

BBMRI-ERIC

Biobanking and
BioMolecular resources
Research Infrastructure

WORK PROGRAMME 2016

CORE WORK PROGRAMME 2016

EXECUTIVE SUMMARY OF THE WORK PROGRAMME 2016

On 27 October 2015 in its 5th Session, the Assembly of Members adopted the *Work Programme 2016*. The ultimate goal of BBMRI-ERIC is to facilitate access to biological resources as well as biomedical facilities and to support high-quality biomolecular and medical research. The Work Programme 2016 and Budget are aligned with these objectives.

Structure

The Work Programme 2016 follows the overall structure of previous Work Programmes. It has 10 distinct Work Plans and 26 Work Streams which are divided in the following subsections: background; mission; goals and deliverables; time plan; project group; and resources.

Priorities and their realisation

The Work Programme 2016 aims at realising the following key priorities:

Building an e-infrastructure - Common Service IT: BBMRI-ERIC continues its activities along the developments set in motion in 2015 when several major objectives already set out the basis for the e-infrastructure and provided the operational and sustainable maturity for its IT infrastructure. The first upgrade of the BBMRI-ERIC Catalogue – the Directory 1.0 – was launched in July 2015. It allows users to explore the e-infrastructure of BBMRI-ERIC, provides contact information to communicate with biobanks and helps to identify biobanks of interest based on available sample and data types. Directory 2.0 was released in November with full support for non-overlapping collections embedded in biobanks and biobank networks. To date, the Directory 2.0 includes 515 biobanks in its portfolio. Setting up the BBMRI-ERIC Common Service IT (CS IT) has been a critical activity in 2015. In the coming years, it will act as a sustainable development and operations platform for IT services of BBMRI-ERIC.

In 2016, the CS IT will focus on delivering the updated Directory 3.0 with support for capabilities of biobanks and semantic enhancements, Sample/Data Negotiator 1.0 for facilitating access to the samples and data stored in the biobanks, as well as early development of Sample Locator and Data Harmonisation tools. Another important component is the user forum, which also includes work on refinement of the use case and evaluation of tools already in operation. Last but not least, CS IT will deliver the first versions of reference tools for biobanks and National Nodes, as harmonisation of biobank IT infrastructure and support of biobanks or National Nodes that lack some IT components is a very important aspect of overall BBMRI-ERIC infrastructure. A substantial part of the development will be funded through ADOPT BBMRI-ERIC H2020 project.

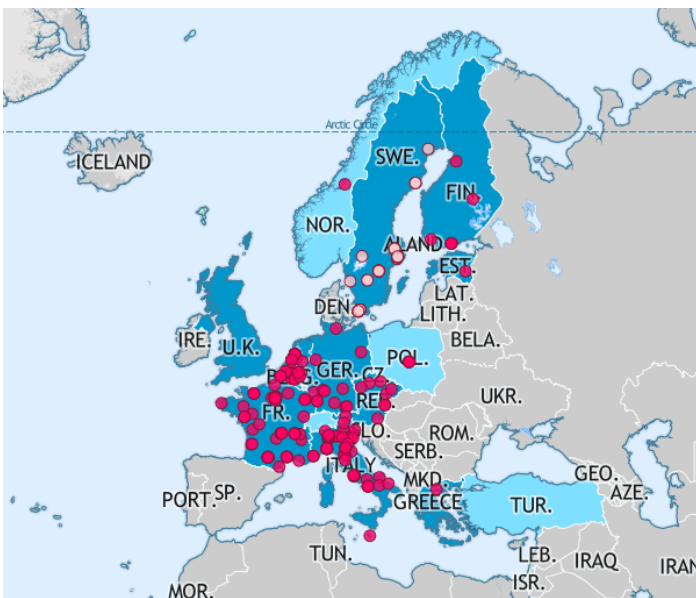


Figure 1: Directory 2.0

The Directory 2.0 is the first service in the portfolio of BBMRI-ERIC's IT tools to be delivered during years 2015-2017. At present the map Directory 2.0 of 515 biobanks.

Contributing to Quality: Since April 2015, BBMRI-ERIC has been actively contributing to the process of international standards development as Observer Liaison to ISO/TC 276 Biotechnology and ISO/TC 212 Clinical Laboratory Testing and In Vitro Diagnostic Test Systems. As Observer Liaison, BBMRI-ERIC has been asked to contribute to the drafting process by addressing comments and references as well as to share the developments of the ISO Working Groups with the BBMRI community. This allows BBMRI-ERIC to fulfil its mandate as an international organisation in the interests of the European biobanking community. Eventually, BBMRI-ERIC aims to facilitate access to samples of human health/disease relevant biological resources including associated data in an efficient, quality-defined, and ethically and legally compliant manner. Ultimately, BBMRI-ERIC will develop performance indicators to monitor the operation of the research infrastructure.

In 2016, BBMRI-ERIC has the objective to strengthen the Quality Management System (QMS) and the quality of sample processing procedures of biobanks.

A comprehensive Self-Assessment Tool will be developed and provided for the BBMRI community. For this task, technical and quality expert working groups will be established to evaluate and benchmark pre-examination processes and QMS within a single biobank and across associated biobanks of the 18 members and observers of BBMRI-ERIC.

The output of the developments will be templates of process descriptions, standard operating procedures and checklists. The Self-Assessment Tool will be based on specific modules compiled by the expert working groups and will cover a detailed survey for the QMS and specifications for pre-examination processes for sample handling.

Project involvement

As of November 2015, BBMRI-ERIC is involved in 10 externally funded projects (IMI, FP7, H2020). The H2020 project **ADOPT BBMRI-ERIC** aim is to boost and accelerate the implementation of the BBMRI-ERIC and its services and is therefore interlinked with the core activities as specified in this Work Programme. The aims of ADOPT BBMRI-ERIC are furthermore in line with the objectives identified in the policy document on "Prioritisation of Support to European Strategy Forum on Research Infrastructures (ESFRI) Projects for Implementation" of 7 April 2014. In the context of ADOPT BBMRI-ERIC, cases (samples and data) of colorectal cancer patients have been selected for a pilot study because both genetic and environmental factors are known to contribute to the etiology of colorectal cancer. It is also known that an early diagnosis of the disease improves the prognosis for the patient. Colon cancer is a sufficiently common cancer in Europe to constitute a significant public health problem. For rare disease patients, a pilot study on osteogenesis imperfecta has been included.

Additionally, the ADOPT BBMRI-ERIC allows enlargement of the tasks of the Common Service ELSI (CS ELSI), which was established in February 2015. The CS ELSI aims to facilitate and support cross-border exchanges of human biological resources and data attached for research uses, collaborations and sharing of knowledge, experiences and best practices among Member States. In 2016, the key activities of the CS ELSI are to set up the 'Help-Desk' on ethical, legal and societal issues; to establish the 'Ethics Check' for projects that seek to access resources via and of BBMRI-ERIC; and to monitor and report on the latest developments on regulations, recommendations and guidelines (e.g., General Data Protection Regulation) relevant to biobanking activities.

Further Work Plans

The Work Programme 2016 builds on several existing strands of work specified in previous programmes and introduces new ones:

Work Plan 'Clinical Biobanks' has been enlarged and consequently renamed to 'Healthcare Integrated Biobanking' focusing on disease-oriented biobanks, archived tissues, liquid biopsies, immortalised cell

lines, the microbiome and biomarker verification and validation models.

Work Plan 'Population-Based Cohorts' indicates how the achievements of the FP7 projects BBMRI-LPC will be put on a sustainable platform within BBMRI-ERIC.

Work Plan 'Common Services for BBMRI-ERIC' specifies the goals for the Common Service ELSI for 2016 and reveals how both rare diseases and biomolecular resources are to be best integrated in BBMRI-ERIC.

Work Plan 'Bioimaging' monitors and liaises with existing imaging biobanks in Europe.

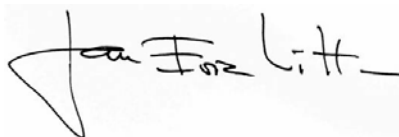
Work Plan 'Assessment and Improvement of BBMRI-ERIC' aims at self-evaluating BBMRI-ERIC's governance model including its Common Services as well as internal rules and administrative processes on the one hand, and integrating the activities of National Nodes on the other hand.

Work Plan 'Biobank Outreach' specifies the involvement in the major biobank event 2016 in collaboration with ESBB and others.

Work Plan 'Continued Work Streams' provides an overview of several strands of work initiated in the previous Work Programmes, which continue throughout the years to come without major changes including: yearly scientific retreat, administrative activities of the HQ, communication activities, webinars, Newsletter, education and training activities, Expert Centres, fundraising activities (involvement in project applications), and the Stakeholder Forum.

BBMRI-ERIC brings together the know-how of many disciplines in order to operate the pan-European research infrastructure for biobanks and biomolecular resources for the benefit of health research and ultimately for the benefit of the European citizens. The contributions of the National Nodes can only be partially acknowledged in the format of the Core Work Programme but will be more fully described in the Annual Reports.

Graz 2015/11/20

A handwritten signature in black ink, appearing to read 'Jan-Eric Litton', written over a light grey rectangular background.

Prof. Jan-Eric Litton
BBMRI-ERIC Director General

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1 WORK PLAN: E-INFRASTRUCTURE

The e-Infrastructure toolset of the BBMRI-ERIC aims to become the pivotal tool for the biomedical and bioinformatics researchers who need access to human-related biobank samples and/or related data. The toolset will also provide functionality and services needed for users of the BBMRI-ERIC infrastructure, such as biobankers, clinicians, patients/donors and their organisations, funding agencies, and data protection agencies. The main challenges include (a) harmonisation of formats and ontologies, in order to provide consistent semantics of data presented to the user, (b) consistent linking of the samples with all the potentially relevant data, including clinical data, phenotype data, as well as omics data, (c) implementation of robust privacy and security architecture to ensure due protection of patient-related information, (d) development of interfaces to suit various types of users, (e) ensuring good performance and robustness of a highly distributed computing system, while also (f) providing traceability on all levels. All of these aspects are reflected in the proposed Work Programme 2016. Traceability stands out as particularly important in the view of the central commitment of BBMRI-ERIC to quality. Traceability begins with the complete information on sample processing and collection of all the quality-related information relevant to assess their 'fit-for-purpose' and proceeds all the way to the quality assurance of related clinical data and data generated by analysis of the samples. Traceability is also important in order to monitor impact of the BBMRI-ERIC infrastructure, thus supporting implementation of Key Performance Indicators (Work Stream 2.3).

The Work Plan for 2016 follows up on the developments in 2015, where the most activity has been invested into several major objectives that already define basics of the e-Infrastructure, its long term development and its operations: (1) setup of the Common Service IT, (2) update of the use cases, and (3) development of first versions of BBMRI-ERIC Directory (1.0/2.0). Another important aspect was interactions with standardisation bodies, other related infrastructures, as well as other projects and external entities (Figure 2), namely to ensure harmonisation of terminology and data models.

Setting up of the BBMRI-ERIC Common Service IT (CS IT) has been a critical activity of 2015, since the CS IT will act as a sustainable development and operations platform for IT of BBMRI-ERIC for the coming years. The setup of CS IT included collection and revision of the use cases coming from the preparatory phase of the BBMRI related projects, such as provision of aggregate information about biobanks and collections (implemented using BBMRI-ERIC Directory) and lookup of individual samples (planned to be implemented by Sample Locator). Newly understood use cases have been defined as well, such as Sample Negotiator for simplifying many-to-many communication between biobankers and sample/data requesters, or a platform for secure high-throughput processing of biobank data. These use cases were utilised to create Call for Tender for the CS IT. For it, the BBMRI-ERIC IT community has aligned itself and submitted a consolidated single proposal, which has undergone evaluation by external reviewers and is pending in the approval process by Assembly of Members as of writing this Work Programme. All of these use cases create foundations for the major development effort in the years 2016 and 2017. The majority of software development during these years will be funded through the WP3 of ADOPT BBMRI-ERIC (see 11.1), while remaining the development and operations will be funded from the CS IT core budget.

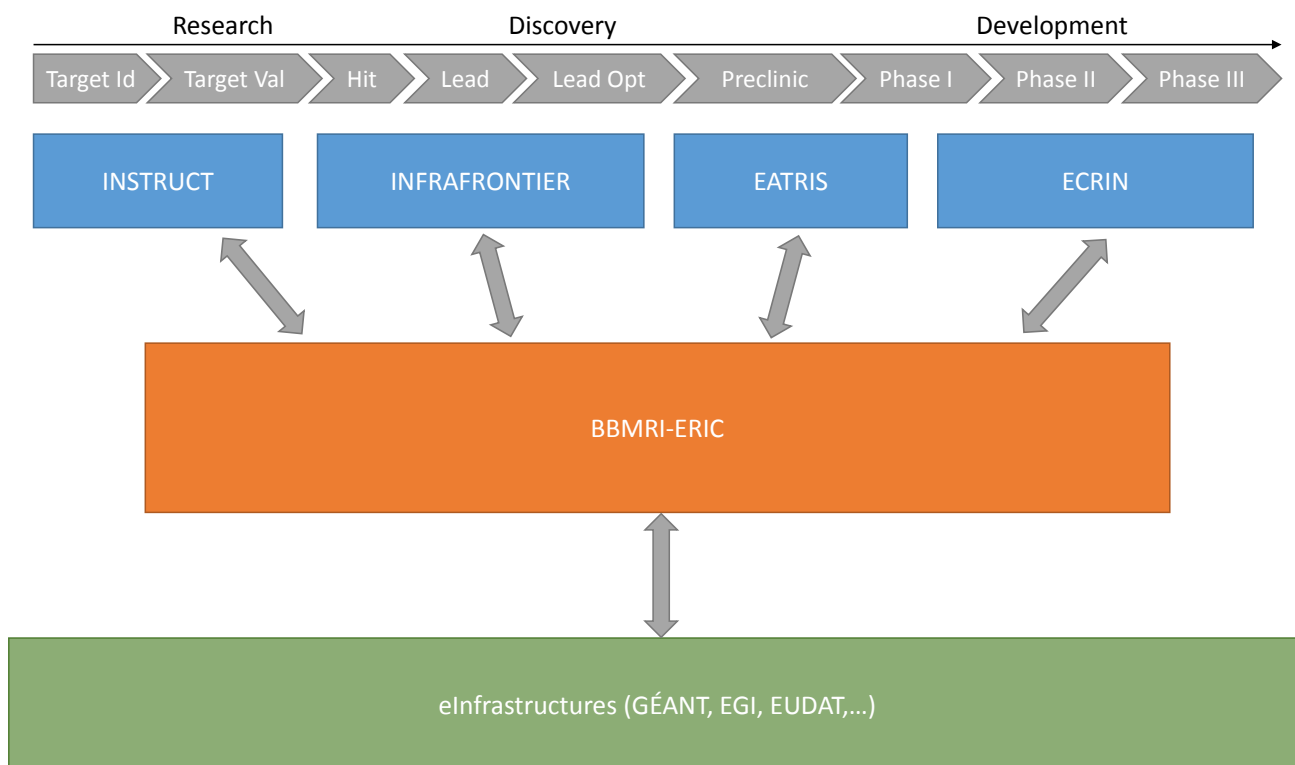


Figure 2: Relation of BBMRI-ERIC to other Projects and Infrastructures.

