



BBMRI-ERIC[®]

Biobanking and
BioMolecular resources
Research Infrastructure

WORK PROGRAMME 2017

www.bbmri-eric.eu

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

BBMRI-ERIC Statutes, Article 1(1)

Executive Summary

As of today, BBMRI-ERIC has managed to lay the foundation for being one of the largest research infrastructures in Europe—recognised also globally. It is based on the vision that I presented during the hearing on 3rd April 2013 for the committee to select the first Director General of BBMRI-ERIC. Already then, my vision was to start by focusing on the “first B” of BBMRI—*biobanking*—in order to solve the global problem of finding samples and data that are of high-quality and fit-for-purpose for multiple research purposes. This was also specified in an internal White Paper¹ that was jointly agreed upon with the National Node Directors in the context of the first BBMRI-ERIC scientific retreat in 2014. The Work Programme 2017 stays true to this common path, and now also lays the ground for services that include the “second B” of BBMRI-ERIC—*biomolecular resources*.

Moreover, BBMRI-ERIC partakes in many projects and call applications. To date, we as BBMRI-ERIC have been involved in a total number of 42 H2020 calls (thereof: three as coordinator/co-coordinator), of which 11 proposals were accepted (thereof: all three as coordinator/co-coordinator). This equals an overall success rate of 26%, in contrast to the average rate of 14%. I see this as a joint accomplishment of the Headquarters’ team, the Common Services ELSI and IT as well as the National Nodes and our ambitious Work Programmes 2014–2016. Of the current active projects BBMRI family is involved in, many synergies for the core business of BBMRI-ERIC can be demonstrated by the relations between the projects and our products/services as visualised in Figure 1 on page 7. Among the projects, however, the H2020 project ADOPT BBMRI-ERIC is special. It is coordinated by BBMRI-ERIC and provides the funding to develop and deploy core BBMRI-ERIC services. Thus, it has become an important part of the research infrastructure in the period of 2015–2018. Without this “boosting money”, the infrastructure would not be able to implement at current speed (the acceleration of implementation is clearly documented in Figure 1). The aims of ADOPT BBMRI-ERIC are directly in line with the objectives identified in the policy

¹ Kemal Baysal et al. *What Are the Key Factors for the Success of BBMRI-ERIC?*. Sept. 2014. DOI: 10.5281/zenodo.164636. URL: <https://doi.org/10.5281/zenodo.164636>.

document “Prioritisation of Support to ESFRI Projects for Implementation”² of April 2014:

- to organise national biobanks and the details of precisely what each country will offer in terms of data and services, and then combine these efforts into a coherent project plan for the European layer,
- to increase discoverability and access to data by setting up infrastructure, standards and tools for data sharing in a common central software and data framework whilst protecting privacy, and harmonise data and IT across biobanks,
- to fully develop access procedures and services for researchers,
- to fully develop a strategy and ensure solutions to the ethical, legal and societal issues related to access to personal data, and involving all relevant sectors,
- to enhance the connection between basic research through to the clinical application,
- take steps to continue expanding BBMRI’s membership.

We—the BBMRI community—will continue the work started with the H2020 project ADOPT BBMRI-ERIC taking colon cancer as the use case to illustrate the benefits and usefulness of the pan-European research infrastructure BBMRI-ERIC. Indeed, it cannot be highlighted often enough that BBMRI-ERIC per se is not a project but a research infrastructure; it is not about finalising deliverables and reaching milestones, but about building and implementing sustainable services for the European biobank and biomolecular resources community.

