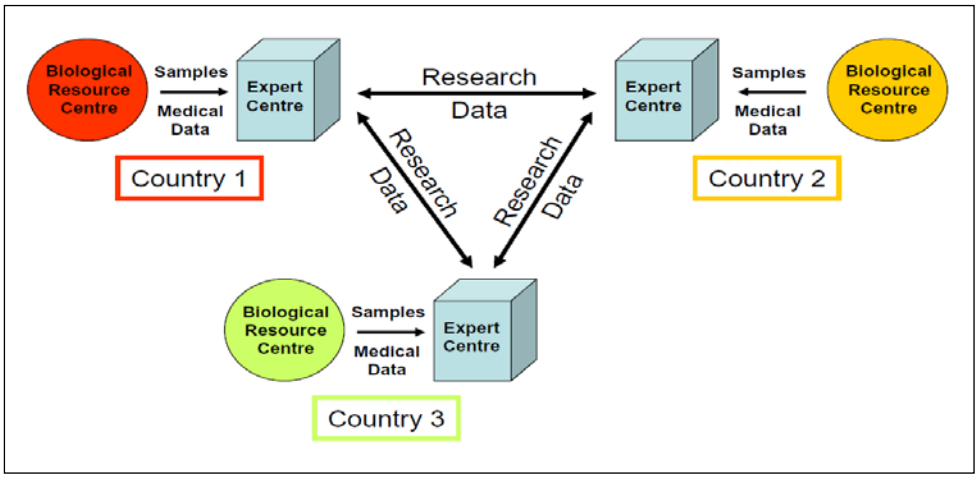

Figure 5: Expert Centres as New "Highways" for Transnational Research Collaborations

7.1.3 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 at an advanced stage 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 list of criteria for certification.

7.1.4 Time Plan

Deliverable \ month of 2015	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 finalized by the Q4 2014.

7.1.5 Priority

3. (This Work Stream is continued from the Work Programme 2014, 6.1).

7.1.6 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

7.1.7 Resources

HQ

Staff Function	Full Time Equivalent in Person Month
DG	0.5
AD	0.5
QUM	1
total	2

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BBMRI.nl

BBMRI.fr

8. BUDGET

The budget tables for 2015 are included in the separate document "Budget 2015" and provide full transparency for both estimated expenses as well as calculation for membership fees for 2015, 2016 and 2017.

	2014 expected (€)	**2014 Q 1-3 actual (€)**	**2015 expected (€)**	**2016 expected (€)**	**2017 expected (€)**
EARNINGS, total	1,544,682	**-326,598**	2,159,356	not yet available	
EXPENDITURES, total	-1,544,682	not yet available	-2,159,356	not yet available	

For the purpose of this version submitted to the 3rd Session of the AoM it is important to mention that 2 countries still have not yet paid (as of 28 October 2014) their annual contribution, namely France and Greece. With the French authority INSERM, an individual contract needed to be developed and was signed last week. For Greece, no explanation for the long delay has been received until now. 3 additional countries have not yet paid their 2nd instalment, namely Belgium, Malta, and Turkey. These sum of unpaid contributions is € 326,598. The budget tables of the other document AoM/3/5 include estimates of expenditures for the years 2016 and 2017 to provide the AoM members tools for planning of their budgets. Detailed justifications for all estimated expenses are provided.

The assumptions behind the proposed budget 2015 are as follows:

Two more countries will join before the end of 2014, namely the United Kingdom and Luxembourg. We have positive signals also form other countries, but have excluded the latter from our calculations as very likely they will joint only at a later stage (discussions are on going or in preparation with Croatia, Cyprus, Denmark, Ireland, Latvia, Portugal, Slovenia, Spain, and China). The other assumption is that Norway will have implemented the ERIC regulation into their National law by the end of this year and will therefore join as Member (not continue as Observer). Our latest information is that Poland has decided to upgrade to membership too and will send in the request before the AoM meeting in November. This version of the draft budget for 2015 has been altered again in response to the feedback of the MC meeting in Tartu and subsequent discussions in the FC and SC. Changes have been made primarily in the Common Services ELSI, IT and the Stakeholder Secretariat by dramatically reducing personnel costs. Also within the HQ, the two planned new Junior Project Managers positions have been deleted. The MC meeting in Helsinki has had an additional impact in the further amendment of the draft budget, taking into consideration that we will propose the start of the Common Service IT not before the 2nd half of 2015. This was necessary because the 2nd preparatory meeting on 15 September 2014 in Berlin showed that there is still too much uncertainty about funding blocks for IT coming from H2020 applications which are under evaluation right now and that a thorough preparation of the call for tender is necessary. Considering the necessity for a later start, the budget for the Common Service IT was again reduced in contrast to the latest draft provided to the MC. As all National Directors have clearly expressed the urgency for developing a solution for the update of the Biobank Catalogue as the major priority within BBMRI-ERIC, some resources of this reduction have been shifted towards HQs to allow buying in technical expertise to fulfil this request. After discussion in the SC, the appointment of a lawyer is again put on hold and is therefore postponed to 2016. Some minor amendments compared to the version submitted to the FC have been incorporated especially to recalculate reserves for the Common Services.

As a contingency plan in case the UK does not request membership, would we postpone the start of the Common Service IT to 2016. The reserved amounts are almost identical. In the event of another bigger country joining during early 2015, the start of the Common Service IT could again be brought forward to September 2015.