The e-Infrastructure Work Plan 2016 is split into three Work Streams corresponding to the most important aspects of the BBMRI-ERIC IT Gateway: (1.1) design, development and delivery of the IT tools for BBMRI-ERIC and its users, including evaluation of existing use cases and provided services, possibly followed by definition of new use cases; (1.2) operations of the IT infrastructure, including both custom developed software and a standard set of tools intended for support of the BBMRI-ERIC community; and (1.3) interactions with other European and global infrastructures, as well as other related projects.

The e-Infrastructure will also contribute to other parts of the Work Programme 2016, including interaction with standardisation bodies (Work Plan 6) and processing and analysis of BBMRI-ERIC key performance indicators (Work Stream 2.3).

1.1 Work Stream: Development of IT Gateway to European Biobanks

1.1.1 Background

Most of the design and development in 2015 has been focused on (a) refinement of existing use cases and definitions of new ones based on the feedback from the users, (b) design and development of the first two releases of the BBMRI-ERIC Directory, which provide aggregate information about biobanks and sample collections hosted in them, and (c) harmonisation of data interoperability formats and standards, as well as clarification of terminology. The component-based architecture as a result of (a) is summarised in the Figure 3 and has become a roadmap for future design and development activities in CS IT.

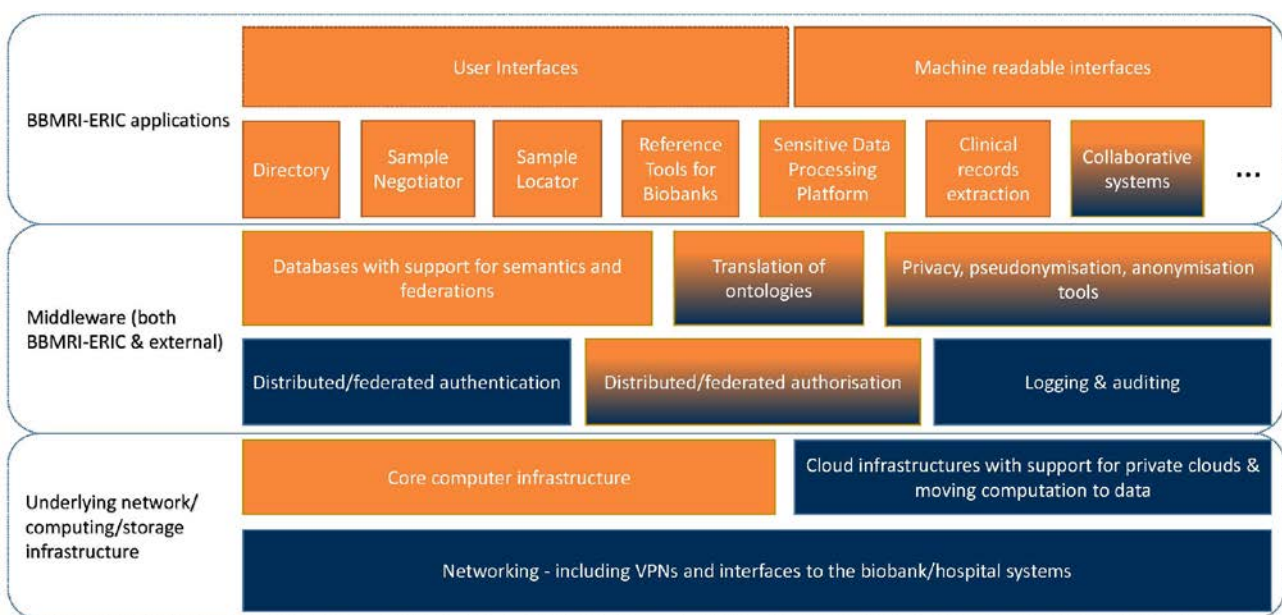


Figure 3: Layered Component-based Architecture of the IT Gateway to European Biobanks

Orange indicates BBMRI-ERIC activities. Blue indicates synergies used with other projects and RIs.

1.1.2 Mission

Most of the development focus in 2016 will be on the two most critical components: Sample Negotiator and Sample Locator. Particular attention needs to be paid to developing a modular system with well-defined interfaces (APIs); this will allow components to be interchanged based on the users' needs, possibly also allowing for direct interfacing by the users' own applications. These two tools also require development of other supporting systems, such as ontology mapping services, authentication and authorisation infrastructure, etc.

1.1.3 Goals and Deliverables

In 2016, the Work Stream 1.1 will focus on the following goals:

- Development of *Directory 3.0*, as a follow-up to Directory 1.0 and 2.0 developed and released in 2015. The Directory provides aggregate view of biobanks, biobank networks, and sample

collections, allowing users to identify biobanks that may potentially host samples of interest. The important new features for the Version 3.0 will include support for explicit semantics using the Linked Data¹ approach and extensions toward capabilities of biobanks, studies, and quality aspects of biobanking. The user interface will be updated based on experiences with the previous versions. After delivery of Directory 3.0, we will begin work on Directory 4.0, with the expected interface for extraction from sample-level source data from the biobanks and National Nodes and for using the ontology translation service described below.

- Development of *Sample Negotiator 1.0*, a tool designed to simplify communication between the sample and/or data requester and the biobankers. This communication is many-to-many in its nature, because each requester typically communicates with multiple biobanks at the same time in order to collect a large enough sample set with the requested characteristics (based on the information in the Directory 1.0 as of mid-2015 and pilot requests we have received from the users, the number of biobanks can easily exceed 50 and in some cases even 100), and many requesters are issuing their requests at the same time. The requests are usually subject to iterative refinement, while biobankers from different biobanks often pose very similar questions related to fitness for the purpose of the samples they may offer. This communication creates a large time overhead for both the biobankers and the requesters and an efficient communication tool tailored to this scenario will simplify the communication dramatically. The first version of the Sample Negotiator is expected to be released in mid-2016, being integrated with the Directory to allow users to look-up the biobanks of potential interest to be communicated with.
- By the release of Sample Negotiator 1.0 at the latest, the development team will begin work on the *Sample Locator* application, which will allow users to identify individual samples of interest and will start negotiation with the biobankers specifically about these samples. As one of the most sensitive applications from the privacy protection perspective, particular attention will be paid to the integration of the 'privacy and security by design' principle for the Sample Locator. Before the actual implementation, privacy and security architecture will be delivered, aligned with the ADOPT BBMRI-ERIC project Deliverables. The development of the Sample Locator is expected to be finalised in the course of 2017.
- Because of the distributed hub-and-spokes architecture of BBMRI-ERIC, *reference tools for the National Nodes and for local biobanks* will be developed. These will include both connectors to the custom-developed BBMRI-ERIC software such as the Directory, the Sample Negotiator, and the Sample Locator, as well as the other commonly available software suites that are of relevance. For example for local biobanks, integration of the open-source Laboratory Information Management System (LIMS), such as OpenSpecimen or Bika Labs, will be considered to create a modular workflow system with well-defined APIs. We will utilise synergy with the B3AFRICA project, where BBMRI-ERIC and BBMRI.at have certain capacity to deliver parts of this workflow. We will also set-up and operate a registry of software tools that are available in the fields related to biobanking, in order to avoid unnecessary duplication of software development.
- In order to allow for data translation and harmonisation in various components of the BBMRI-ERIC software ecosystem, we will be developing in a modular reusable *ontology translation service*, while utilising outcomes of the previous project such as BioMedBridges and BioSHaRE. The end of 2016 expects first version, with further development extending into 2017.
- Biobank-specific *ontologies and data models* will be published in the course of 2016, to allow for broader interoperability and harmonisation on the global level. These will be coordinated with the development in the standardisation bodies (such as CEN and ISO, see Work Plan 2 and 6), where BBMRI-ERIC will play an active role, as well as with the activities of BBMRI-ERIC in the CORBEL project (see 11.7).

¹ Bizer, Christian; Heath, Tom; Berners-Lee, Tim (2009). "Linked Data—The Story So Far" (PDF). *International Journal on Semantic Web and Information Systems* 5 (3): 1-22.

- In order to allow for evaluation of existing BBMRI-ERIC services and to develop new use cases and services that are needed by the users, the CS IT will establish *User Forum*, led by BBMRI.uk based on their extensive experience in this field.
- As described in the ADOPT BBMRI-ERIC project, we will also develop and deploy *tools for semi-automated data collection* of approx. 7,000 colon cancer cases, which together with a further 3,000 manually collected cases will serve as a basis for further exploration of possible automation of this process. The major complexity stems from often-unstructured clinical records in various languages and differing ontologies, as well as the sheer variety of the data that needs to be extracted (such as clinical and phenotype data). In 2016 a first set of tools will be piloted using selected advanced biobanks, in order to evaluate feasibility of the proposed approach. The next strategy will be decided upon based on the outcomes of the pilot.

1.1.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Development of Directory (3.0)	█	█	█	█	█	█	█	█	█			
Development of Sample Negotiator (1.0)	█	█	█	█	█	█						
Development of Sample Locator (1.0)							█	█	█	█	█	█
Tools for National Nodes and biobanks	█	█	█	█	█	█	█	█	█	█	█	█
Publishing data models and ontologies	█	█	█	█	█	█	█	█	█	█	█	█
Operations of User Forum and continuous evaluation of services	█	█	█	█	█	█	█	█	█	█	█	█
Development of tools to support semi-automated collection of 7,000 cancer cases	█	█	█	█	█	█	█	█	█	█	█	█
Development of ontology translation services	█	█	█	█	█	█	█	█	█	█	█	█

1.1.5 Project Group

HQ: DG, ITM, CS IT team

NN: BBMRI.uk

Projects: ADOPT BBMRI-ERIC, CORBEL, B3Africa

1.1.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	2
ITM	6
CS IT	46,85
Total	54,85

1.2 Work Stream: Operations of BBMRI-ERIC IT Infrastructure

1.2.1 Background

Design and development in the IT are intentionally implemented as distinct activities from the operations and user support/training. While the feedback from both operations and user support must be channelled back into the design and development, these two activities require different IT qualifications, skills, and personality types. Therefore, in order to ensure user satisfaction, BBMRI-ERIC will run a distinct IT operations Work Stream.

1.2.2 Mission

In the course of 2016, we will take over results of design and development activities from 2015 and 2016 and shift them into the operation.

1.2.3 Goals and Deliverables

These will include:

- operation of Directory 2.0 and 3.0,
- operation of Sample Negotiator 1.0,
- operation of the common IT infrastructure of BBMRI-ERIC, which allows for efficient collaboration and organisation of the community, including mailing lists, collaborative tools, and shared web sites.

User support and training will be run as a part of the infrastructure operations. This includes operation (or use of hosted services) of appropriate tools for quality assurance of the developed systems, request tracking to support reliable tracking of users' requests, as well as remote learning tools for efficient knowledge dissemination.

1.2.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Operations of the Directory (2.0/3.0)												
Operations of the Sample Negotiator (1.0)												
Operations of common BBMRI-ERIC IT infrastructure												
User support and training												

1.2.5 Project Group

HQ: ITM, CS IT

Projects: ADOPT BBMRI-ERIC

1.2.6 Resources

Staff Function	Full Time Equivalent in Person Month
ITM	1
CS IT team	4,6
Total	6,6

1.3 Work Stream: Interfaces to Other e-Infrastructures and IT-related Projects

1.3.1 Background

The e-Infrastructure of BBMRI-ERIC interacts closely with other e-Infrastructures and projects as partially shown in Figure 2. BBMRI-ERIC is strongly committed to reusing existing solutions provided by other e-Infrastructures, such as ELIXIR, GÉANT, EGI, or EUDAT, that are fit for the purpose. BBMRI-ERIC also focuses on defining new scenarios and facilitating their implementation in case that the current services of e-Infrastructures are not capable of supporting BBMRI-ERIC needs.

BBMRI-ERIC will utilise synergy with a number of external projects, in which BBMRI-ERIC plays an active part. Linking to WP3 of ADOPT BBMRI-ERIC (see 11.1). PhenoMeNal (see 11.5) and B3AFRICA (see 11.2) has already been mentioned in the Work Stream 1.2. Other projects relevant for 2016 include EGI-ENGAGE (see 11.6), where results of the BiobankCloud project will be integrated, and the Research Data Alliance (RDA).

Although being closely related to the e-Infrastructure, too, this Work Stream does not include interaction with the ISO TC276 WG1/5, since there is a separate Work Plan 6 for interaction with the ISO standardisation body.

1.3.2 Mission

Interaction with other e-infrastructures and projects.

1.3.3 Goals and Deliverables

In 2016, BBMRI-ERIC will focus on the following activities:

- BBMRI-ERIC plays a leading role in the BBMRI-ERIC Competence Centre in EGI-ENGAGE, which is the major project implemented by the European Grid Infrastructure (EGI), which is also related to the BiobankCloud project. We will use participation in this project to foster the omics data processing platform that can be then deployed at the level of individual biobanks. The goal of the project is to perform the pilot deployment of the tools developed in the BiobankCloud using the Federated Cloud technology of EGI; the Federated Clouds provide very close approximation to what BiobankCloud worked with as private clouds. BBMRI-ERIC will also participate in the cross-border procurement analysis activities of EGI-ENGAGE.
- We will closely collaborate with partners in the CORBEL project on data harmonisation and standardisation, which will be integrated as a follow-up to the BioMedBridges project. BBMRI-ERIC will collaborate with other players in the field of biology-related data, as well as to support wider adoption and further development of biobanking-related data standards.
- Interaction with RDA and EUDAT on use cases for long-term data preservation and persistent data referencing (generating identifiers for the data and queries including time stamping), which will enable substantial improvement of the data traceability and thus also reproducibility of both biobank-related and data-driven research. The BBMRI-ERIC Competence Centre of EGI-ENGAGE will also support collaboration with EUDAT.
- Incorporation of efficient distributed authentication is still one of the major challenges for building

European and in the future possibly also global biobanking infrastructure. We will work closely with GÉANT Association on utilisation of the SAML²-based eduGAIN infrastructure. There, is also the possibility of synergy with the EGI e-Infrastructure, which is currently considering becoming a central interconnection for improving more efficient of the many-to-many communication between identity providers (i.e., institutions verifying users' identities) and service providers (i.e., the services that use the verified identities). Outcomes of this effort are expected to be integrated into the services developed in the Work Stream 1.2 that require access control.