We especially acknowledge the fact that pre-analytical errors still account for nearly 60–70% all problems accounting in laboratory diagnostics³ and that there is an increasing concern about the reliability of medical research, with recent articles suggesting that up to 85% of research is wasted.⁴ Hence, we work hard to facilitate both better quality and accessibility of biological samples and data collected and curated in European biobanks. Ultimately, we will implement quality tools to support European biobankers and researchers in their daily work. This take is unique on the global scale and has never been done before. All in all, the Work Programme 2017 builds on the achievements of the previous years, well in line with the vision I presented in 2013. It consists of eight topical work plans, the core budget description and an overview on our active projects. Each work plan consists of at least one workstream, which then describes the goals and expected outcomes in detail in the sub-sections: (1) objectives, (2) expected outcomes and time plan (also including an outlook for 2017–2018), and (3) responsible parties. Some workstreams are interconnected with each other or build on the achievements of the other. This is specified through

² https://ec.europa.eu/research/infrastructures/pdf/ESFRI_projects_for_impl_7_april_2014.pdf, page 21.

³ Giuseppe Lippi et al. “Preanalytical quality improvement: from dream to reality”. In: *Clinical chemistry and laboratory medicine* 49.7 (2011), pp. 1113–1126.

⁴ Stephen A Bustin. “The reproducibility of biomedical research: sleepers awake!” In: *Biomolecular Detection and Quantification* 2 (2014), pp. 35–42.

cross-references, equally so when we can build on synergies with FP7 and/or H2020 projects. Compared to previous years, the Work Programme 2017 has been both expanded in content and simplified in structure. Expanded, because it introduces the services on the “second B” (biomolecular resources) and specifies the activities of the Stakeholder Forum. Simplified, because it is divided into thematic areas such as e-Infrastructure (Work Plan 1) and quality (Work Plan 2) as well as it highlights better the contributions of the National Nodes, each of them being a cornerstone of BBMRI-ERIC.

Specific Focus Areas of the Work Programme 2017 are:

e-Infrastructure (Work Plan 1) The main aim of this work plan is to build a sustainable e-Infrastructure covering the current needs of European biobanks and biobank users. One of the most important objectives of BBMRI-ERIC—implemented by Common Service IT is to ensure findability and accessibility of biobanks, their sample and data collections as well as services. Findability is targeted by the Directory (a tool for various users including researchers and biobankers), which supports the harmonization of biobank data and enables semantic search and harmonization of data coming in different terminologies (ontologies). Through the development of the Connector (a tool for biobanks) and the Locator (a service for researchers), we further expand the available search capabilities by allowing to search the availability of individual samples and related data in a privacy-respecting manner. The Connector also streamlines extraction of information from biobanks into the Directory in order to make the data as up-to-date as possible. Access to the biobanks is facilitated by the Negotiator (a tool for researchers and biobanks) which enables efficient communication (less time consuming) between multiple biobanks and one (or more) researchers. As a part of the aim to support emerging biobanks, BBMRI-ERIC further pursues the development of BIBBOX, a modular reference set of open-source software for biobanks and their data management and processing workflows. In addition, already established services are continuously updated, maintained and supported, including user-training activities. Last but not least, in order to improve reproducibility in medical research, BBMRI-ERIC is involved in the ISO Technical Committee 276 to pursue the development of interoperable provenance data-models that cover both biological material and data. BBMRI-ERIC works with established European e-Infrastructures (e.g., GÉANT, EGI.eu) and other relevant projects (e.g., AARC/AARC2, EGI-Engage, CORBEL) to maximize the utilization of previous and ongoing European investments in relevant fields such as federated authentication and cloud computing.

Quality (Work Plan 2) The main focus in 2017 will be to implement the quality tools for BBMRI-ERIC users—biobankers and researchers. In order to place biobanks that have high-quality standards prominently on the European map, we introduce the BBMRI-ERIC Quality Grade, which aims at enhancing visibility of European biobanks and sample collections. Biobanks that provide evidence of their biological material meeting the applicable criteria as specified in the BBMRI-ERIC self-assessment surveys (e.g., the CEN Technical Specifications as well as the International Organization for Standardization (ISO) and Quality Management System) will be flagged as such in the Directory. Furthermore, BBMRI-

ERIC will develop an Audit Programme concept aiming to provide quality consultancy, internal audit services and support biobanks in their efforts to reach certification and accreditation by authorized national qualification bodies. This helps biobanks to improve their quality standards and competitiveness, hence empowering biobanks to maintain sustainability.