Given the shift in priorities, the overall expenses for 2015 for the HQ compared to 2014 is now slightly lower (now € 1,324,105 instead of € 1,340,479). This has been achieved by reducing the reserve to zero as the reserve of 2014 has not been fully used.

Of this budget, additional staff includes a half position for a Communication Assistant, for which the vacancy was advertised in September 2014. This is reflected by the higher demand for qualified communication activities both within the BBMRI family as well as outside. Maintaining the Intranet and contributing to internal communication activities are the main tasks of this new post. Because of the intranet responsibilities an outsourcing was not feasible.

The Common Services budget estimates are based on either the ELSI application – though reduced – or for the Common Services for IT and the Stakeholder Forum Secretariat, on the figures from the Business Plan.

From the € 344,626 requested funding for the ELSI Common Service as of the Budget proposal submitted to the FC (which excludes now the funding of additional experts in each Member States) the majority could be funded by in-kind contribution of personnel (€ 247,580) and through obligatory hosting contribution (€ 21,500). It is important to mention that this budget request does not represent the received application of the ELSI experts (which was much higher). This sum represents a draft budget designed by the HQ in order and on request of the MC and FC to keep expenses as low as possible and provide some core funding at the same time. It is furthermore important to bear in mind that additional funding for ELSI Common Services is requested in several applications currently under evaluation.

The figures for the Common Service IT, however, are based on the Business Plan. Moreover, they are drastically reduced relative to the version originally submitted, planning the start of the Common Service only in September 2015 (€ 272,615). As with the Common Service ELSI, the majority of expenses could be filled with in-kind contributions, particularly staffing at € 91,530 and obligatory contribution for renting and investment at € 125,000.

As shown in previous sections, a very large number of grant applications with BBMRI-ERIC participation had been submitted by 2 September 2014. BBMRI-ERIC is the primary recipient of funding within these applications (more than 3.6 Mio applied). Substantial sums are included for 3rd parties [National Nodes] but also for HQ.

In terms of earnings, the finally submitted draft budget 2015 of € 2,028,739 would be split into hosting country contributions of € 258,020 (this is for HQ in Graz, and the Common Services respectively) and a membership contribution of € 1,770,719 as can be seen in the tables of document AoM/3/5. This results in a slight increase of Membership fees ranging from € 53 for Malta up to € 250,024 for the United Kingdom as new member with previously 0 budget (0.1-0.2% increase in average).

BBMRI-ERIC has set up a series of internal regulations which are compiled in our Operations Handbook which has been approved and in place since 10 February of this year (latest version 1.4 approved on 2014/10/03). The basis for the travel policy was the need for a lean, easy to handle and economically sound system.

The subject of in-kind contributions was dealt with and the AoM approved the general principles in Rule 5 of the Financial Rules on Membership Contribution (Document AoM/1/7/Rev1). These principles allow staff secondment as one form of in-kind contribution. The Work Programme in its final version has to indicate where the HQ or a Common Service would allow such secondments and countries can apply for it. The valuation of such posts is given in the Work Programme, namely the budget figures associated with such staff positions

(all staff positions of the Common Services ELSI, IT and of the Stakeholder Forum Secretariat are open to in-kind contribution as discussed in detail above).

In case all expenses of personnel of Common Services ELSI, IT and the Stakeholder Forum Secretariat could be provided in kind, the cash contribution for Member States would be reduced by € 381,516 to € 1,389,203 (instead of € 1,770,719). This could reduce the cash contribution for some countries drastically, namely those hosting some of the Common Services.

Future priority on funding opportunities will be based on the approved Work Programme. In addition the Management Committee has set up Working Group 8: Financial Workflow, which is dealing with these issues. More details are provided in previous sections and a detailed table on all submitted applications can be found on the BBMRI-ERIC intranet (Working Group 01 - H2020/Overview On going calls H2020/Documents). Any prioritisation suggested by the Working Group has to follow (1) the legal obligations set out in the Statutes, (2) the approved objectives of the annual Work Programmes and (3) any other needs discussed and recommended. The Working Group has taken up as its main task to develop a strategy ensuring its implementation.

ANNEX

Table 1: Working Groups

Working Group 1: H2020 / Chair: Prof. Maria Luisa Lavitrano, BBMRI.it
Working Group 2**: Partner Charter / Chair: Prof. Anu Jalanko, BBMRI.fi* **- *completed
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: MSc Markus Pasterk, BBMRI-ERIC.eu
Working Group 9: Rare Diseases / Chair: Dr. Luca Sangiorgi, Italian Delegate AoM
Working Group 10: Journal Proposal / Chair: Dr. Georges Dagher, BBMRI.fr
Working Group 11: Archived Tissue / Chair: Prof. Kurt Zatloukal, BBMRI.at; Prof. Giorgio Stanta, BBMRI.it
Working Group 12: Infectious Diseases / Chair: Dr. Sissy Kolyva, BBMRI.gr

Table 2: HQ Person Months Distribution

Legend: Director General (DG), Administrative Director (DG), Senior Project Manager (SPM), IT Manager (ITM), Project and Finance Assistant (PA), Secretary/Receptionist (SEC), Communication Assistant (COM).
Note: This table highlights the Person Months allocated to specific Work Streams. The light blue colouring highlights the Work Streams specified in the Work Programme 2015.
Blank cells indicate continued Work Streams from 2014, such as running the Central Executive Management Office (CEMO).