1.3.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
BBMRI Competence Centre in EGI-ENGAGE												
Data harmonisation in CORBEL												
Collaboration with RDA and EUDAT												
Collaboration on eduGAIN integration												

1.3.5 Project Group

HQ: DG, ITM

NN: BBMRI.xx

Projects: ADOPT BBMRI-ERIC, EGI-Engage, BioBankCloud, CORBEL, B3Africa, PhenoMeNal

1.3.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	2
ITM	2
Total	4

² N. Ragouzis et al., Security Assertion Markup Language (SAML) V2.0 Technical Overview. OASIS Committee Draft, March 2008. Document ID sstc-saml-tech-overview-2.0-cd-02 <http://www.oasis-open.org/committees/download.php/27819/sstc-saml-tech-overview-2.0-cd-02.pdf>

2 WORK PLAN: QUALITY

BBMRI-ERIC will provide guidance to establish and improve an appropriate Quality Management System (QMS) for biobanks of human derived materials. A biobank shall have validated standard operational procedures (SOPs) in place, proven fit-for-purpose. The biobank's staff shall follow these procedures by any means and shall take all training, documentation and recording efforts to safeguard biobank processes such as acquisition, reception, labelling, tracking, access, processing, replication, storage, packaging, distribution and transportation of samples, along with measurement, analysis, quality control and risk management aspects in compliance and respect to ethical, legal and societal aspects, in particular data protection requirements.

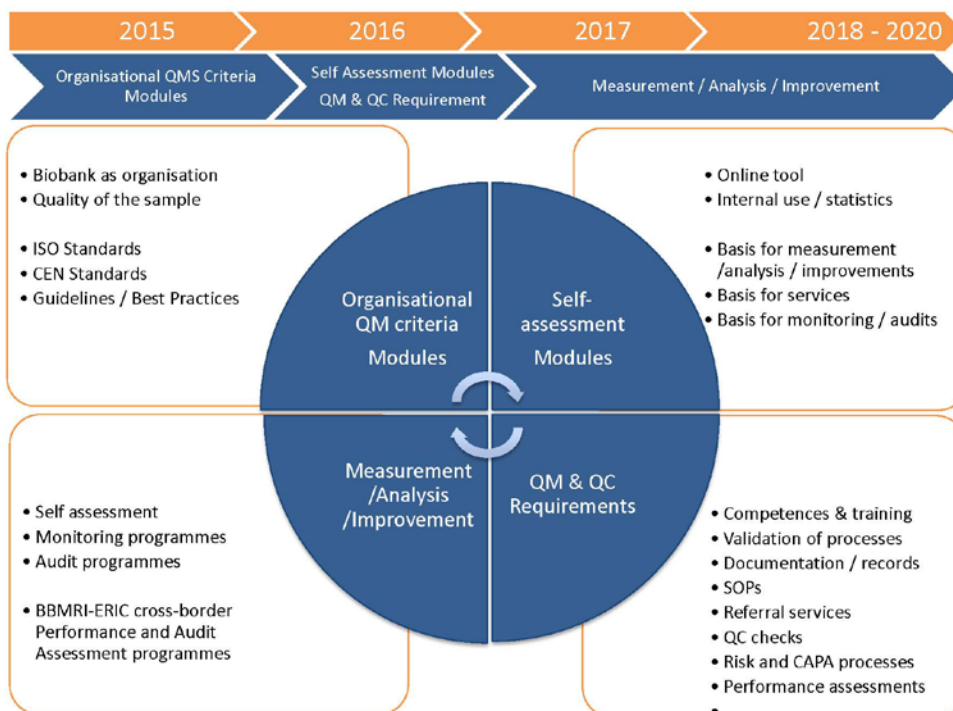
To provide basic instruments for biobankers supporting the adaption to these requirements, BBMRI-ERIC will jointly develop:

1) Common SOPs and appropriate auxiliaries with expert groups. At first level, the CEN Technical Standards (CEN/TS), developed for the Molecular in vitro diagnostic examinations - Specifications for pre-examination processes will be evaluated in Work Stream 2.1. At the second level, all additional validated standardisation protocols elaborated in Work Plan 3 will be included. These deliverables will provide details on sample processing.

2) Common requirements of an appropriate QMS for biobanks will be elaborated in Work Stream 2.2 with the aim to develop and deploy a Self-Assessment Tool for biobankers. At the first level, this Self-Assessment Tool will be based on guidelines recommended in the Partner Charter. Complementary to these guidelines the deliverables of Work Stream 2.1 will be integrated and furthermore updated with the ongoing developments of the International Standardisation Organisation (ISO) outlined in the Work Plan 6, International Standard Developments.

The QM Infrastructure will also contribute and closely interact with Work Plan 1: e-Infrastructure, Work Plan 3: Healthcare integrated Biobanking (especially in relation to the H2020 projects ADOPT BBMRI-ERIC and CORBEL) and Work Plan 5: Common Services for BBMRI-ERIC (especially Work Stream 5.3 Biomolecular Resources).

Figure 4: Key Pillars of QM Infrastructure Developments



In 2016, the BBMRI-ERIC community will elaborate common organisational QMS criteria and a Self-Assessment Tool, this refers to Work Stream 2.1 and 2.2 and Work Plan 7.

In the next step, BBMRI-ERIC will contribute to general QMS requirements such as Measurement/Analysis/Improvement. It will be recommended to the biobanks, as an organisation, to plan and implement monitoring, measurement, analysis and improvement processes needed to demonstrate conformity to product (sample) requirements, as well as to ensure conformity to the quality management system, and to continually improve the effectiveness of the system. BBMRI-ERIC guidance and support features will be defined and planned 2016.

2.1 Work Stream: Molecular In-vitro Diagnostic Examination Standards of CEN/TC 140

2.1.1 Background

The standardisation system in Europe is based on the national pillars, which are the National Standardisation Bodies or the members of CEN. A National Standardisation Body is the one-stop shop for all stakeholders and is the main focal point of access to the concerted system, which comprises regional (European) and international (ISO) standardisation. It is the responsibility of the CEN national Members to implement European Standards as national standards. The National Standardisation Bodies distribute and sell the implemented European Standard and have to withdraw any conflicting national standards.

Table 1: National Standardisation Bodies Representing BBMRI-ERIC Members and Observers

ASI	Austria	Austrian Standards Institute
NBN	Belgium	Bureau de Normalisation/Bureau voor Normalisatie
UNMZ	Czech Republic	Czech Office for Standards, Metrology and Testing
DS	Denmark	Dansk Standard
EVS	Estonia	Estonian Centre for Standardisation
SFS	Finland	Suomen Standardisoimislitto r.y.
AFNOR	France	Association Française de Normalisation
DIN	Germany	Deutsches Institut für Normung
NQIS/ELOT	Greece	National Quality Infrastructure System
UNI	Italy	Ente Nazionale Italiano di Unificazione
MCCAA	Malta	The Malta Competition and Consumer Affairs Authority
PKN	Poland	Polish Committee for Standardization
SNV	Switzerland	Schweizerische Normen-Vereinigung
NEN	Netherlands	Nederlands Normalisatie-instituut
SN	Norway	Standards Norway
SIS	Sweden	Swedish Standards Institute
TSE	Turkey	Turkish Standards Institution
BSI	United Kingdom	British Standards Institution

CEN Technical Committee, CEN/TC 140 – In vitro diagnostic medical devices:

Standardisation in the field of in vitro diagnostic medical devices which are reagents, reagent products, calibrators, control materials, kits, instruments, apparatus, equipment, or systems, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

concerning a physiological or pathological state or

concerning a congenital abnormality or

to determine the safety and compatibility with potential recipients, or

to monitor therapeutic measures. Specimen receptacles are considered to be in vitro diagnostic medical devices.

'Specimen receptacles' are those devices, whether vacuum-type or not, specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination. Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, they are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

CEN/TC 140/WG 3 – Quality management in medical laboratory - developed and published standards (Q4.2015) for molecular in vitro diagnostic examinations - specifications for pre-examination processes.

These standards will meet the specific needs of the BBMRI-ERIC community and have the potential to elaborate the BBRMI-ERIC biobanks into the next level, by examining sample quality on the basis of the CEN standards.

BBMRI-ERIC recommends the implementation of European Standards for pre-examination processes, whenever applicable, to assure that samples dedicated to analytical processes are examined under a high-quality-assured standardised process.

CEN/Technical Specification for Molecular In-vitro Diagnostic Examinations:

- CEN/TS 16826-1: Specifications for pre-examination processes for snap frozen tissue – Part 1: Isolated RNA
- CEN/TS 16826-2: Specifications for pre-examination processes for snap frozen tissue – Part 2: Isolated proteins
- CEN/TS 16827-1: Specifications for pre-examination processes for FFPE tissue – Part 1: Isolated RNA
- CEN/TS 16827-2: Specifications for pre-examination processes for FFPE tissue – Part 2: Isolated proteins
- CEN/TS 16827-3: Specifications for pre-examination processes for FFPE tissue – Part 3: Isolated DNA
- CEN/TS 16835-1: Specifications for pre-examination processes for venous whole blood – Part 1: Isolated cellular RNA
- CEN/TS 16835-2: Specifications for pre-examination processes for venous whole blood – Part 2: Isolated genomic DNA
- CEN/TS 16835-3: Specifications for pre-examination processes for venous whole blood – Part 3: Isolated circulating cell-free DNA from plasma
- Specifications for pre-examination processes for metabolomics in urine, serum and plasma

2.1.2 Mission

The content of these developed and published CEN Standards will be evaluated by the specific experts in the different fields of pre-examination processes of the BBMRI-ERIC community. The outcome of the evaluation will be shared and introduced to the entire BBMRI-ERIC community and will shape the basic principles for the Self-Assessment Tool for biobanks (Work Stream 2.2).

2.1.3 Goals and Deliverables

Evaluation of the pre-examination processes of the published CEN/TC 140 Standards by the BBMRI-ERIC experts in the field:

1. Set up a Working Group³ for evaluation of 8 pre-examination processes
2. Definition of evaluation tasks (criteria, documentation, outcome and timeline)
3. Nomination of experts for specific evaluation tasks
4. Evaluation process
5. WG meetings (TC, webinars, meetings) to discuss and evaluate developments
6. Documentation for self-assessment (deliver main criteria for self-assessment)

2.1.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
1. Set up WG												
2. Definition of evaluation tasks												
3. Nomination of experts for evaluation tasks												
4. Evaluation process												
5. WG meetings												
6. Documentation for Self-Assessment Tool												

2.1.5 Project Group

HQ: DG, QM

NN: Experts of BBMRI.xx, QMs of BBMRI.xx

Projects: ADOPT BBMRI-ERIC

2.1.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0,5
QM	2
Total	2,5

³ BBMRI-ERIC has several internal Working Groups. Complete list is available on the Intranet only.

2.2 Work Stream: Self-Assessment Tool for Biobanks (formerly Self-Evaluation)

2.2.1 Background

BBMRI-ERIC aims to facilitate access to sample and data human health/disease relevant biological resources including associated data in an efficient, ethically and legally and quality defined compliant manner by creating and implementing a Self-Assessment Tool for biobanks.

2.2.2 Mission

In this Work Stream the main focus is on the development and definition of BBMRI common agreed relevant criteria for QMS and pre-examination sample processing of biobanks to ensure high quality of the sample per se.

In order to support biobanks to build up as well as to improve their QMS and pre-examination sample processes, the BBMRI-ERIC community will evaluate criteria for a biobank QMS and appropriate pre-examination processes for sample processing.

The Self-Assessment Tool will cover

- Quality Management System
- Appropriate pre-examination processes for sample processing (based on CEN 140 and equivalent Standards in the first stage Work Stream 2.1)

BBMRI-ERIC will recommend Members to implement this quality management self-assessment and to initiate internal improvements based on the assessment initiating internal improvements. BBMRI-ERIC and the BBMRI-ERIC community will support improvements, if requested by the biobank. This could lead to development of a BBMRI-ERIC QMS prior audit system, which could be done in 2017.

2.2.3 Goals and Deliverables

- National Nodes to nominate experts and Quality Managers for a Working Group
- Evaluation of relevant and appropriate criteria defining the QMS of a BBMRI-ERIC biobank. Regularly updated by de developments of ISO/TC 276 WG 2 Biobank and Bioresources) Work Plan 7.
- Liaise with the outcome of Work Stream 2.1 of the pre-examination processes of the published CEN/TC 140 Standards by the BBMRI-ERIC experts in the field:
 - Building WG for evaluation relevant criteria for a biobank's QMS
 - Evaluation and decision on the appropriate on-line tool (IT assistance)
 - Definition of evaluation tasks (criteria, documentation, outcome and timeline)
 - Nomination of experts for specific evaluation task
 - Evaluation process
 - WG meetings (TC, webinars, meetings) to discuss and evaluate developments
 - Documentation for Self-Assessment Tool

- Implementing the evaluation results of the Work Stream for pre-examination sample processing to the Self-Assessment Tool
- Dissemination of Self-Assessment Tool to biobanks

2.2.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Building Working Group	Yellow											
Online tool examination	Blue	Blue	Blue									
Definition of evaluation tasks	Magenta	Magenta										
Nomination of experts for evaluation tasks		Brown										
Evaluation process		Light Blue	Light Blue	Light Blue	Light Blue	Light Blue			Light Blue	Light Blue	Light Blue	
WG meetings		Orange	Orange	Orange	Orange	Orange			Orange	Orange	Orange	
Documentation for Self-Assessment Tool									Green	Green	Green	
Implementation of results CEN										Dark Green	Dark Green	Dark Green
Dissemination of Self-Assessment Tool												

2.2.5 Project Group

HQ: DG, QM, ITM

NN: Experts of BBMRI.xx, QMs of BBMRI.xx

2.2.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0,25
QM	2
ITM	0,5
Total	2,75

2.3 Work Stream: Implementation of Performance Indicators

2.3.1 Background

A 'performance indicator' or 'key performance indicator' is a type of performance measurement. Performance indicators evaluate the success of an organisation or of a particular activity in which it engages. Accordingly, choosing the right indicators relies upon a good understanding of what is important to the organisation. The AoM has asked BBMRI-ERIC to begin with the work on performance indicators, which is also a task of the ADOPT BBMRI-ERIC project and under the responsibility of the Director General. The performance indicators will serve to monitor the operation of BBMRI-ERIC and its improvement by executing the proposed Work Programme.

The Bioresource Research Impact Factor (BRIF) was introduced in 2003, and later further developed.⁴ The BRIF initiative was set up to construct an adequate framework and provide a set of tools that will allow an objective measure of the actual research utilisation of bioresources as a significant component for establishing their impact on research. Notably, a guideline for citing bioresources in scientific journal articles, has been published the Citation of BioResources in Journal Articles (CoBRA) that was published in BMC Medicine. The performance indicators as specified in the ADOPT BBMRI-ERIC project will contribute to the overall performance assessment of the research infrastructure, including BRIF.