Ethical, Legal and Societal Issues & Stakeholder Engagement (Work Plan 3) The Common Service ELSI aims to facilitate and support cross-border exchanges of human biological resources and/or data 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 European Union, with the aim of promoting excellence in international biobank-based research. In particular, it continues to inform about, monitor and coordinate joint replies to relevant public consultations on the European and international level (most recently, the World Medical Association's Declaration on Ethical Considerations in Health Databases and Biobanks; adopted in October 2016 in Taipei/-Taiwan). The Common Service ELSI also provides practical means and guidance for biobankers on the General Data Protection Regulation, the customized ELSI Helpdesk and user-friendly legal advice tools. Furthermore, it develops a Code of Conduct facilitating EU and third country cross-border data exchange in collaboration with the National Nodes, the Stakeholder Forum and of the Biological and Medical Sciences Research Infrastructures, etc. Moreover, the Common Service ELSI investigates if U.S. proposals for legislation in the biobanking field may be adapted for Europe. With a key focus on societal issues in 2017, the Common Service ELSI develops best practice models for engagement by pooling expertise and best-practices from the National Nodes. The participation in the H2020 projects ADOPT BBMRI-ERIC and CORBEL is instrumental to realise these tasks.

The Stakeholder Forum is a platform of exchange by a participatory governance model to include stakeholders concerns into the activities and policies of BBMRI-ERIC. BBMRI-ERIC aims to engage with its stakeholders on a case-by-case basis on timely topics (e.g., Code of Conduct; Access Policy) in a consultative fashion. The Stakeholder Forum consists, among others, representatives from patient advocacy groups, learned societies and the industry which are directly or indirectly involved and/or affected by biobanking activities. The different stakeholders will be organized in so-called chapters. To date, only the "patient chapter" was formally established and includes the European Institute of Women's Health, the European Cancer Patient Coalition (ECPC), the European Organisation for Rare Diseases (EURORDIS), the Genetic Alliance UK, Alzheimer Europe, and the Dutch Alliance for Rare and Genetic Disorders (VSOP). The chairperson of the Stakeholder Forum will always be a patient representative and is by default part of the Scientific and Ethical Advisory Board of BBMRI-ERIC. As the stakeholder engagement is of strategic relevance to BBMRI-ERIC, the newly established position of an Engagement Officer will ensure the smooth operation of the Stakeholder Forum and the communication with all relevant stakeholders in order to appropriately consider their interests and concerns.

Biomolecular Resources (Work Plan 4) Scientists engaged in biobank-based research need access to information about relevant reagents and state-of-the-art and beyond techniques.

As one of its activities, BBMRI-ERIC will develop services that will support, inform and guide European scientists in academia and industry in questions concerning technologies for collection and analysis of biobank samples. The aims are to assist preparation for, and early adoption of, emerging technologies of relevance and to identify best practice and support harmonisation of methods, together with proper documentation, to promote international collaboration.

Procedures for collecting and using biobank samples are set to undergo dramatic changes in coming years, necessitating efficient provision of support for users of the corresponding techniques. The costs of some analyses are decreasing by orders of magnitude; genome sequencing being a prime example, making entirely new approaches realistic, while new classes of biomarkers that depend on new analytical methods are continually appearing and the types of molecules that are being targeted are steadily increasing. At the same time, growing numbers of individuals are being recruited as donors of blood and other samples for biobanks. Importantly, the shift of emphasis from genetic to other molecular markers, such as transcripts, proteins and metabolites, requires frequently collected, consecutive samples to monitor trends over time and to secure samples suitable to identify markers for early diagnosis, preferably before symptoms appear. All these developments are consistent with the rapidly increasing interest in personalised medicine and for continuous monitoring of individual health. The added value for the BBMRI-ERIC community would come from improving science through combining biomaterials, technologies and expertise for novel solutions, aligning quality and ensuring higher reproducibility of results in biomedical research. More specifically, BBMRI-ERIC will develop a Biomolecular Resources Service that aims to assist preparation for, and early adoption of, emerging technologies of relevance, and to identify best practices and support harmonisation of methods, together with proper documentation, to promote international collaboration as outlined in this work programme.⁵