WS 2015	WS 2014	DG	D	SPM	ITM	QUM	PA	SEC	COM	PM Sub-total	WS 2015 specified
New Gateway/Catalogue	7.1 Biobank Catalogue	5	2,5	2	8	1	1			19,5	new/specified WS
2.1 QMS	5.1 QMS	0,5	0,5			4				5	new/specified WS
2.2 Self Evaluation	5.3 Self Evaluation					1				1	new/specified WS
2.3 BRIF			0,5			2	0,25			2,75	new/specified WS
2.4 Approval			2				0,25			2,25	new/specified WS
2.5 Biobank Lexicon	8.2 Lexicon	0,25		0,25	0,5	0,5				1,5	new/specified WS
3.1. Clin Bio				0,25	0,5	1,5	0,25			2,5	new/specified WS
4.1 BBMRI-LPC		0,25		1						1,25	new/specified WS
5.1 Retreat	2.5 Retreat	0,25		0,5			0,25			1	new/specified WS
5.2 HandsOn: Biobanks	2.1 HandsOn	0,25		1			0,5			1,75	new/specified WS
5.3 E&T	2.4 Education		2				1			3	new/specified WS
6.1 Rare Diseases	3.3 CS RD		0,5				0,25			0,75	continued WS
6.2 BARC		0,5		0,5		1				2	new/specified WS
6.3 Inf Mat	3.5 EVA			0,5			0,25			0,75	continued WS
7.1 Expert Centre	6.1 Expert Centre	0,5	0,5			1				2	new/specified WS

WS 2015	WS 2014	DG	AD	SPM	ITM	QUM	PA	SEC	COM	PM Sub-total	WS 2015 specified
	1.1 CEMO	0,25	1	1	1		1,5	11		15,75	continued WS
	2.2 Communi-cation	0,5		1			1	1	5	8,5	continued WS
	2.3 Stakeholder	0,25	0,5							0,75	continued WS
	2.6 Webinars	0		0,25			0,25			0,5	continued WS
	2.7 Newsletter			0,25			0,25		1	1,5	continued WS
	3.1 CS ELSI	0,5	0,5	1						2	continued WS
	3.2 CS IT	1			1					2	continued WS
	3.4 CS SFS	0,5	0,5	0,5						1,5	continued WS
	4.1 Fundraising	1	1	2			5			9	continued WS
	5.2 Partner Charter		*0*							*0*	*completed*
	7.2 BioBank Cloud	0,25			0,5					0,75	continued WS
	7.3 CoBiBa	0,25			0,5					0,75	continued WS
	8.1 MIABIS									0	included in WS 1.1
Total 2015		**12**	**12**	**12**	**12**	**12**	**12**	**12**	**6**	**90**	

Figure 6: Distribution of Person Months per Work Plan (pie chart)

The distribution of Person Months (PM) is indicated in the number of PM allocated for a task. This chart is not reflecting the actual costs allocated for the Work Plans as the costs of 1 PM for a senior staff differs from the costs of 1 PM for junior staff. Support activities include, for instance, all PMs for the secretarial support of the HQ. Thus, all PMs indicated under support activities have not been added to one specific Work Plan as they are to be understood supporting the goals of all WSs.

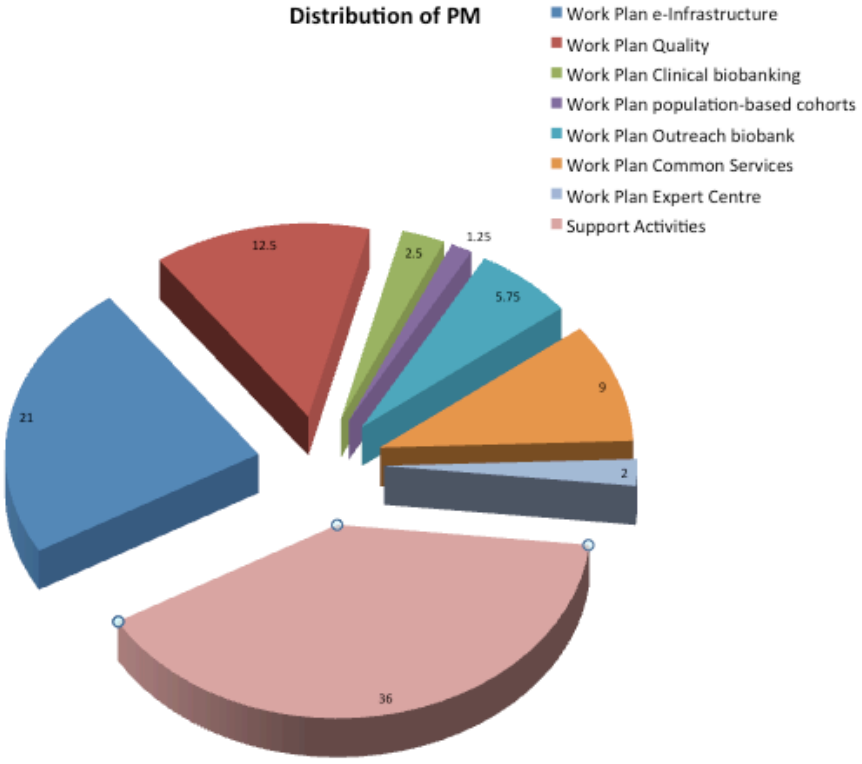

Figure 7: Distribution of Person Months per Work Plan

WS 2015	DG	AD	SPM	ITM	QUM	F/PA	SEC	COM	PM Subtotal
Work Plan e-Infrastructure	5,5	2,5	2	9	1	1	0	0	21
Work Plan Quality	0,75	3	0,25	0,5	7,5	0,5	0	0	12,5
Work Plan Clinical biobanking	0	0	0,25	0,5	1,5	0,25	0	0	2,5
Work Plan population-based cohorts	0,25	0	1	0	0	0	0	0	1,25
Work Plan Outreach biobank	0,5	2	1,5	0	0	1,75	0	0	5,75
Work Plan Common Services	2,5	1,5	2,5	1	1	0,5	0	0	9
Work Plan Expert Centre	0,5	0,5	0	0	1	0	0	0	2
Support Activities	2	2,5	4,5	1	0	8	12	6	36
Total in 2015	12	12	12	12	12	12	12	6	90