The objective of performance indicators must be DUMB; Doable. Understandable. Manageable. Beneficial.

2.3.2 Mission

- To define the performance indicators for BBBMRI-ERIC, BBMRI.xx and biobanks.
- To monitor the overall performance of BBMRI-ERIC as a Research Infrastructure a series of performance, outcome and impact indicators will be established.

2.3.3 Goals and Deliverables

See ADOPT BBMRI-ERIC

2.3.4 Time Plan

See ADOPT BBMRI-ERIC

2.3.5 Project Group

HQ: DG, QM

Projects: ADOPT BBMRI-ERIC

⁴ Elena Bravo et al (2015), see <http://www.biomedcentral.com/content/pdf/s12916-015-0266-y.pdf>

2.3.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0,5
QM	2
total	2,5

3 WORK PLAN: HEALTHCARE INTEGRATED BIOBANKING

Healthcare Integrated Biobanks (HIB) are playing an increasingly important role both in biomedical research and in transferring knowledge to health systems. Many countries envision that their biobanks will become integral parts of their health care structures.

This Work Plan is expanding on the previous "Work Plan: Clinical Biobanks" (as specified in the Work Programme 2015). It is revised and renamed as "Work Plan: Health Integrated Biobanking" and proposes to set up new Working Groups. Existing Working Groups will be assessed in 2016. The content of this Work Plan overlaps with some activities described in the ADOPT BBMRI-ERIC project, especially in WP2, 3, 4 and 7 as well as tasks of the BBMRI-ERIC Common Services ELSI and IT. Hence, the goal of this Work Plan is to identify wherever joint actions have to be taken across the Work Streams and if even more Working Groups have to be established if needed.

This Work Plan is related to the community of researchers implicated in disease-oriented projects that relies of the use of collections of biological resources. These resources include among others: collections of frozen tissue, archived tissue (FFPE), liquid biopsies, immortalised cell lines, microbioma. This Work Plan is also related to communities operating in the fields of Laboratory Medicine, Medical Imaging, -omics analyses and Biomarker verification and validation. The collaboration of experts from these communities, the harmonised integration of their workflows as well as the interoperability of generated data will be beneficial for the advancement of biomedical research and improved health care.

Ultimately, this Work Plan will be executed with having patient care as the highest priority in a clinical setting. The networking of the BBMRI-ERIC disease-oriented biobank community with other communities involved in health care, such as laboratory medicine and medical imaging (for the latter see 7. Work Plan: Bioimaging) can contribute to improved health care management and outcomes.

3.1 Work Stream: Disease-oriented Biobanks

3.1.1 Background

Realising the full promise of personalised medicine, whose goal is to provide the best available care for each individual, requires that researchers and health-care providers have access to very large sets of samples and health and disease-related data linked to individual patients.

The quality of interoperable samples and data are defined through the standard operating procedures (SOPs) of each biobank as well as CEN/ISO standards (see WORK PLAN: QUALITY) of each biobank and harmonisation among biobanks. Harmonisation, standardisation and validation of methods, samples and data are pursued to ensure that samples are collected, transported, processed, tested and stored in compliance with the procedures, which assure consistently high quality samples. Integrate evidence-based criteria and criteria that meet the 'intended use' taking into account the different areas of research. In fact, the use determines pre-analytical condition requirement and several uses with special reference to new technologies (e.g., metabolomics, next generation sequencing, and omics data) applied to solid and liquid biopsies.

3.1.2 Mission

To realise the full promise of personalised medicine in providing access to very large sets of samples and health and disease-related data linked to individual patients and the appropriate adaptation of Mutual Transfer Agreements (MTA) as specified in projects like BBMRI-LPC.

3.1.3 Goals and Deliverables

To set up a Working Group which should deal with issues that are shared in all Work Streams of 3.1., particularly in relation to the issues specified in the ADOPT BBMRI-ERIC proposal. The Working Group should especially ensure the liaison across the WPs 2, 3, 4.

3.1.4 Time Plan

See ADOPT BBMRI-ERIC

3.1.5 Project Group

NN: BBMRI.xx / Working Group composition to be defined as first deliverable

Projects: ADOPT BBMRI-ERIC (WP2 - Datasets, lead by BBMRI.it/Marialuisa Lavitrano and WP3 - Gateway, lead by BBMRI.de/Michael Hummel; WP4 - Access, lead by BBMRI.fr/Georges Dagher)

3.1.6 Resources

See ADOPT BBMRI-ERIC

3.2 Work Stream: Archived Tissues

3.2.1 Background

The Working Group 11: Archived Tissues (overview **Fehler! Verweisquelle konnte nicht gefunden werden.**, page 85) was constituted in September 2014 at a BBMRI-ERIC meeting on clinical tissues held in Berlin under the coordination of Giorgio Stanta (BBMRI.it) and Kurt Zatloukal (BBMRI.at). The WG aims to develop an Archived Tissue Network within BBMRI-ERIC. The BBMRI-ERIC Archived Tissue Network will be based on country hubs and spokes according to the usual BBMRI-ERIC model. The network is composed of pathology archives of FFPE tissues as a virtual network to be developed in every BBMRI-ERIC member country. This virtual network will support the community of the pathologists in Europe and will connect and organise the pathology archives so that they can assume the biobanking function after pseudo-anonymisation of the cases for a specific research project.

3.2.2 Mission

The mission of the BBMRI-ERIC Archived Tissue Network is to involve, through each national delegate, the national societies of pathology, to start with the first network in Europe with defined rules and controls. The project was already proposed to the country delegates of the WG, and the rules and modalities were already largely discussed. The proposal was developed in the SIAPEC (Società Italiana di Anatomia Patologica e Citodiagnostica) meeting in Milan in September 2015.

3.2.3 Goals and Deliverables

The goal is to develop the first European network of archived clinical tissues with defined rules and activities. The activities of this Work Stream can build on the actions of BBMRI.it, which through NIPAB (Network of Italian Pathology Archives Biobanks) has signed an agreement with SIAPEC.

The major deliverable is to set out a framework of activities of such a kind of network with defined rules for clinical research projects. As a use case, large collections of archived tissues associated to the medical history of the patients will be made available for retrospective studies on ovary and other carcinomas. These samples will be used for biomarker verification and validation in ADOPT BBMRI-ERIC WP6 and other European projects. The work should also become a precursor of a BBMRI-ERIC associated Expert Centre for biomarkers.

3.2.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Define rules and activities												
Biomarker verification & validation												

3.2.5 Project Group

HQ: DG

NN: BBMRI.xx/Working Group 11: Archived Tissues (lead by BBMRI.it/Giorgio Stanta & BBMRI.at/Kurt Zatloukal)

Projects: ADOPT BBMRI-ERIC (WP6, jointly lead by BBMRI.at/Kurt Zatloukal & BBMRI.fi/Anu Jalanko)

3.2.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0,25
Total	0,25

3.3 Work Stream: Liquid Biopsies

3.3.1 Background

Information about disease mechanisms can be directly derived from liquid biopsies. For example, in solid tumors, monitoring response to treatment and disease progression is crucial due to changes in tumour biology and therapy responsiveness. However, solid tumours are usually sampled only the time of initial diagnosis, because obtaining tissue biopsies is an invasive procedure. Recent evidence indicates that blood and other body fluids could replace surgical biopsies and represent a "liquid biopsy" containing cells, exomes and nucleic acids released by primary and metastatic lesions, characterised by easy non-invasive procedures, and would be suitable for longitudinal analyses. Thus, liquid biopsies represent promising approaches for tracking cancer progression and treatment response.

However, there are relevant issues that need to be solved before liquid biopsies can be implemented in clinical practice, including technical, biological and clinical validations. BBMRI-ERIC is an ideal platform to establish and validate SOPs as well as CEN standards at pre-analytical level.

3.3.2 Mission

To facilitate access to quality-defined human disease relevant liquid biopsies.

3.3.3 Goals and Deliverables

The goal is to foster interoperability of liquid biopsy biobanks with defined rules and activities, and produce Standard Operating Procedures and Best Practices, in order to characterise liquid biopsies through robust assay development, technical validation and standardisation. This will be achieved through a pilot project on colorectal cancer as a model system to track tumour dynamics in real time and for the early detection of relapse (see especially ADOPT BBMRI-ERIC WP2).

SOPs, Best Practices for assay development, technical validation and standardisation of liquid biopsies.

3.3.4 Time Plan

See ADOPT BBMRI-ERIC

3.3.5 Project Group

NN: all BBMRI.xx Project: ADOPT BBMRI-ERIC (WP2 lead by BBMRI.it/Marialuisa Lavitrano)

3.3.6 Resources

See ADOPT BBMRI-ERIC

3.4 Work Stream: Immortalised Cell Lines

3.4.1 Background

Human and animal cell lines are widely used in basic and translational biomedical research, as they constitute a simple and representative model system for functional studies and identification of diagnostic tools and therapeutic targets. Each cell line has unique features and can be used for specific studies. Recent results, obtained using high-throughput genomic analyses, confirm that cross-contamination of human and animal cell lines is a repeated and frequent cause of scientific misrepresentation.

3.4.2 Mission

To increase awareness in the BBMRI-ERIC community of the issue of authentication of established and primary cell lines and human tissues in order to foster reproducibility of research.

3.4.3 Goals and Deliverables

BBMRI.it (Barbara Parodi) will explore setting up a Working Group on human sample authentication, to produce agreed Standard Operating Procedures and Best practices and to provide a human sample authentication service to the research community. This may serve as a building block for a future Common Service on Biomolecular Resources.

3.4.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Set up Working Group												
SOP's produced												

3.4.5 Project Group

NN: BBMRI.xx/Working Group composition to be defined as first deliverable

Project: ADOPT BBMRI-ERIC (in close collaboration with WP4 - Access, lead by BBMRI.fr/Georges Dagher)

3.4.6 Resources

See ADOPT BBMRI-ERIC

3.5 Work Stream: Microbiome

3.5.1 Background

The human microbiome is the collection of all the microorganisms living in association with the human body. These communities consist of a variety of microorganisms including eukaryotes, archaea, bacteria and viruses. The Human Microbiome Project (HMP) revealed the significance of the gut microbiome in promoting health. The pathogenesis of numerous diseases is associated with disruptions in microbiome composition. Reduction in microbiome biodiversity can compromise the human immune system and predispose individuals to several modern diseases. Several international projects aim at setting up biobanks in this field. The collaboration of health care integrated biobanks with the community of researchers studying microbiomes would favour the creation of specialised biobanks for archiving native microbiomes in order to enable future research on the relationships between the microbiome to the and health and disease status.

3.5.2 Mission

The mission is to connect the microbiome community. This will be explored by BBMRI.fr (Georges Dagher) and BBMRI.at (Kurt Zatloukal). Thereafter, a joint Working Group will be set up to streamline the collaboration.

3.5.3 Goals and Deliverables

To set up a Working Group and to explore the possibility of a catalogue.

3.5.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Set up Working Group												
Explore catalogue possibility												

3.5.5 Project Group

HQ: DG

NN: BBMRI.xx/Working Group composition to be defined as first deliverable

3.5.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0,25
Total	0,25

3.6 Work Stream: Biomarkers Verification and Validation Models

3.6.1 Background

New prognostic and predictive biomarkers for clinics and related molecular targets for big pharma development are of paramount importance in molecular and precision medicine. The capability of fast verification and validation of biomarkers and their related models were proposed in the Graz Workshop 'Tissue-based Biomarkers for Advancement of Personalised Cancer Treatment' held in March 2014. The models are reported in the Workshop White Paper⁵.

3.6.2 Mission

One of the first missions is to develop the models of biomarkers verification (BBMRI-ERIC model) and validation (OECI model) within a H2020 project on high-grade ovary serous carcinomas just approved but still in negotiation (BBMRI.it, Giorgio Stanta).

3.6.3 Goals and Deliverables

The aims are to verify the new biomarkers directly in large multiple retrospective case studies, to develop a preliminary kit (to be done by the industry) and then to validate it in three cancer centres with OECI accreditation (also related to clinical research – www.oeci.eu). The deliverables are new biomarkers for high-grade serous ovary carcinomas, but also a model to reach a preliminary clinical validation of the biomarkers within a couple of years instead of ten years that have been the typical development period until now.

3.6.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Define activities												
Biomarker verification & validation												

3.6.5 Project Group

HQ: DG, QM

NN: BBMRI.xx/Working Group composition to be defined as first deliverable

Projects: Hercules (liaison through BBMRI.it/Giorgio Stanta)⁶;

⁵ <http://www.impactsnetwork.eu/userfiles/file/10WHITE%20PAPER25-09-14.pdf>

⁶ it is based on a [BBMRI.it](http://www.bbMRI.it) project on Biomarker Verification and Validation. We developed a model for verification of new biomarkers directly in large multiple retrospective case studies and then to validate it in 3 cancer centers with OECI accreditation. The pilot project (Hercules) on high-grade ovary serous carcinoma has been already funded.

ADOPT BBMRI-ERIC (especially WP6 - Biomarker Development, lead by BBMRI.at/Kurt Zatloukal and BBMRI.fi/Anu Jalanko)

3.6.6 Resources

See ADOPT BBMRI-ERIC

4 WORK PLAN: POPULATION-BASED COHORTS

4.1 Work Stream: BBMRI-LPC

4.1.1 Background

In 2013, an EU-funded (FP7) multinational BBMRI-LPC-project (Biobanking and Biomolecular Resources Research Infrastructure – Large Prospective Cohorts) was established to benefit the European research community. While addressing several objectives of importance, the focal point for BBMRI-LPC is in facilitating transnational access to samples and health data in the large European follow-up studies, thereby increasing their utilisation for health research:

- Three pan-European scientific BBMRI-LPC calls are launched to support specific research projects involving multiple LPCs (1st and 2nd calls were conducted in spring 2014 and 2015, the 3rd call was launched in autumn 2015).
- A web-based access portal and a cohort catalogue has been established enlisting sample collections available for access within BBMRI-LPC, including 2 EU-wide biobank networks and 18 country specific cohorts.
- Improved harmonisation of individual lifestyle and exposure data, and establishing the unified definitions for clinical endpoints are ongoing.
- A networking platform that connects the established and emerging biobanks has been established as well as other functions in support of the biobanking activities.

To map the cohort-specific access operations in large prospective cohorts in Europe, and to determine the bottlenecks and future refinement needs, all BBMRI-LPC call procedures are closely monitored and recorded, the main deliverable from BBMRI-LPC being the improved access process itself.

4.1.2 Mission

BBMRI-LPC, a 4-year project (ending in Feb 2017), involves 33 partners from 18 countries, including universities, research centres/institutes and private companies. BBMRI-LPC was launched to support the existing research infrastructure (FP7-INFRASTRUCTURES-2012-1) in the mission to facilitate networking, harmonisation and access to available large prospective cohort samples and data in Europe. In relation to BBMRI-ERIC, the BBMRI-LPC endeavours to produce concepts and solutions that are applicable and in line with the needs of BBMRI-ERIC. Thus the significant and available results of the BBMRI-LPC shall be implemented in the operations of BBMRI-ERIC as they emerge, and can be applied.