Further Thematic Areas of the Work Programme 2017 are:

Cohorts (Work Plan 5) specifies how it will ensure that developed concepts and solutions of BBMRI-LPC are sustainably integrated within BBMRI-ERIC wherever feasible and especially as regards to relevant knowledge has been gained about the access procedure across multiple cohorts in Europe. This experience shall be used optimally to help BBMRI-ERIC in its aim to facilitate access, and to encourage collaborative transnational research projects in the future.

Biomedical Imaging (Work Plan 6) shows the collaboration of BBMRI-ERIC with, for instance, the Research Committee of European Society of Radiology, the European Imaging Biomarkers Alliance, the European Institute for Biomedical Imaging Research, the European So-

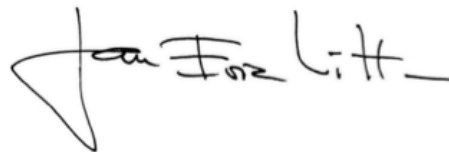
⁵ The Work Plan on Biomolecular Resources is based on the report of the workshop in Uppsala, 12th – 13th April 2016, which most of the National Node Directors attended as did international recognised experts in the field of biomedical resources, including representatives of big pharmaceutical companies.

ciety of Pathology as well as the National Nodes as regards to supporting imaging extensions.

Outreach (Work Plan 7) aims to promote the success, achievements and services of BBMRI-ERIC as well as the National or Organisational Nodes. Proactive communication and engagement activities (internal/external; local/national/European/global) as well as educational and training measures tailored to fit the needs of the biobanking community and its stakeholders.

Continued Activities (Work Plan 8) recognizes activities that have been launched in previous work programmes and will be continued in 2017 without major strategic changes.

In conclusion, the Work Programme 2017 builds on previous Work Programmes 2014–2016. It is more streamlined and shows that we, the BBMRI-ERIC Headquarters and the National Nodes, are well on track to implement this research infrastructure for biobanks and biomolecular resources for the benefit of the European research community with a global impact.

A handwritten signature in black ink, appearing to read 'Jan-Eric Litton', with a stylized flourish at the end.