AMENDMENT 2015/1

AMENDMENT TO THE PRIORITISATION OF WORK STREAMS 2015

The following prioritisation changes of WSs of the Core Work Programme 2015 V2.0 were agreed during the MC#7 Meeting in Vienna on 15-16 December 2014.

Nr.	Work Stream 2015	Priority	WS Specification
1.1	A New Gateway for European Biobanks Priority 1 (This WS was included in the WP 2014; 7.1	1	specified
2.1	Quality Management System (QMS)	1	specified
2.2	Self-Evaluation	2	specified
2.3	Implementation of BRIF	2	new/specified
2.4	Development of a BBMRI-ERIC Approval Process	2	new
3.1	Clinical Biobanks	1	new
4.1	BBMRI-LPC	1	new
5.1	Scientific Retreat	1	specified
5.2	HandsOn Biobanks	2	specified
5.3	Education & Training	3	specified
6.1	Rare Diseases	2	specified
6.2	Biological Resources	3	new
6.3	Infectious Materials	3	specified
7.1	Expert Centres	2	specified

AMENDMENT TO WORK STREAM: COMMON SERVICE ELSI

Continued WS 3.1 Work Programme 2014

Background

According to the BBMRI-ERIC Statutes (Art.3, paragraph 4) the activities of BBMRI-ERIC shall be politically neutral and guided by the following values: pan-European in scope, combined with scientific excellence, transparency, openness, responsiveness, ethical awareness, legal compliance, and human values. The Common Service ELSI will function according to these values. In addition, a broad participation from all European Countries and the assurance that the work is deeply rooted within the different national socio-cultural and legal contexts are considered essential.

During a preparatory meeting in Toulouse in March 2014, the representatives of ELSI experts within BBMRI-ERIC National Nodes and Observer Countries or organisations have expressed their willingness for actively participating in the building of the Common Service ELSI taking into account the BBMRI Preparatory Phase ELSI domain achievements and other relevant expertise. There are common regulatory frameworks internationally and in the EU to take into consideration in biobanking especially for data protection and database aspects; but for sample exchanges for research and research biobanking operations, each Country has its own legislations and no specific EU level legislation applies. Legal expertise is thus essential in the various Countries involved, and will be essential as well for the Common Service ELSI to address the relevant EU and international level dimension for applicable or ongoing legislation and regulations. For the ethical aspects of biobanking the role and work of different national authorities and research ethics committees are strong elements and mandatory procedures exist in each Country that need to be respected. BBMRI-ERIC will have to respect the different national legislative frameworks that together with common European legislations and directives provide the legal basis for carrying out collaborative research as well as the European Commission research ethics framework. After this meeting the steps towards the establishment of the Common Service ELSI was a call for tender and selection process in 2014[2] leading to the approval of BBMRI-ERIC's Assembly of Members in November 2014 and detailed definition and hierarchy of tasks at MC#7 in December 2014. The service started its operations on Feb. 1, 2015. The Common Service ELSI is co-directed by Anne Cambon-Thomsen, Marialuisa Lavitrano, Mats Hansson and Jasper Bovenberg.

Mission

- According to the call for tender and taking into account the remarks of reviewers, AoM and MC the missions are formulated as follows:
- Ethics check mission: for research proposals submitted to BBMRI-ERIC
- Monitoring mission: based on state of the art and relevant ethical and legal frameworks
- Policy mission: follow up relevant evolution and coordinate answers to relevant public consultations and other possible intervention
- Advising mission: build conclusions and advise (solidly based)
- Help-desk mission: provide updated background information and practical guidance especially in relation to the exchange of human samples and data for research use

[2] http://www.bbmri-eric.eu/web/guest/callsvacancies

- Dissemination mission: disseminate results of relevant surveys and studies
- Tools oriented mission: organize tools and services (existing or new tools)
- Experience sharing mission: organize sharing between BBMRI-ERIC members
- Education mission: set up training and education on relevant ELSI matters

Goals and Deliverables for 2015

The priorities done for 2015 are:

- Prepare & circulate Ethics-check draft template
- Establish procedure how to screen public circulation documents (limit to CoE and European Union)
- Update BBMRI-ERIC Website section for CS ELSI
- Include ELSI news & relevant meetings in monthly mailchimp news service & website
- Set up Intranet section for CS ELSI
- Dissemination: attract further ELSI experts

The deliverables are indicated in the table below.