4.1.3 Goals and Deliverables

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

- Implementing the applicable access solutions and know-how from BBMRI-LPC for the use of the wider BBMRI-ERIC biobanking community at large: the procedure of access (description and available instructions), access rules, the cost model of access (definition), and available MTA/DTA solutions.
- Participating, organising and continuing the work on the established platform connecting the early

stage and emerging biobanks with the established ones: Forum 2016, organised in conjunction with the Europe Biobank Week 2016.

- Communicating the updated information on practical biobanking to the BBMRI-ERIC community at large: the Handbook for Practical Biobanking (information on how to start, run and maintain a biobank).
- Enlisting the applicable harmonisation solutions for the biobanking community (implementing the knowledge from BBMRI-LPC harmonisation efforts).
- Dissemination of biobanking-related courses, conferences and activities in Europe.

4.1.4 Time Plan

Deliverable \ month of 2016	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 Project Group

HQ: DG, EPM

Projects: BBMRI-LPC

4.1.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0,5
EPM	Projects
Total	0,5

5 WORK PLAN: COMMON SERVICES FOR BBMRI-ERIC

5.1 Work Stream: Common Service ELSI

5.1.1 Background

The proper consideration of ethical, legal and social issues (ELSI) is key to any biobanking activity and is essential for BBMRI-ERIC. The Common Service ELSI aims to facilitate and support cross-border exchanges of human biological resources and data attached for research uses, collaborations and sharing of knowledge, experiences and best practices among Member States. This must be done in full respect of the Charter of the Fundamental Rights of the EU, with the aim of promoting excellence in international biobank-based research. The CS ELSI came into operation on the 1st of February 2015.

5.1.2 Mission

The missions of the Common Service are as follows:

- Ethics check: for research proposals submitted to BBMRI-ERIC using the BBMRI-ERIC resources
- Monitoring ELSI: based on state of the art and relevant ethical and legal frameworks
- Policy in ELSI matters: follow up relevant evolution and coordinate answers to relevant public consultations and other possible intervention
- Advice: build conclusions and provide reliable advice to BBMRI-ERIC and its users in a solidly based manner
- Help desk: provide updated background information and practical guidance
- Dissemination: disseminate results of relevant surveys and studies
- Tools for ELSI: organise tools and services (existing or new tools)
- Experience sharing: organise sharing between BBMRI-ERIC members
- Education and training: set up training and education on relevant ELSI matters

5.1.3 Goals and Deliverables

- Organise Register of ELSI experts – leader Gauthier Chassang, along with Anne Cambon-Thomsen (Director CS ELSI)

The list of experts begun in 2015 needs to be organised as a database as originally planned with relevant information on specialties and competencies. This is essential for the functionality of the service in its advice and help desk function as well as for training purposes.

Goal 1: Register of ELSI experts operational

- ELSI Tools – leader Irene Schluender (CS ELSI)

The experience with two tools (hSERN for information regarding legal requirements for cross border exchange of samples, and the legal wiki platform with an editorial board validating contributions) in 2015 showed that a further work was necessary to optimise the tools for a range of users and that an orientation portal pointing to the various tools is needed. A Working Group has started a first

assessment in collaboration with the BioMedBridges project.

Goal 2: ELSI tools orientation, access and use procedure

- Help desk in place and further work on tools - Leader Mats Hansson (Co-Director CS ELSI)

The tasks performed in 2015 showed that the help desk needed to be further defined and refined and its organisation integrated with tools and a set of FAQ developed.

Goal 3: Help desk in place

- Evaluate ethics check - leader Anne Cambon-Thomsen (Director CS ELSI)

The development of the ethics check (criteria and procedure adapted to a variety of projects and situations) has been a major task in 2015. The assessment of how it works and how it can be potentially amended is a priority to make it efficient and sustainable and to take into account comments and suggestions from users.

Goal 4: Ethics check assessment

- Dialogue workshop with RECs from different countries - Main responsible Jasper Bovenberg (Co-Director CS ELSI)

Among the fundamental stakeholders of the CS ELSI are the research ethics committees in the various countries; the establishment of a good dialogue with these bodies is a priority for an harmonious operation of the CS ELSI and for it to take its intended place among existing ethical and legal frameworks in Europe. A workshop was chosen as a good start format for 2016. Synergies can be used with the ADOPT-BBMRI-ERIC proposal (D5.4: Operational platform for sharing experience: meeting with representatives of national/regional ethics committees dealing with biobanking research to share experience).

Goal 5: Workshop with REC report

- Inclusion of ELSI aspects in BBMRI-ERIC MoU with relevant international organisations - Leader Anne Cambon-Thomsen (Director CS ELSI)

The representation by the CS ELSI of BBMRI-ERIC as observer in international organisations with ELSI impact of relevance for biobanking and biomolecular resources will be pursued; in addition in order to fully operate for its various missions on the international scene the CS ELSI needs to define clearly terms of collaboration with others.

Goal 6: ELSI in MoUs

- Procedure to enhance public debate and engagement with society - Leader Marialuisa Lavitrano (Co-Director CS ELSI) along with Martin Boeckhout, Gillian Martin, and Johannes Starkbaum of the CS ELSI team.

Although the social dimension of ELSI was always considered highly important, little work was done on this aspect in 2015, as the legal aspects and especially the Data Protection Regulation development were prioritised. Now the fact that several social science experts are members of the CS ELSI team and the link with the Stakeholder Forum can be organised, this area becomes a priority for 2016.

Goal 7: Tools and methodologies for public debate and engagement with society available

- Annual Workshop organisation and topics - Leader Mats Hansson (Co-Director CS ELSI)

Based on the workshop held in Paris, September 2015, this activity appears to be an important way of sharing experiences and of grounding policies in sound expertise. Several topics are considered such as ELSI of high throughput, large scale sequencing, exome of whole genome, (WES; WGS; biobanking for children) are especially considered. The final selection will be made considering also what topics can be addressed in the framework of ADOPT-BBMRI-ERIC/CORBEL projects. Additional topics may be discussed for example in the ELSI part of the EBW meeting in Vienna.

Goal 8: Annual workshop report

- Education - A Summer school - Main responsible Jasper Bovenberg (Co-Director CS ELSI)

In liaison with BioShare, a Summer School had been organised by the Dutch cohort Lifelines in 2015 focusing on a biobanking training course. Such an event will be organised in 2016 and the CS ELSI will take responsibility for a substantial part on ELSI. If possible, CS ELSI will participate in other training actions and their dissemination.

Goal 9: Summer school ELSI outline

5.1.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Register of experts operational	Orange	Orange	Orange	Orange								
ELSI tools orientation, access and use procedure	Blue	Blue	Blue	Blue	Blue	Blue	Blue	Blue				
Help desk in place	Green	Green	Green	Green	Green	Green						
Ethics check assessment									Cyan	Cyan	Cyan	
Workshop with REC report	Light Green	Light Green	Light Green	Light Green	Light Green							
ELSI in MoUs									Olive	Olive		
Tools and methodologies for public debate and engagement with society			Yellow	Yellow	Yellow	Yellow	Yellow	Yellow	Yellow			
CS ELSI Annual workshop report					Purple	Purple	Purple					
Summer school ELSI outline									Red	Red		

5.1.5 Project Group

HQ: CS ELSI, SPM

Projects: ADOPT BBMRI-ERIC

5.1.6 Resources

Staff Function	Full Time Equivalent in Person Month
SPM	4
CS ELSI	51,16
total	55,16

5.2 Work Stream: Rare Diseases

5.2.1 Background

EU framework programmes and foundations have funded several important initiatives on rare diseases and biobanking. However, most of these initiatives lack sustainable governance structures and/or funding solutions. This creates the risk that significant investments made will be lost for both society and patients. A long-term 'home' for these valuable initiatives is still needed. Many RD research projects (e.g., RD-CONNECT, other FP7 projects and the Joint Research Centre) and networks (e.g., EuroBioBank, TREAT-NMD, ORPHANET) have developed shared tools and unified platforms on either biobanks or registries; or both. They have collected biomaterials and data to allow accessibility for research and clinical trials, but how to link biobanks and rare disease-oriented registries to pool samples and clinical information still remains a critical issue. However transnational collection of samples and data from selected populations is even more essential for research on rare diseases than for more common diseases. BBMRI-ERIC is now official partner of RD Connect and alignment with BBMRI-ERIC's procedures is considered greatly beneficial for RD Connect and EuroBioBank biobanks. Moreover, developing synergies between BBMRI-ERIC and RD-Connect training activities will maximise efforts.

Finally, two meetings (the first one in Bologna on 28 March 2015 and the second one during the EATRIS Conference in Amsterdam on 28 May 2015) have been organised by BBMRI-ERIC to kick-start a more structured collaboration in the RD field between the existing ERICs and other Research Infrastructures (such as EATRIS, ECRIN, ELIXIR, EU-OPENSREEN, INFRAFRONTIER) and the projects (e.g., RD Connect, E-RARE PARENT JA, ORPHANET). A follow up meeting took place on 18 September 2015 in Luxemburg. Its goal was to better define the procedure of creating a shared infrastructure on RD among the different ERICs/RD Projects and BBMRI-ERIC is acting as facilitator of further collaborations including the involvement in H2020 calls. The next meeting was scheduled to take place in Hinxton on 19 November 2015.

5.2.2 Mission

To provide real-time support to RD biobanks and/or registries to meet requirements for participation in BBMRI-ERIC, using achievements of different projects on RD biobanks, registries and infrastructures and mapping procedures and tools already available and planning facilities.

5.2.3 Goals & Deliverables

- Coordinating efforts and achievements of different projects involving Rare Disease biobanks, registries and infrastructures and providing a sustainable base for biobanking activities within the RD community,
- Mapping procedures and tools already available in BBMRI-ERIC and adapt for RD biobanking,
- Mapping procedures and tools already available for RD biobanking (RD Connect, JRC, etc.)
- Starting to plan a common ontology between biobanks and registries (in collaboration with RD Connect)
- Starting a Help-desk facility to provide real time support to RD biobanks and/or registries to meet requirements for participation to BBMRI-ERIC,
- Investigate sustainability options for RD biobank networking; this will start next year according to

the timeplan from RD-connect.

5.2.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Reports from meetings of the coordination activity												
Registry/biobank support service/Help-desk facility												
Set and implement quality standards for RD biobanks												
Develop training materials and hold training workshops												

5.2.5 Project Group

HQ: DG, SPM

NN: Contact points for RD as indicated by BBMRI.xx

Projects: RD Connect (amendment ongoing to become participant), ADOPT BBMRI-ERIC (WP6, lead by IOR/Luca Sangiorgi)

5.2.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0,5
SPM	0,25
Total	0,75

5.3 Work Stream: Biomolecular Resources

In 2015, the Biobanking Analysis Resource Catalogue (BARC) database was launched in the Work Stream for Biomolecular Resources, and has now many users from Europe. This year the Molecular Methods Database (MolMeth) protocol will be a part of this Work Stream, which also is a part of the BBMRI-LPC and B3Africa projects.

During the Management Committee meeting in Paris in 2015, Ulf Landegren, Uppsala University and Michael Taussig, Babraham Institute (leaders of the WP4 during BBMRI PP 2008-2011) gave a presentation called: 'BBMRI WP4 and beyond - biomolecular resources in BBMRI-ERIC'. The biomolecular resources include antibody and affinity binder collections, cell lines, clone collections, siRNA libraries and other research tools needed for analysis of biobanked samples. Also repositories of model organisms are considered biomolecular resources when relevant to human diseases. Members of BBMRI-ERIC are convinced that biological human samples including associated medical data and biomolecular research tools are a key resource in unravelling the interplay of genetic and environmental factors causing human diseases and impact on their outcome, identification of new biomarkers and targets for therapy as well as contributing to reduce attrition in drug discovery and development.

The Committee agreed to hold a Workshop 2016 to explore a roadmap for this important task. BBMRI-ERIC biomolecular research tasks could be:

- Implementing quality management including standardised procedures, best practices and appropriate tools to increase the quality of the resources collected and their associated data;
- establishing and operating Common Services for the European biobanking community,
- providing research services for public and private institutions,
- creating and implement technological innovations related to the resources and services and
- providing training and facilitating mobility of researchers to support the establishment of new biobanks and Biomolecular Resource Centres to strengthen and structure the European Research Area.

5.3.1 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. In the current Work Programme, BBMRI-ERIC will build the activities for the second "B" on the open source tool MolMeth. It was created to provide protocols and SOPs to support the collection and usage of biobank material through an open access database. This contributes to an increased usage of biobanking materials and provides a digital infrastructure for harmonisation of biobanking practices.

MolMeth is a publicly accessible database for laboratory protocols accessible at www.molmeth.org containing protocols, standardised methods and data storage recommendations for analysis of DNA, RNA, proteins and metabolites, applicable to biobank samples. Even though MolMeth is functional and

open to the public, it remains under continuous development and expansion of protocols.

MolMeth will focus on partnering with organisations such as SciLife lab and IARC to collect protocols as well as support the development of harmonised standards within BBMRI-ERIC and B3Africa associated programs.

A liaison between Work Plan 2, Work Stream 2.1 Molecular In-vitro Diagnostic Examination Standards of CEN/TC 140 will be build up to evaluate and validate methods offered for research use.

5.3.2 Mission

The mission of this Work Stream is to provide an open platform to support the development and dissemination of methods relevant to biobanking and biomolecular examinations. Standard operating procedures (SOPs) will be developed for molecular examination of samples, added with sample processing and handling procedures and will be based on traceability of track change records for the applicable further development of SOPs. The platform will offer secured and protected areas for sharing methods.

Furthermore a Workshop meeting will take place during Q1 2016.

5.3.3 Goals & Deliverables

MolMeth is fully operational due to an initial development phase funded by BBMRI.se and is now focused on increasing the size of the database and provide custom solutions for key partners such as BBMRI-ERIC, BBMRI-LPC and the B3Africa project.

- Liaise with the development of WP2, WS 2.1 and implement SOPs to the platform
- Implement BBMRI-LPC published SOPs and protocols
- Build up cooperation with non-commercial and commercial services providing biomolecular solutions and implement applicable methods to the platform for research use
- Continuous accommodation of new standards and protocols on the platform according to evaluated best practices.
- Create case model for a link to scientific publications, including as a source or supplementary on-line information for simplifying methods reporting.
- Liaise with B3Africa project, potentially IT training programme
- Set up a Workshop

5.3.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
1. Liaise with WP2, WS2.1												
2. Implement BBMRI-LPC SOPs												
3. Build up (non-)commercial cooperations												
4. Accommodate new standards & prot.												
5. Create case model...												
6. Liaise with B3Africa project												
7. Workshop												

5.3.5 Project Group

HQ: DG, QM

NN: BBMRI.se

Others: SLU Global Bioinformatics Centre

Projects: crosslinks with BBMRI-LPC and B3Africa.