Time Plan

Task	Task Name	Deliv Id	Deliverable Name	Deliv type	when ?	how ? / where ?	by whom ?
1	Ethics check - Organisation of the expert network, advice function and help desk	**D1**	Criteria	int doc	M3-M7	Consultation + Website	A Cambon-Thomsen + all
		D2	Procedures	int doc	M5-M8	Consultation + Website	A Cambon-Thomsen + all
		D3	Report devices + Annual report	int doc	M5-M12 (M36)	report to General Director	A Cambon-Thomsen + all
		D10	MoU with relevant international organisations	ext doc	M13-M18	meetings+Email	J Bovenberg
		D11	Planned certification ISO 9001	int doc	M13-M24	planning and audit	A Cambon-Thomsen + G Chassang + QM
2	Follow up of legal, regulatory, ethics framework evolution at European/international level	**D4a**	Procedure to follow public consultations and policy documents	int doc	M2-M6	network+Website	A Cambon-Thomsen + M Lavitrano
		D4b	Procedure to enhance public debate	int doc	M13-M18	network+Website	M Lavitrano
3	Implementation of the experience sharing mission	**D12**	Internet work room (for ELSI internal meetings)	meeting	M18	IT	A Cambon-Thomsen
		D5	Annual Workshop (Focus 2015 : Data protection and access)	meeting	M7	meeting	M Hansson + M Lavitrano
4	Implementation of the dissemination action	**D6a** **D6b**	Website (simple 1st year; elaborated later)	tool	M6 - ...	Website	A Cambon-Thomsen + IT
		D7a **D7b**	Newsletter (1-2/year, 1st year; 4/year later)	tool	M6 - M12 -...	Email+post+Website	A Cambon-Thomsen
5	Implementation of the specific tool oriented mission	**D8**	Editorial board of the wiki legal platform	network	M7-M8	Web-meeting	J Bovenberg
		D9	Network of legal experts for the tool www.hsern.eu	network	M7-M9	network+IT	G Chassang
		D13	List of ethics tools & user guide	ext doc	M13-M18	Website	Germany
		D14	List of society oriented tools shared & use guide	ext doc	M7-M24	Website	M Lavitrano
6	Implementation of the education mission	**D15**	List of events (*participation to events & training courses*)	int doc	M36	Website	M Hansson + M Lavitrano

Project Group

(Total estimated for 2015: 3,5 FTE)

At the start of the Common Service the following team is in place or envisaged. Some countries still need to identify the expert(s) to be involved. When still to be specified, 12,5% involvement was assumed. Table below reflects status as of 9 March 2015.

Name	Country	Scale of Employment (%)
Cambon-Thomsen Anne	France (Dir)	25
Chassang Gauthier	France (expert)	43,8
Sanchez Albor Maria del Rosario	France (Secretary)	43,8
Policar Radek	Czech Republic (Expert)	12,5
Hansson Mats G	Sweden (Co-Dir)	12,5
Kindström Moa	Sweden (expert)	19,8
Howard Heidi	Sweden (expert)	19,8
N.N.	Greece	12,5
Martin Gillian	Malta (expert)	12,5
Durnova Anna P	Austria (expert)	12,5
Southerington Tom	Finland (expert)	12,5
Lõuk Kristi	Estonia (expert)	12,5
Bovenberg Jasper	Netherlands (Co-Dir)	12,5
N.N.	Netherlands (assitant)	39,6
Schlünder Irene	Germany (expert)	33,0
Lavitrano Marialuisa	Italy (Co-Dir)	12,5
Casati Sara	Italy (expert)	39,6
N.N.	Belgium (expert)	12,5

The expertise is distributed between law, ethics and social sciences.

Priority

1.

Resources

The agreed budget for 2015 is 344 626 €. The detailed budget is in the Table below.

	Coordinator // Codirectors	Lawyer	Post doc	Assistant	Secretary	ELSI expert in each Member country	TOTAL
Salaries per year							**266 257,50**
total costs (based on real employment)	60 350,00	55 689,88	27 463,31	47 770,75	17 615,06	57 368,50	266 257,50
expenditures in Year 1	60 350,00	55 689,88	27 463,31	47 770,75	17 615,06	57 368,50	266 257,50
Fringe benefits							**1 799,82**
private health insurance							
legal settlement on dissmissal (1,53%)	0,00	191,19	0,00	730,89	0,00	877,74	1 799,82
relocation grant							
education grant (75% of real expenses with limit)							
travel grant (1 air ticket per year)							
first month accomodation							
Investment							**11 677,50**
furniture	500,00	892,50	395,83	791,67	437,50	875,00	3 892,50
IT infrastructure	1 000,00	1 785,00	791,67	1 583,33	875,00	1 750,00	7 785,00
Rent							**3 892,50**
office							

recurrent renting costs							
contents insurance office							
internet/phone	500,00	892,50	395,83	791,67	437,50	875,00	3 892,50
Consumables							**1 750,00**
Marketing (dissemination) material							**1 000,00**
other material							
Travel							**21 750,00**
to meetings in Europe							15 000,00
when co-direction (1 pers a year)							3 000,00
Experts from observer members							0,00
Presentation of ELSI services in external meetings							3 750,00
Workshops							**7 500,00**
1 WS p.a. (travel & subsistence for 5 external experts + meeting organization)							7 500,00
Outsourcing Services & Consulting							**4 680,00**
review in place (16 a year; €450/day)							3 600,00
remote review (20 a year; €90/project)							1 080,00
Sous-TOTAL							320 307,32
Reserve / Miscellaneous (complement to 344 626, between 7.5% and 7.6%)							24 318,68
TOTAL							**344 626,00**