5.3.6 Resources

The resource is currently funded by BBMRI-LPC.

Staff Function	Full Time Equivalent in Person Month
DG	0,5
QM	1
Total	1,5

6 WORK PLAN: INTERNATIONAL STANDARD DEVELOPMENTS

Since April 2015 BBMRI-ERIC actively contributes in the function of a Observer Liaison to the international standard developments of ISO/TC 276 Biotechnology as well as ISO/TC 212 Clinical laboratory testing and in vitro diagnostic test systems.

ISO/TC 212 is the further development of CEN Standards to international standards.

BBMRI-ERIC is invited to share with the BBMRI-ERIC community the developments of the Working Groups and is asked to contribute to the developments by addressing comments and references.

ISO/TC 276 Biotechnology constituted following Work Groups:

1. ISO/TC 276 WG 1 'Terminology'
2. ISO/TC 276 WG 2 'Biobanks and bioresources'
3. ISO/TC 276 WG 3 'Analytical Methods'
4. ISO/TC 276 WG 4 'Bioprocessing'
5. ISO/TC 276 WG 5 'Data Processing and integration'

ISO/TC 212 further develops following CEN Standards

- ISOTC212 ISO/CD 20166 FFPE RNA
- ISOTC212 ISO/CD 20165 FFPE proteins
- ISOTC212 ISO/CD 20164 FFPE DNA
- ISOTC212 ISO/CD 20186 Blood cellular RNA
- ISOTC212 ISO/CD 20185 Isolated genomic DNA
- ISOTC212 ISO/CD 20091 Isolated ccf DNA
- ISOTC212 ISO/CD 20184 FT isolated RNA
- ISOTC212 ISO/CD 20167 FT isolated proteins

6.1 Work Stream: WG1, 'Terminology'

6.1.1 Background

The ISO/TC 276 WG 1 'Terminology' was constituted by ISO/TC 276 Biotechnology.

Is working on the identification of currently used national and international standards, guidelines and other relevant documents, as well as terms and definitions, related to ISO/TC 276 Biotechnology. The work of this Working Group focuses initially on harmonisation (where possible) rather than on standardisation.

6.1.2 Mission

The central role of BBMRI-ERIC is to keep track of the developments of the Working Groups and act as an information hub for the BBMRI-ERIC community.

6.1.3 Goals and Deliverables

- Conducting active knowledge exchange (ISO ↔ BBMRI-ERIC ↔ BBMRI-ERIC community)
- Initiating commenting phases to ongoing document developments of ISO
- Defending comments of the BBMRI-ERIC family towards the ISO
- Disseminating documents whenever available (ISO ↔ BBMRI-ERIC ↔ BBMRI-ERIC community)
- Attendance in WG Meetings whenever scheduled
- Attending 4th Plenary Meeting and WG Meetings 9-13 May 2016, Washington, DC/USA

6.1.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Dissemination/Commenting												
Participation in WG Meetings												
Participation in 4 th Plenary Meeting												

6.1.5 Project Group

HQ: DG, QM

NN: Experts of BBMRI.xx, QMs & ITMs of BBMRI.xx

6.1.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0,25
QM	0,5
total	0,75

6.2 Work Stream: WG2, 'Biobanks and bioresources'

6.2.1 Background

ISO/TC 276 WG 2 'Biobanks and bioresources' was constituted by ISO/TC 276 Biotechnology.

Is elaborating a package of International Standards in the Biobanking field including human, animal, plant and microorganism resources for Research & Development, but excluding therapeutic products.

6.2.2 Mission

The central role of BBMRI-ERIC is to keep track on the developments of the Working Groups, act as an information hub for the BBMRI-ERIC community.

Evaluation of the pre-examination processes of the published CEN/TC 140 Standards by the BBMRI-ERIC experts of the field.

6.2.3 Goals and Deliverables

- Conducting active knowledge exchange (ISO ⇔ BBMRI-ERIC ⇔ BBMRI-ERIC community)
- Initiating commenting phases to ongoing document developments of ISO
- Defending comments of the BBMRI-ERIC family towards the ISO
- Disseminating Documents whenever available (ISO ⇔ BBMRI-ERIC ⇔ BBMRI-ERIC community)
- Attendance in WG Meetings whenever scheduled
- Attending 4th Plenary Meeting and WG Meetings 9-13 May 2016, Washington DC/USA

6.2.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Dissemination/Commenting												
Participation in WG Meetings												
Participation in 4 th Plenary Meeting												

6.2.5 Project Group

HQ: DG, QM

NN: Experts & QMs of BBMRI.xx

6.2.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0,25
QM	1
Total	1,25

6.3 Work Stream: WG3, 'Analytical Methods'

6.3.1 Background

The ISO/TC 276 WG 3 'Analytical Methods' was constituted by ISO/TC 276 Biotechnology.

Is developing standards for accurate, reproducible and robust measurement and analysis in support of biotechnologies. WG 3 will develop a package of International Standards for biologically relevant molecules and entities, including nucleic acids, proteins, and cells. This WG will develop horizontal standards and, when applicable, vertical / particular standards for industry sectors. The WG will also coordinate with relevant technical committees and standardisation initiatives.

6.3.2 Mission

The central role of BBMRI-ERIC is to keep track of the developments of the Working Groups, act as an information hub for the BBMRI-ERIC community.

Evaluation of the pre-examination processes of the published CEN/TC 140 Standards by the BBMRI-ERIC experts of the field.

Evaluation of processes relevant to molecules, nucleic acids, proteins and cells.

6.3.3 Goals and Deliverables

- Conducting active knowledge exchange (ISO ⇔ BBMRI-ERIC ⇔ BBMRI-ERIC community)
- Initiating commenting phases to ongoing document developments of ISO
- Defending comments of the BBMRI-ERIC family towards the ISO
- Disseminating Documents whenever available (ISO ⇔ BBMRI-ERIC ⇔ BBMRI-ERIC community)
- Attendance in WG Meetings whenever scheduled
- Attending 4th Plenary Meeting and WG Meetings 9-13 May 2016, Washington DC/USA

6.3.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Dissemination/Commenting												
Participation in WG Meetings												
Participation in 4 th Plenary Meeting												

6.3.5 Project Group

HQ: DG, QM

NN: Experts & QMs of BBMRI.xx

6.3.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0,3
QM	0,5
Total	0,8

6.4 Work Stream: WG4, 'Bioprocessing'

6.4.1 Background

The ISO/TC 276 WG 4 'Bioprocessing' was constituted by ISO/TC 276 Biotechnology.

Is identifying standardisation needs in four major technology spaces: 1) component materials control; 2) bioreactor processes; 3) collection, separation, purification and formulation; and 4) handling, transportation & storage. Each category of materials / technology space may affect many current and future applications.

6.4.2 Mission

The central role of BBMRI-ERIC is to keep track of the developments of the Working Groups, act as an information hub for the BBMRI-ERIC community, if applicable for BBMRI-ERIC.

6.4.3 Goals and Deliverables

- Conducting active knowledge exchange (ISO ↔ BBMRI-ERIC ↔ BBMRI-ERIC community)
- Initiating commenting phases to ongoing document developments of ISO
- Defending comments of the BBMRI-ERIC family towards the ISO
- Disseminating Documents whenever available (ISO ↔ BBMRI-ERIC ↔ BBMRI-ERIC community)
- Attendance in WG Meetings whenever scheduled
- Attending 4th Plenary Meeting and WG Meetings 9-13 May 2016, Washington DC/USA

6.4.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Dissemination/Commenting												
Participation in WG Meetings												
Participation in 4 th Plenary Meeting												

6.4.5 Project Group

HQ: DG, QM

NN: Experts, QMs & ITMs of BBMRI.xx

6.4.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0,25
QM	0,5
Total	0,75

6.5 Work Stream: WG5, 'Data Processing and integration'

6.5.1 Background

The ISO/TC 276 WG 5 'Data Processing and integration' was constituted by ISO/TC 276 Biotechnology. Will develop standards in the field of processing and integration of life science data and derived models, simulations and graphical representations. This includes annotation, analysis, validation, integration and comparison of data and models from heterogeneous sources. The main focus is the definition of interfaces; formats and metadata connecting related data and models.

6.5.2 Mission

The central role of BBMRI-ERIC is to keep track of the developments of the Working Groups, act as an information hub for the BBMRI-ERIC community.

6.5.3 Goals and Deliverables

- Conducting active knowledge exchange (ISO ↔ BBMRI-ERIC ↔ BBMRI-ERIC community)
- Initiating commenting phases to ongoing document developments of ISO
- Defending comments of the BBMRI-ERIC family towards the ISO
- Disseminating Documents whenever available (ISO ↔ BBMRI-ERIC ↔ BBMRI-ERIC community)
- Attendance in WG Meetings whenever scheduled
- Attending 4th Plenary Meeting and WG Meetings 9-13 May 2016, Washington DC/USA

6.5.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Dissemination/Commenting												
Participation in WG Meetings												
Participation in 4 th Plenary Meeting												

6.5.5 Project Group

HQ: DG, QM, ITM

NN: QMs & ITMs of BBMRI.xx

6.5.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0,3
ITM	0,8
QM	1
Total	2,3

7 WORK PLAN: BIOIMAGING

7.1 Work Stream: Biobanks meet Imaging

7.1.1 Background

In March 2014, the European Society of Radiology (ESR) established a dedicated working group (ESR WG on Imaging Biobanks) with the task of monitoring the existing imaging biobanks in Europe. The goal of the WG is to investigate the existence, consistency, geographical distribution and type of imaging biobanks in Europe, so as to promote the federation of imaging biobanks and communication of their findings in a white paper.

On 29 April 2015, the ESR Research Committee, EIBALL-European Imaging Biomarkers Alliance, EBIR-European Institute for Biomedical Imaging Research and the Head of European/International Affairs had a joint meeting with BBMRI-ERIC in Graz to explore future collaboration. During the meeting ESR showed persuasively that imaging biobanks are essential and should be linked with biobanks. The ESR would like to motivate centres that are already part of a National Node of BBMRI-ERIC to connect imaging data to their biobanks. Some IT related issues were raised; also, it was explained how DICOM standards are used for the exchange of medical images and explored if the MIABIS/OMIABIS models provide a potential basis for the modelling of imaging biobanks.

A first workshop took place on 7 October 2015 (back-to-back with the ESR Management in Radiology Annual Meeting in Barcelona) to elaborate in depth all topics as well as to bring together experts from different biobanks using images. A second larger workshop-like meeting is planned for the European Congress of Radiology – ECR 2016.

7.1.2 Mission

The 'ECR 2016 - European Congress of Radiology' will take place in Vienna, Austria between 2 and 6 March 2016. More than 10,000 attendees are expected to attend the meeting. ECR/BBMRI-ERIC will sign an MoU and will have a joint session under the Professional Challenges Session: Biobanks meet imaging. This will include both population based studies, digitalised pathology and common ontologies. BBMRI-ERIC will also present the state of the art for biobanking. ECR will attend the Europe Biobank Week in Vienna, Austria in September 2016, as they did during HandsOn: Biobanks in Milan 2015.

Additionally, a Working Group connecting the medical imaging community will be set up to streamline the collaboration in order to involve, through each National delegate, the National societies of medical imaging.

7.1.3 Goals and Deliverables

A joint Working Group will be set up to streamline the collaboration. A section about biobanks and imaging will be held at the 2016 European Congress of Radiology.

7.1.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Preparing the meeting Biobanks meet imaging												
BBMRI-ERIC/ESR meeting in Vienna 2016												
Follow up meeting with ECR for further plans, setting up a WG												
Invite ESR to the EBW meeting												

7.1.5 Project Group

HQ: DG, AD, EPM

Other: ERC

7.1.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0.5
AD	0,5
EPM	Projects
Total	1

8 WORK PLAN: ASSESSMENT AND IMPROVEMENT OF BBMRI-ERIC

The Community legal framework for a European Research Infrastructure Consortium (ERIC) came into effect on 28 August 2009. This specific legal form is designed to facilitate the joint establishment and operation of research infrastructures of European interest. The ERIC Regulation was amended in December 2013 to allow better reflection of the contributions of associated countries in the ERIC by putting those countries at a more equivalent level as Member States in the governing bodies of the ERIC in terms of voting rights in the light of the possible of ERICs and to encourage their increased participation of associated countries in ERICs. Most recently, the European Commission has announced plans for an evaluation of the ERIC instrument and its model statutes.

8.1 Work Stream: BBMRI-ERIC Evaluation

8.1.1 Background

BBMRI-ERIC was founded on 3 December 2013, making it one of the few existing Research Infrastructures opting for the ERIC legal framework (currently 11). BBMRI-ERIC constituted its respective governance boards and approved the appointment of its directors during the 1st session of its Assembly of Members on 22 January 2014. The Headquarters of BBMRI-ERIC is located in Graz, Austria. BBMRI-ERIC can be considered a pioneer for setting up a research infrastructure: In 2008, BBMRI was one of the first projects entering the Preparatory Phase of the Roadmap of the European Strategy Forum on Research Infrastructures (ESFRI). Funded by the EC's Framework Programme 7, the Research Infrastructure was formulated and has been presented to the Member States of the European Union and Associated States for approval and funding. These efforts culminated in some Member States decision to apply for the European Research Infrastructure Consortium (ERIC) legal framework, which was ultimately supported by sixteen Member States and one International Organisation (IARC). Most recently, the UK joined BBMRI-ERIC as its 18th member.

8.1.2 Mission

In the autumn of 2016, when BBMRI-ERIC has been up and running about half of its first 5-year period, and as a part of the Work Programme 2016, BBMRI-ERIC will perform a self-evaluation. This will be done in conjunction with an AoM meeting with two extra days. AoM, MC, CS, HQ, SEAB as well as members from the commission will be invited for this self-evaluation.

8.1.3 Goals and Deliverables

The plan is to conduct a review on the Statutes, the Governance model, the Common Services principal rules (tender process, directorship, host country contribution, etc.), internal rules (staffing, RoPs, financial rules), administrative processes (Operations Handbook) and the Work Programme's general structure (Work Plans-Work Streams, Annexes, etc.)

As a result, a report will be written by the DG.

8.1.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Planning of the self-evaluation												
Scientific Retreat #3												
Self-evaluation in conjunction with AoM meeting												
Report												

8.1.5 Project Group

HQ: all

NN: all

8.1.6 Resources

Staff Function	Full Time Equivalent in Person Month
DG	0,5
AD	0,5
SPM	0,5
QM	0,5
EPM	Projects
ITM	0,5
CA	0,5
SEC	0,5
FPA	0,5
FCA	Projects
CS ELSI	0
CS IT	0
Total	4

8.2 Work Stream: Integrating Activities of National Nodes

8.2.1 Background

On 21 September 2015, Working Group 8: Financial Workflows had a meeting to discuss how to open up national and regional activities for other BBMRI-ERIC member and observer countries thereby gaining access to VAT exemption.