AMENDMENT TO WORK STREAM: FUND RAISING EFFORTS

Continued WS 4.1 of Work Programme 2014

H2020

ADOPT BBMRI-ERIC

Topic: H2020-INFRADEV-3-2015 **Type of Action:** RIA **Duration:** 36 months
Total requested Grant by Consortium: € 4.950.860,00
Total requested Grant by BBMRI-ERIC: € 3.786.840,00 (Common Service ELSI, Common Service IT)
Assigned linked 3rd Parties/BBMRI-ERIC Framework Agreement:
(1) BBMRI.at/MUG; (2) BBMRI.fi/THL; (3)BBMRI.mt/UoM; (4)BBMRI.it/UNIMIB
Benefit/tasks for BBMRI-ERIC: Coordinated by BBMRI-ERIC
Status: score 12 (threshold 10) / accepted

Abstract: BBMRI-ERIC: the Biobanking and BioMolecular resources Research Infrastructure - European Research Infrastructure Consortium, aims to establish, operate and develop a Pan-European distributed research infrastructure in order to facilitate the access to biological resources as well as facilities and to support high quality biomolecular and biomedical research. The ADOPT BBMRI-ERIC proposal aims at boosting and accelerating implementation of BBMRI-ERIC and its services. Its main deliverables are designed to complete or launch the construction of key Common Services of the Research Infrastructure as required for ESFRI-projects "under implementation", reflecting the targets of the European Research Area (ERA). One of the challenges in the post-genomic era is the research on common complex diseases, such as cancer, diabetes and Alzheimer's disease. Revealing these diseases will depend critically on the study of human biological samples and data from large numbers of patients and healthy individuals. The EU's ageing population is will result in an increase in many of those diseases and consequently an increased healthcare expenditure for senior citizens. BBMRI-ERIC is a specific European asset having become a fundamental component in addressing the ongoing and future requirements particularly of Europe's health service frameworks, including competitiveness and innovativeness of health- related industries. Its implementation is essential for the understanding of the diversity of human diseases, biological samples and corresponding data, which are required for the development of any new drug or diagnostic assay and are, therefore, critical for the advancement in health research, ultimately leading to personalised medicine. BBMRI-ERIC will provide a gateway access to the collections of the European research community, expertise and services building on the outcome of ADOPT BBMRI-ERIC.

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

B3AFRICA

Topic: INFRASUPP-6-2014 **Type of Action:** CSA **Duration:** 36 months

Total requested Grant by Consortium: € 201.250,00

Total requested Grant by BBMRI-ERIC: € 70.000,00

Assigned linked 3rd Parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: contacts to Africa

Status: score 13 (threshold 10) / accepted

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

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

RITRAIN

Topic: H2020 INFRASUPP-3 **Type of Action:** RIA **Duration:** 48 months

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

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

Assigned linked 3rd Parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: Coordinated by BBMRI-ERIC

Definition of required competences in distributed RIs throughout the lifecycle of an RI, from the initiation preparatory phase through to operational maturity.

Status: score 11,5 (threshold 10) / accepted

Abstract: The overarching goal of RItrain is to identify the competency requirements for the leadership of European research infrastructures (RI) and design a training programme to fulfil these requirements. Our highest priority is those professionals who are already working in research infrastructures, including directors, coordinators, senior project managers, legal representatives, heads of Finance and HR, and heads of communication. However, by designing a flexible, modular programme, we will also be able to provide a new qualification aimed at future leaders of research infrastructure – the Master in Research Infrastructure leadership.

Another important consideration is that many RIs, including the new ESFRI (European Strategy Forum on Research Infrastructures) RIs have a distributed operations structure, building on existing RIs or networks of RIs. These RIs therefore require a different set of unique competences to deal with issues such as multinational operations, transnational access and data flow; different social security systems, different administrative cultures, different legal systems etc. They face those challenges that the European Commission (EC) has identified as roadblocks for the establishment of the European Research Area: (i) increased effectiveness of national research systems, (ii) improved trans-national cooperation and competition including establishing and effectively operating key research infrastructures, (iii) a more open labour market for researchers, (iv) gender equality and mainstreaming in organisations carrying out and selecting research projects and (v) optimal circulation and transfer of scientific information, including via digital means and broader and more rapid access to scientific publications and data.

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

CY BIOBANK

Topic: H2020-WIDESPREAD-2014-1 **Type of Action:** FPA-SGA **Duration:** 12 months

Total requested Grant by Consortium: € 460,637.50

Total requested Grant by BBMRI-ERIC: € 64,475.00 (4PM BBMRI-ERIC)

Assigned linked 3rd Parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC:

WP5: Standards, ELSI Compliance and Data Management ; T5.1: Standards/Procedures Adoption & Quality Processes; T5.2: ELSI Compliance; T5.3: Data Management Plan (raw data availability and Gold access policy); Deliverable T5.1-D5.1, T5.2-D5.2, T5.3-D5.3

Status: score 13 (threshold 10) / accepted

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

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

PHENOMENAL

Topic: H2020 -EINFRA-1-2014 **Type of Action:** RIA **Duration:** 36 months

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

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

Assigned linked 3rd Parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: proposal trying to organize the metabolomics community at the European level, and we are keen to do it in full synergy with BBMRI.

Status: score 13 (threshold 10) / accepted

Abstract: During the next 10 years, a significant number of the a significant number of the 742.000.000 European citizens will have their genome determined routinely. This will be complemented with much cheaper measurement of the metabolome of biofluids which will link the genotype with data on the exposome of patients, which for the first time enables the development of a truly personalised and hand tailored medicine based on hard scientific measurement.