The basis of any activities is the Annual Work Programme agreed upon by the Assembly of Members. Any opening up of activities, which might then require purchase of goods and services, must therefore also be included in the Work Programme and approved by the AoM.

8.2.2 Mission

For the Work Programme 2016, we are developing a process by which such opening of activities and its related financial implications can be easily implemented. The intention is to negotiate with the National Nodes a process by which the Finance Committee can evaluate such requests on a regular basis and the Work Programme can be amended.

8.2.3 Goals and Deliverables

Explore in which way the National Nodes and their national/regional activities can benefit from the ERIC status.

8.2.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Draft process document ready												
AoM approves Work Programme 2016 amendments including process												
Quarterly FC sessions												

8.2.5 Project Group

HQ: AD, FPA

NN: input by all BBMRI.xx

8.2.6 Resources

Staff Function	Full Time Equivalent in Person Month
AD	2
FPA	1
Total	3

9 WORK PLAN: BIOBANK OUTREACH

9.1 Work Stream: Biobanking Conference (formerly HOBb)

9.1.1 Background

The *HandsOn: Biobanks* (HOBb) conference is a yearly event by BBMRI-ERIC hosted by a National Node(s). The HOBb's concept includes thematic idea labs, science cafés, exhibitions, poster presentations and knowledge sharing to present, discuss and develop ideas for improving and sharing the practice of biobanking. It brings together academics, representatives of industry, physicians and healthcare professionals, patient groups, policy makers, public representatives and legislators. Part of the conference's programme is an interactive sequence of displays where participants can go through the biobanking process step by step. The aim of the HOBb is to share visions, knowledge and solutions.

It was agreed to host the *HandsOn: Biobanks 2016* by BBMRI.at focusing on CEN and ISO standards, the General Data Protection Regulation (GDPR), new tools for public engagement, data management, medical imaging and biobanking, and host a roadshop of innovative business ideas related to biobanking for partnering.

On 30 September 2015, BBMRI-ERIC and ESBB formed a strategic alliance for the benefit of European biobanking efforts. Starting in 2016, the two organisations will jointly organise the most important annual biobanking conference in Europe and facilitate collaboration on activities related to biobanking and biopreservation of samples for research and development. This agreement emphasises that biobanks are a European strength.

ESBB is an association established under French law (Loi 1901) for people involved in the collection and storage of biological materials from all species. The society is focused on Europe, the Middle East and Africa.

ESBB and BBMRI-ERIC agreed to name the joint biobanking conference henceforth Europe Biobank Week (EWB).

9.1.2 Mission

As a part of strengthening overall collaboration in several complementary fields in biobanking between both organisations the purpose of this MoU is to define areas of collaboration between BBMRI-ERIC and ESBB, including four consecutive joint annual conferences from 2016 through to 2019. In autumn 2016, the first joint conference will take place in Vienna and 2017 in Stockholm.

9.1.3 Goals and Deliverables

A joint organising committee will be formed for each of the conferences, to plan joint aspects of the conference, including location and site negotiation, registration services, general office services, public relations, sponsorship/revenue generation, exhibition services, financial/accounting services, promotions, meeting logistics and onsite services, contract negotiation, as well as abstract, organisation, speaker, marketing, committee, and website management. The organising committee will have equal representation from ESBB and BBMRI-ERIC. The chair of the committee will alternate between ESBB and BBMRI-ERIC each year. Workshops and meetings from other organisations and/or projects might be held in conjunction (e.g., LPC Forum).

9.1.4 Time Plan

Deliverable \ month of 2016	01	02	03	04	05	06	07	08	09	10	11	12
Pre-Production (Vienna)	■	■	■	■	■	■	■	■	■			
Joint Conference (Vienna)									■			
Post-Production/Exploitation									■	■	■	■
Pre-Production (Stockholm)									■	■	■	■

9.1.5 Project Group

HQ: AD, EPM, FCA, FPA, CA

NN: BBMRI.at (local host Vienna 2016)

Other: ESBB, IBS, ISBER & other potential partners

Projects: BBMRI-LPC (LPC Forum)

9.1.6 Resources

Staff Function	Full Time Equivalent in Person Month
AD	0,5
FPA	2
CA	1
Total	3,5

10 WORK PLAN: CONTINUED WORK STREAMS

BBMRI-ERIC commits to continue the following Work Streams as established and specified in previous Work Programmes.

The HQ Person Month Distribution is specified in Fehler! Verweisquelle konnte nicht gefunden werden. in the Annex.

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

Equals Work Stream 5.1 of the Work Programme 2015

The Scientific Retreat features short talks, breakout sessions, and the opportunity for the National Node and Common Service Directors and distinguished colleagues to meet and exchange information and ideas away from the pressures of daily business.

The BBMRI-ERIC Scientific Retreat 2016 is foreseen to take place from 23 to 25 May in Greece. It is planned to discuss preliminary Work Programme 2017 and to identify the key fields of action for the years to come.

10.2 Work Stream: Central Executive Management Office

Equals Work Stream 1.1 of the Work Programme 2014

The Central Executive Management Office (CEMO or Headquarters) based in Graz is led by the Director General and is responsible for the executive management of BBMRI-ERIC.

The CEMO will continue its activities as specified in Article 13 of the BBMRI-ERIC Statutes.

10.3 Work Stream: Communication

Equals Work Stream 2.2 of the Work Programme 2014

Our communication platform consists of the following elements: public website, intranet, multiple mailing lists, e-Newsflash (mailchimp), templates and promotional material (e.g., poster, brochure...). It is based on a corporate design identity package as specified in a corporate design manual.

The communication platform is regularly updated and improved to suit the needs of the BBMRI-ERIC family. The possibility of holding an Open Biobank Day throughout Europe is being explored, together with streamlining communication and public engagement activities in close collaboration with the CS ELSI.

10.4 Work Stream: Webinars

Equals Work Stream 2.6 of the Work Programme 2014

Webinars are interactive seminars or presentations conducted via the web. Regular webinars are understood as important communication tools for BBMRI-ERIC, its stakeholders and its users.

BBMRI-ERIC will continue and intensify its webinar activities in 2016.

10.5 Work Stream: Newsletter

Equals Work Stream 2.7 of the Work Programme 2014

The periodic 'Biobanks Europe' Newsletter addresses recent developments, current challenges, and achievements of BBMRI-ERIC and the National and Organisational Nodes. Each issue focuses on one National Node and current key topics (e.g., GDPR). The Newsletter is available in print and online.

10.6 Work Stream: Education and Training

Equals Work Stream 5.3 of the Work Programme 2015

Education and Training is the backbone of a knowledge-based society. 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, to deliver a European curriculum, sustainability, access and training. This Work Stream is cross-linked with the tasks and deliverables of the H2020 project RItrain.

10.7 Work Stream: Infectious Material

Equals Work Stream 6.3 of the Work Programme 2015

The mission of this Work Stream is to develop a common strategy on how biobanks with infectious material should be integrated into BBMRI-ERIC based on the cooperation with ERINHA and EVAg (European Virus Archive goes global) under the leadership of Working Group 12: Infectious Diseases.

10.8 Work Stream: Expert Centres

Equals Work Stream 7.1 of the Work Programme 2015

BBMRI-ERIC is developing the concept of Expert Centre as public-private partnerships in the precompetitive, not-for-profit field to provide a new structure to perform research projects that would face difficulties under currently established models of academic-industry collaboration. By definition, Expert Centres are key intermediaries between public and private sectors performing the analysis of biological samples under internationally standardised conditions. The concept and rationale have been presented together with model cases (European Journal of Human Genetics (2015) 23, 893-900; doi:10.1038/ejhg.2014.235; published online 19 November 2014) and will be developed further along these specifications.

10.9 Work Stream: Fundraising Activities

Equals Work Stream 4.1 of the Work Programme 2014

BBMRI-ERIC continues its activities to allocate additional funding (e.g., H2020).

10.10 Work Stream: Stakeholder Forum

Equals Work Stream 3.4 of the Work Programme 2014

Within BBMRI-ERIC, the Stakeholder Forum (SF) will relaunch its activities from the Preparatory Phase. To ensure sustainable coordination of the SF activities, a SF Secretariat shall be established

11 PROJECTS ACTIVE

This section shows all projects that BBMRI-ERIC is currently involved in (as of November 2015).

11.1 ADOPT BBMRI-ERIC

implemEntation and Operation of the gateway for health into BBMRI-ERIC

Topic: H2020-INFRADEV-3-2015 **Type of Action:** RIA **Duration:** 36 months

Start Date: 1 October 2015 **Grant Agreement Nr:** 676550

Web: <http://bbmri-eric.eu/adopt-bbmri-eric>

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, funding for key activities

Status: score 12 (threshold 10) / accepted

Abstract: **Lead by 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), BELSPO on behalf of BBMRI.be, Belgium; SNF on behalf of BBMRI.ch, Switzerland; MMCI on behalf of BBMRI.cz, Czech Republic; Charité on behalf of BBMRI.de, Germany; UT on behalf of BBMRI.ee, Estonia; INSERM on behalf of BBMRI.fr, France; AA on behalf of BBMRI.gr, Greece; LUMC on behalf of BBMRI.nl, The Netherlands; NTNU on behalf of BBMRI.no, Norway; Kierujący Biobankiem Wrocławskiego Centrum; Badań EIT on behalf of BBMRI.pl, Poland; KI on behalf of BBMRI.se, Sweden; Dokuz Eylul University on behalf of BBMRI.tr, Turkey; IARC, France; TUM, Germany; IOR, Italy, University College London, United Kingdom

11.2 B3Africa

Bridging Biobanking and Biomedical Research across Europe and Africa

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

Start Date: 1 July 2015 **Grant Agreement Nr:** 654404 **Web:** <http://www.b3africa.org/>

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, ELSI activities will be informative for the work of the CS ELSI

Status: score 13 (threshold 10) / accepted

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

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

11.3 Rltrain

Research Infrastructures Training Programme

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

Start Date: 1 September 2015 **Grant Agreement Nr:** 654156 **Web:** <http://rltrain.eu/>

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: Lead by BBMRI-ERIC: The overarching goal of Rltrain 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, [ref]) 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

11.4 CY-Biobank

Biobanking and the Cyprus Human Genome Project

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

Start Date: 1 September 2015 **Grant Agreement Nr:** 664561

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

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); T5.1-D5.1, T5.2-D5.2, T5.3-D5.3

Status: score 13 (threshold 10) / accepted

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

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

11.5 PhenoMeNal

PhenoMeNal: A comprehensive and standardised e-infrastructure for analyzing medical metabolic phenotype data

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

Start Date: 1 September 2015 **Grant Agreement Nr:** 654241

Web: <http://bbmri-eric.eu/phenomenal>

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 organise the metabolomics community at the European level, and we are keen to do it in full synergy with BBMRI.

Status: score 13 (threshold 10) / accepted

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

List of Participants: EMBL-EBI, Imperial College of Science, Technology and Medicine, Leibniz-Institut für Pflanzenbiochemie, Universitat de Barcelona, University of Birmingham, Consorzio Interuniversitario 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

11.6 EGI-Engage

EGI-Engage **Engaging the EGI Community towards an Open Science Commons**

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

Start Date: 1 May 2015 **Grant Agreement Nr:** 654142

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

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: score 15 (treshold 10) / accepted

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

List of Participants: Stichting European Grid Initiative, 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 Pravnickyh 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 Tudományos 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, Akademia 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

11.7 CORBEL

Coordinated Research Infrastructures Building Enduring Life-science services

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

Start Date: 1 September 2015 **Grant Agreement Nr:** 654248

Web: <http://bbmri-eric.eu/corbel>

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 € 454,340.08)
- (2) bbmri.fi /THL € 80500,00
- (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-ordinated by BBMRI-ERIC

WP3: case studies (National Nodes); WP7: CS ELSI; WP9: Training

Status: score 11 (treshold 10) / accepted

Abstract: Lead by European Molecular Biology Laboratory: 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 (CIRMMMP), Agencia Estatal Consejo Superior de Investigaciones Cientificas (CSIC), Centre National de la Recherche Scientifique (CNRS), Stazione Zoologica Anton Dohrn (SZN), The University Court of the University of St Andrews (USTAN), Forschungsverbund Berlin e.V. (FVB), Imperial College of Science, Technology and Medicine (Imperial), Max Delbrueck Centrum fuer Molekulare Medizin (MDC), The University of Manchester (UNIMAN), Stichting VU-VUMC (VU/VUmc), Deutsches Krebsforschungszentrum (DKFZ), Leibniz-Institut DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH (DSMZ), Jacobs University Bremen GGmbH (JACOBS UNI), Koninklijke Nederlandse Akademie van Wetenschappen (KNAW), Tieteen Tietotekniikan Keskus Oy (CSC), CAB International (CABI), Medical University of Vienna (MUW), Academisch Ziekenhuis Groningen (UMCG), Universita Degli Studi di Torino (UNITO), Erasmus MC, Univ Groningen

11.8 BBMRI-LPC

Biobanking and Biomolecular Resources Research Infrastructure – Large Prospective Cohorts

Topic: INFRA-2012-1.1.9 **Type of Action:** CP&CSA **Duration:** 48 months

Start Date: 1 February 2013 - BBMRI-ERIC full partner: as of 1 April 2014 (amendment ongoing)

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

Total requested Grant by Consortium: € 8M

Total requested Grant by BBMRI-ERIC: € 14,552

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

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

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

List of Participants: HELSINGIN YLIOPISTO (UH-FIMM); ACADEMISCH ZIEKENHUIS LEIDEN - LEIDS UNIVERSITAIR MEDISCH CENTRUM (LUMC); CENTRE INTERNATIONAL DE RECHERCHE SUR LE CANCER (IARC-WHO); IMPERIAL COLLEGE OF SCIENCE, TECHNOLOGY AND MEDICINE (ICL); MEDIZINISCHE UNIVERSITAT GRAZ MEDUNI GRAZ (MUG); KAROLINSKA INSTITUTET (KI); GENOME RESEARCH LIMITED (WTSI); ACADEMISCH ZIEKENHUIS GRONINGEN (UMCG); HELMHOLTZ ZENTRUM MUENCHEN DEUTSCHES FORSCHUNGSZENTRUM FUER GESUNDHEIT UND UMWELT GMBH (HMGU); NORGES TEKNISK-NATURVITENSKAPELIGE UNIVERSITET (NTNU); TARTU ULIKOOL (UTARTU); UPPSALA UNIVERSITET (UU); CENTRE NACIONAL D'ANÀLISI GENÒMICA-FUNDACIO CENTRE DE REGULACIO GENOMICA (CNAG-CRG); CAMBRIDGE PROTEIN ARRAYS LTD (CPA); PECSI TUDOMANYEGYETEM - UNIVERSITY OF PECS (UP); The Research Institute of the Mc Gill University Health Centre (RI MUHC); LEGAL PATHWAYS BV (Legal Pathways); ISLENSK ERFDAGREINING EHF (DECODE); TERVEYDEN JA HYVINVOINNIN LAITOS (THL); INTERNATIONAL PREVENTION RESEARCH INSTITUT-IPRI MANAGEMENT (IPRI); LATVIJAS BIOMEDICINAS PETIJUMU UN STUDIJU CENTRS (LBMC); SVEUCILISTE U SPLITU (UNIVERSITY OF SPLIT, CCGH); WROCLAWSKIE CENTRUM BADAN

EIT+ SP Z O.O (EIT+); KLINIKUM RECHTS DER ISAR DER TECHNISCHE UNIVERSITAT MUNCHEN (TUM-MED); INSTITUT NATIONAL DE LA SANTE ET DE LA RECHERCHE MEDICALE (INSERM); MedLawconsult (Medlaw); UNIVERSITEIT MAASTRICHT (MU); NASJONALT FOLKEHELSEINSTITUTT (NIPH); STATENS SERUM INSTITUT (SSI)

Amendment on-going:

UNIVERSITY OF BRISTOL (UBRIS)

BBMRI-ERIC

UNIVERSITA' DEGLI STUDI DI MILANO-BICOCCA (UNIMIB)

11.9 EMTRAIN

European Medicines Research Training Network

Topic: FP7/2007-2013 **Type of Action:** IMI **Duration:** 84 months

Start Date: 1 October 2009 **BBMRI-ERIC full partner:** as of 1 October 2015

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 Institute / 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

11.10 BioMedBridges

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

Topic: FP7 INFRA-2011-2.3.2 **Type of Action:** CP-CSA Infra **Duration:** 36 months

Start Date: 1 January 2012 **BBMRI-ERIC full partner:** as of 1 October 2014

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 1,000 institutions from more than 36 ESFRI Member States and Associated Countries.
- Each of them brings together its own large community of users to build a coordinated infrastructure. This process has already had a major impact on coordination of national infrastructures within each member state.
- Essentially all BMS RIs are distributed infrastructures, with nodes in many European member states.

List of Participants: European Molecular Biology Laboratory, University of Oxford, Karolinska Institutet, Science and Technology Facilities Council, Heinrich Heine Universität Düsseldorf, Leibniz-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

12 CORE BUDGET

According to the Statutes, BBMRI-ERIC’s budget shall consist of a) financial contribution of Members and Observers, b) contributions by the Host Member State and the hosting countries of Common Services; and c) any other income. Categories a) and b) are called the 'core budget', whereas category c) is called external funding.

The budget tables for 2016 are included as for the previous years in the separate document 'Budget 2016' and provide full transparency for both estimated expenses as well as a calculation for expected Membership Fees for 2016, 2017 and 2018 for both for the core budget and external funding. As it is very difficult to forecast which countries will join BBMRI-ERIC in 2018, the same estimates of membership and observership fees as 2017 are used.

Table 2: Core Budget Table

Core Budget	2015 approved (€)	2015 Q 1-3 actual (€)	2016 expected (€)	2017/2018 expected (€)
EARNINGS	2,028,739.00		2,134,814.00	2,281,554.00
EXPENDITURES	-2,028,739.00	-	-2,134,814.00	-2.281.554.00

For the purpose of this version, which is submitted to the SC and FC, it is important to mention that Greece and Switzerland still have not paid (as of 25 September 2015) their annual contributions for either the years 2014 or 2015. For Greece, to date, no formal explanation was given for this long delay. The budget tables of the document AoM/5/5 include estimates of expenditures for the years 2017 and 2018 in order to provide the AoM tools for including the membership fees in the planning their respective budgets. Detailed justifications for all estimated expenses are provided in case of deviation of previous years.

The assumptions behind the proposed budget 2016 are as follows:

Four more countries may join during 2016, namely the Croatia, Cyprus, Ireland and Latvia. With Croatia we are planning a follow up meeting with ministerial representatives in late 2015 or early 2016. Cyprus has expressed its will to join and Ireland has expressed its interest in joining BBMRI-ERIC in 2016 in their National Roadmap. Latvia is currently updating its National Roadmap and Ministerial representatives have indicated joining next year. With Portugal, separate discussions have been in progress allowing us to consider their application also during 2016. To give a conservative estimate, we have calculated their contribution as observers only (cumulative for those 4 countries the fee is €35,967.00). We have positive signals also from other countries, but have excluded the latter from our calculations as they will very likely join only at a later stage. Norway has implemented the ERIC regulation into its national law and is a full member to BBMRI-ERIC as of 1 January 2016. Poland also seems likely to upgrade to Membership too and might send in the request before the end of the year. *As a contingency plan – in case the mentioned countries do not request observership – we will reduce expenses within the core budget (e.g., travel expenses) accordingly and shift some of the expenses for CS IT and CS ELSI from the ADOPT BBMRI-ERIC project (i.e., external funding) to the core budget.*

The Common Services' budget estimates are based on the ELSI application on the application for the Common Service for IT and the Stakeholder Forum Secretariat (reduced by deleting the reserve and increased to take account of the UK joining).

As shown in previous sections, a large number of grant applications with BBMRI-ERIC participation had not only been submitted but also approved. BBMRI-ERIC is the primary recipient of funding within these applications (€3,745,873.00 are foreseen as pre-finance payment or actual payments during 2015). Substantial amounts are earmarked for linked 3rd parties (National Nodes) and other partners

totalling €1,003,416.00 during 2015.

In terms of earnings, the finally submitted draft budget 2016 of €2,134,814.00 would be split into hosting country contributions of €290,820.00 (this is for the HQ in Graz, and the Common Services respectively) and Membership contributions of €1,843,994.00 as can be seen in the tables of document AoM/5/5. This results in an overall decrease of Membership Fees for all countries.

The subject of in-kind contribution 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 way 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 then 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 for in kind contribution as discussed in detail above).

In the event that all expenses of personnel of the Common Services ELSI and IT as well as the Stakeholder Forum Secretariat could be provided by in kind, the cash contributions of Member States would be reduced by €381,516.00 to €1,389,203.00 (instead of €1,770,719.00). This has reduced the cash contribution for some countries drastically, especially those hosting the Common Services. Common Service staff are either directly employed at BBMRI-ERIC, or seconded based on a formal agreement with the employer.

ANNEX

Table 3: HQ Person Month Distribution per Work Stream of the Work Programme 2016

Legend: Director General (DG), Administrative Director (AD), Senior Project Manager (SPM), Senior IT/Data Protection Manager (ITM), Quality Manager (QM), Finance and Project Assistant (FPA), Secretary/Receptionist (SEC), Communication Assistant (CA). EU Project Manager (EPM) and Finance and Communication Assistant (FCA) are financed through Projects (Work Plan 11).

Work Plan	2016	2015	2014	DG	AD	SPM	ITM	QM	FPA	SEC	CA	EPM	FCA	CS ELSI	CS IT	Specification
1	1.1 Development of IT Gateway to European Biobanks	1.1 New Gateway/Catalogue	7.1 Biobank Catalogue	2			6								46,85	new/specified WS
1	1.2 Operations of BBMRI-ERIC IT Infrastructure						1								4,6	new/specified WS
1	1.3 Interfaces to other e-Infrastructures and IT-related Projects			2			1									new/specified WS
2	2.1 Molecular In-vitro Diagnostic Examination Standards of CEN/TC 140	2.1 QMS	5.1 QMS	0,5				2								new/specified WS
2	2.2 Self-Assessment Tool for Biobanks	2.2 Self Evaluation	5.3 Self Evaluation	0,25			0,5	2								new/specified WS
2	2.3 Implementation of Performance Indicators	2.3 BRIF		0,5				2								new/specified WS
3	3.1 HIB - Disease-oriented Biobanks															ADOPT BBMRI-ERIC
3	3.2 HIB - Archived Tissues	3.1. Clin Bio		0,25												new/specified WS
3	3.3 HIB - Liquid Biopsies															ADOPT BBMRI-ERIC
3	3.4 HIB - Immortalised Cell Lines															ADOPT BBMRI-ERIC
3	3.5 HIB - Microbiome			0,25												new/specified WS
3	3.6 HIB - Biomarkers Verification and Validation Models															ADOPT BBMRI-ERIC
4	4.1 BBMRI-LPC	4.1 BBMRI-LPC		0,5												new/specified WS
5	5.1 Common Service ELSI					4								51,16		new/specified WS
5	5.2 Rare Diseases			0,5		0,25										new/specified WS
5	5.3 Biomolecular Resources			0,5				1								new/specified WS
6	6.1 WG1, 'Terminology'	2.5 Biobank Lexicon	8.2 Lexicon	0,25				0,5								new/specified WS
6	6.2 WG2, 'Biobanks and bioresources'			0,25				1								new/specified WS
6	6.3 WG3, 'Analytical Methods'			0,3				0,5								new/specified WS
6	6.4 WG4, 'Bioprocessing'			0,25				0,5								new/specified WS
6	6.5 WG5, 'Data Processing and integration'			0,3			0,8	1								new/specified WS
7	7.1 Biobanks meets Imaging			0,5	0,5											new/specified WS
8	8.1 BBMRI-ERIC Evaluation			0,5	0,5	0,5	0,5	0,5	0,5	0,5	0,5					new/specified WS
8	8.2 Integrating Activities of National Nodes				2				1							new/specified WS
9	9.1 Biobanking Conference	5.2 HandsOn:Biobanks			0,5				2		1					new/specified WS
10	10.1 Scientific Retreat with the BBMRI-ERIC National Nodes	5.1 Retreat				1										continued WS
10	10.2 Central Executive Management Office		1.1 CEMO		5				6,5	11,5	1					continued WS
10	10.3 Communication		2.2 Communication			3					5,5					continued WS
10	10.4 Webinars		2.6 Webinars													continued WS
10	10.5 Newsletter		2.7 Newsletter			1					1					continued WS
10	10.6 Education & Training	5.3 E&T			1				1							continued WS
10	10.7 Infectious Material	6.3 Inf Mat														continued WS
10	10.8 Expert Centres	7.1 Expert Centre	6.1 Expert Centre					1								continued WS
10	10.9 Fundraising Activities		4.1 Fundraising		2	2			1							continued WS
10	10.10 Stakeholder Forum		5.2 Partner Charter		0,5	0,25										completed
			7.2 BioBankCloud													completed
			5.2 Partner Charter													completed
			7.2 BioBankCloud													completed
		2.4 Approval														completed
			8.1 MIABIS													completed (MIABIS 2.0)
			7.3 CoBiBa													included in WS 6.2
			7.3 CoBiBa													included in WS 6.2
11	11 Projects Active											12	12			
				9,6	12	12	9,8	12	12	12	9	12	12	51,16	51,45	

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ABBREVIATIONS

AD	Administrative Director
ADOPT BBMRI-ERIC	impleMentAtion anD OPeration of the gaTeway for health into the Biobanking and BioMolecular resources Research Infrastructure – European Research Infrastructure Consortium (H2020 Project)
AoM	Assembly of Members
B3Africa	Bridging Biobanking and Biomedical Research across Europe and Africa
BARCdb	The Biobanking Analysis Resource Catalogue database
BBMRI	Biobanking and BioMolecular resources Research Infrastructure
BioMedBridges	Building data bridges and services between biological and medical infrastructures in Europe
BMS	Biological and Medical Sciences
BRC	Biological Resource Centre
BRIF	Bioresource Research Impact Factor
BSL	Biosafety level
CD	Corporate design
CS	Common Service
CA	Communication Assistant
CoBRA	Citation of BioResources in journal Articles
CORBEL	Coordinated Research Infrastructures Building Enduring Life-science services (H2020 project)
CY-Biobank	Biobanking and the Cyprus Human Genome Project
DG	Director General
E&T	Education and Training
EATRIS	European Advanced Translational Research Infrastructure in Medicine
EBW	Europe Biobank Week
ECRIN	European Clinical Research Infrastructures Network
eduGAIN	EDUcation Global Authentication INfrastructure
EFNA	European Federation of Neurological Associations
EGAN	European Genetic Alliance Network
EGI	European Grid Infrastructure
EGI-Engage	Engaging the EGI Community towards an Open Science Commons
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
ERINHA	European Research Infrastructure on Highly Pathogenic Agents
ESBB	European, Middle Eastern & African Society for Biopreservation & Biobanking
ESFRI	European Strategy Forum on Research Infrastructure
EU	European Union
EUDAT	pan-EUropean DATa infrastructure
EUOPENSREEN	European Infrastructure of Open Screening Platforms for Chemical Biology
EPM	EU Project Manager
Europa Donna	The European Breast Cancer Coalition
EURORDIS	European Organization for Rare Diseases
EVAg	European Virus Archive goes global
FC	Finance Committee
FCA	Finance/Communication Assistant
FPA	Finance/Project Assistant
FP	Framework Programme
GDPR	General Data Protection Regulation
GWAS	Genome-wide association study
HQ	Headquarters
IAPO	International Alliance of Patients' Organizations
IARC	International Agency for Research on Cancer
IBS	International Biobanking Summit
ICD	International Classification of Diseases
IMI	Innovative Medicines Initiative
INSERM	Institut national de la santé et de la recherche médicale
IOR	Instituto Ortopedico Rizzoli
ISBER	International Society for Biological and Environmental Repositories
ISO	International Organization for Standardization
ITM	Senior IT / Data Protection Manager
LIMS	Lab Information Management System
MC	Management Committee
MIABIS	Minimum Information About Biobank data Sharing
MoU	Memorandum of Understanding
NIPAB	Network of Italian Pathology Archives Biobanks
NN	National Node
OECI	Organization of European Cancer Institutes
ORPHANET	Portal for rare diseases and orphan drugs

P ³ G	Public Population Project in GenomicsPM
PM	Person Month
PP	Preparatory Phase
PR	Public relations
Q	Quarter
QA	Quality assurance
QC	Quality control
QMS	Quality Management System
QM	Quality Manager
R&D	Research & development
REC	Research Ethics Committees
RD	Rare diseases
RDA	Research Data Alliance
RI	Research Infrastructure
RItrain	Research Infrastructures Training Programme (H2020 project)
SEAB	Scientific and Ethical Advisory Board
SEC	Secretary/Receptionist
SF	Stakeholder Forum
SIAPEC	Società Italiana di Anatomia Patologica e Citodiagnostica
siRNA	small interfering RNA
SOP	Standard Operating Procedure
SPM	Senior Project Manager
T	Task
VSOP	Dutch Genetic Alliance
WGS	Whole Genome Sequencing
WES	Whole Exome Sequencing
WP	Work Package
WS	Work Stream
WHO	World Health Organisation