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

EGI-ENGAGE

Topic: H2020 EGI-EINFRA-1-6 **Type of Action:** RIA **Duration:** 30 months

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

Total requested Grant by BBMRI-ERIC: € 128,550.00

Assigned linked 3rd Parties/BBMRI-ERIC Framework Agreement: BBMRI.cz, BBMRI.se, BBMRI.nl

Benefit/tasks for BBMRI-ERIC:

WP1: Technology exchange, outreach, training and support with the following deliverables T1.1: Support and outreach to the user community T1.3: Coordination.

Status: accepted

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

List of Participants: Stichting European Grid Initiative, Oesterreichische Akademie der Wissenschaften, Vlaams Instituut voor de Zee VZW, Institute of Information and Communication Technologies, - Bulgarian Academy of Sciences, Swiss National Grid Association, CESNET, Zajmove Sdruzeni Pravnickych OSOB, Fraunhofer-Gesellschaft zur Foerderung der Angew Andten Forschung E.V, Gesellschaft fur Wissenschaftliche Datenverarbeitung MBH Gottingen, Agnecia Estatal Consejo Superior de Investigaciones Cientificas, CSC-Tieteen Tietotekniikan Keskus Oy, Centre Nationale de la Recherche Scientifique, Institut National de la Recherche Agronomique, The Greek Research and Technology Network S.A., Sveuciliste u Zagrebu Sveučilišni Računski Centar, Magyar Tudomanyos Akademia Szamitastechnikai es Automatizalasi Kutatointezet, Istituto Nazionale di Fisica Nucleare, Consorzio Interuniversitario Risonanze Magnetiche di Metallo Proteine, Provincia Lombardo Veneta Ordine Ospedaliero di San Giovanni di Dio - Fatebenefratelli, Consiglio Nazionale delle Ricerche, Engineering – Ingegneria Informatica SpA, SURFsara B.V, Akademia Górniczo-Hutnicza im. Stanisława Staszica – Academic Computer Centre CYFRONET AGH, Laboratorio de Instrumentacao e Fisica Experimental de Particulas, ICETA - Instituto de Ciências e Tecnologias Agrárias e Agro-Alimentares, Institut za Fiziku, Beograd, Uppsala Universitet - Swedish National Infrastructure for Computing, Ustav Informatiky, Slovenska Akademia Vied, Turkiye Bilimsel ve Teknolojik Arastirma Kurumu, Science and Technology Facilities Council, Biobanking and BioMolecular Resources Research Infrastructure - European Research Infrastructure Consortium, European Molecular Biology Laboratory, European Organisation for Nuclear Research, EISCAT Scientific Association, Food and Agriculture Organisation of the United Nations, Agro-Know I.K.E, Maat France SARL, The Trustees of Indiana University, Academia Sinica, Advance Science and Technology Institute, Institut Teknologi Bandung BHMN, Korea Institute of Science and Technology Information, Universiti Putra Malaysia, National Science & Technology Development Agency

CORBEL

Topic: H2020 INFRADEV-4 **Type of Action:** RIA **Duration:** 48 months

Total requested Grant by Consortium: € 14.000.000,00

Total requested Grant by BBMRI-ERIC: € 1.900.093,00 (including 3rd party)

Assigned 3rd Parties/BBMRI-ERIC Framework Agreement:

(1) bbmri.nl /LUMC, LEIDEN, ERASMUS MC & GRONINGEN: € 454.340,08
(2) bbmri.fi /THL: € 80.500,00
(3) bbmri.no /NIPH,NTNU: € 80.500,00
(4) bbmri.ee /UTARTU: € 80.500,00
(5) bbmri.at /MUG: € 177.850,00
Benefit/tasks for BBMRI-ERIC: Co-Coordinated by BBMRI-ERIC
WP3: case studies (national nodes) WP7: ELSI
WP9: Training and case studies (WP3-4)

Status: score 11 (treshold 10) / accepted

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

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

FP7/IMI

EMTRAIN

Topic: FP7/2007-2013 **Type of Action:** IMI **Duration:** 01/10/2009-30/09/2016

BBMRI-ERIC full partner: as of 01/10/2014

Grant Agreement Nr: 115015 **Web**: http://www.emtrain.eu/

Total requested Grant by Consortium: € 4.000.000,00

Total requested Grant by BBMRI-ERIC: € 9.754,45

Assigned linked 3rd Parties/BBMRI-ERIC Framework Agreement: no

Benefit/tasks for BBMRI-ERIC:

Education & training platform, IMI.

Status: GA amended, BBMRI-ERIC included as full partner

Abstract: EMTRAIN will establish a pan-European platform for education and training covering the whole lifecycle of medicines from basic research through clinical development to pharmaco-vigilance. The public consortium consists of the six pan-European biomedical research infrastructures from the ESFRI roadmap, that cover a broad spectrum of competencies from molecules to humans, with a pan-European dimension. The EFPIA consortium has considerable experience in training and education, management,pan-European geographical outreach, and an extensive external network of contacts.The participants, together with the coordinators of IMI&T topics will participate in the Strategic Co-ordination Board to ensure coordination between the IMI&T topics whereas the Steering Committee will supervise the management of the project. E&T topics representatives will be invited to participate in work packages activities. Based on extensive mapping of existing resources and on a gap and overlap analysis (WP3) the consortium will develop and implement a strategy for harmonisation and accreditation (WP4) of Master level WP5) and PhD programmes (WP6) as well as continuous education programmes (WP7). It will develop innovative concepts and methods in conjunction with the other topics (WP8) that will support the content for the IMI education programmes. National implementation will be facilitated through contacts with university authorities, ministries of higher education, and through national liaison offices. After implementation in a core group of institutions, extension is planned both within countries represented and in additional countries (WP4) , with the support of a dissemination and communication activity (WP9) The harmonisation and the modular nature of these programmes will allow trans-disciplinary curricula as well as trans-border mobility, and PhD programmes will be designed to foster industry/academia mobility and collaboration.

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

BIOMEDBRIDGES

Topic: FP7 INFRA-2011-2.3.2 **Type of Action:** CP-CSA Infra **Duration:**01/01/2012-31/12/2015

BBMRI-ERIC full partner: as of 01/10/2014

Grant Agreement Nr: 284209 **Web**: http://www.biomedbridges.eu/

Total requested Grant by Consortium: € 10.494.998,69

Total requested Grant by BBMRI-ERIC: € 8.400,00

Assigned linked 3rd Parties/BBMRI-ERIC Framework Agreement: no

Benefit/tasks for BBMRI-ERIC: Connecting BMS RIs

Status: BBMRI-ERIC added as new participant through amendment to GA

Abstract: BioMedBridges will form a cluster of the emerging biomedical sciences research infrastructures (BMS RIs) and construct the data and service bridges needed to connect them.

- The BMS RIs are on the ESFRI roadmap
- The missions of the BMS RIs stretch from structural biology of specific biomolecules to clinical trials involving thousands of human patients
- Most serve a specific part of the vast biological and medical research community, estimated to be at least two million scientists in Europe across more than 1000 institutions from more than 36 ESFRI Member States and Associated Countries
- Each of them brings together its own large community of users to build a coordinated infrastructure. This process has already had a major impact on coordination of national infrastructures within each member state
- Essentially all BMS RIs are distributed infrastructures, with nodes in many European member states

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

ANNEX

Table 3: HQ Person Months Distribution Amended

Legend: Director General (DG), Administrative Director (AD), Senior Project Manager (SPM), Senior IT/Data Protection Manager (ITM), Quality Manager (QUM) Finance and Project Assistant (F/PA), Secretary/Receptionist (SEC), Communication Assistant (COM).

Note: This table highlights the Person Months allocated to specific WSs. The light blue colouring highlights the WSs specified in the Work Programme 2015. Those left blank indicate continued WSs from 2014, such as running the Central Executive Management Office (CEMO).

WS 2015	WS 2014	DG	AD	SPM	ITM	QUM	F/PA	SEC	COM	PM Subtotal	WS 2015 specified
1.1 New Gateway/Catalogue	7.1 Biobank Catalogue	5	2,5	2	8	1	1			19,5	new/specified WS
2.1 QMS	5.1 QMS	0,5	0,5			4				5	new/specified WS
2.2 Self Evaluation	5.3 Self Evaluation					1				1	new/specified WS
2.3 BRIF			0,5			2	0,25			2,75	new/specified WS
2.4 Approval			2				0,25			2,25	new/specified WS
2.5 Biobank Lexicon	8.2 Lexicon	0,25		0,25	0,5	0,5				1,5	new/specified WS

WS 2015	WS 2014	DG	AD	SPM	ITM	QUM	F/PA	SEC	COM	PM Subtotal	WS 2015 specified
3.1. Clin Bio				0,25	0,5	1,5	0,25			2,5	new/specified WS
4.1 BBMRI-LPC		0,25		1						1,25	new/specified WS
5.1 Retreat	2.5 Retreat	0,25		0,5			0,25			1	new/specified WS
5.2 HandsOn:Biobanks	2.1 HandsOn	0,25		1			0,5			1,75	new/specified WS
5.3 E&T	2.4 Education		2				1			3	new/specified WS
6.1 Rare Diseases	3.3 CS RD		0,5				0,25			0,75	continued WS
6.2 BARC		0,5		0,5		1				2	new/specified WS
6.3 Inf Mat	3.5 EVA			0,5			0,25			0,75	continued WS
7.1 Expert Centre	6.1 Expert Centre	0,5	0,5			1				2	new/specified WS

WS 2015	WS 2014	DG	AD	SPM	ITM	QUM	F/PA	SEC	COM	PM Subtotal	WS 2015 specified
	1.1 CEMO	0,25	1	1	1		1,5	11		15,75	continued WS
	2.2 Communication	0,5		1			1	1	5	8,5	continued WS
	2.3 Stakeholder	0,25	0,5							0,75	continued WS
	2.6 Webinars	0		0,25			0,25			0,5	continued WS
	2.7 Newsletter			0,25			0,25		1	1,5	continued WS
	3.1 CS ELSI	0,5	0,5	1						2	continued WS
	3.2 CS IT	1			1					2	continued WS
	3.4 CS SFS	0,5	0,5	0,5						1,5	continued WS
	4.1 Fundraising	1	1	2			5			9	continued WS
	5.2 Partner Charter		*0*							*0*	*completed*
	7.2 BioBankCloud	0,25			0,5					0,75	continued WS
	7.3 CoBiBa	0,25			0,5					0,75	continued WS
	8.1 MIABIS									0	included in WS 1.1
Total 2015		**12**	**12**	**12**	**12**	**12**	**12**	**12**	**6**	**90**	

Photo: elasfreiberger.at