Prof. Jan-Eric Litton, Ph.D.
Director General

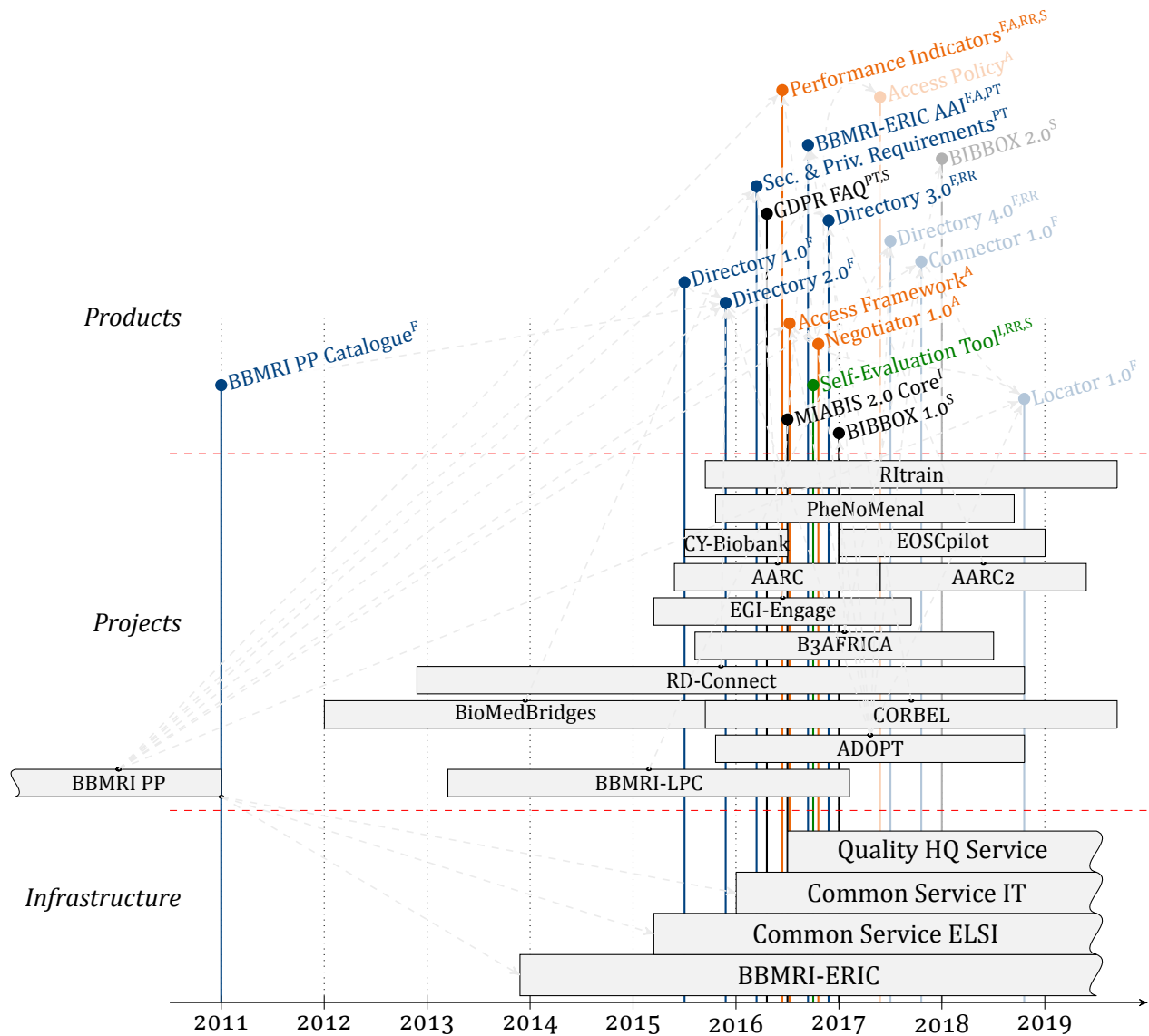


Figure 1: BBMRI-ERIC projects and their input into infrastructure products (deliverables). For readability reasons, this chart shows only select products of BBMRI-ERIC and only the milestone of the product delivery (not the ongoing operations and minor updates).

Legend: Abbreviations: F ... Findability, A ... Accessibility, I ... Interoperability, RR ... Reproducibility and Reusability, PT ... Privacy and Trust, S ... Support of National or Organisational Node and biobanks. The blue products are mainly for findability, orange ones for accessibility, green for quality, black others. The light colour for products denotes future products. BBMRI PP stands for BBMRI Preparatory Phase.

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1 Work Plan: e-Infrastructure

The e-Infrastructure aims at connecting biobanks and National or Organisational Nodes into a common information technology infrastructure that promotes *findability* and *facilitates access* to biobanks and their services. e-Infrastructure targets various users of the BBMRI-ERIC infrastructure—(bio)medical researchers and biobankers are considered primary users, but some services are also aimed at clinicians, research participants (patients/donors), and other stakeholders (e.g., funding bodies, data protection agencies).

The plan for 2017 follows up on the developments in the year 2016, during which BBMRI-ERIC launched Common Service IT (see Figure 2) to implement and maintain the e-Infrastructure toolset. Initially, the most effort was put into updating the BBMRI-ERIC Directory and implementing Sample/Data Negotiator to facilitate access to the biological material and data stored in the biobanks. This also required complementary activities such as design of data harmonization services and integration of reference tools for biobanks. In order to involve users in the development and to evaluate and improve delivered services, Common Service IT has established a User Forum.⁶ During 2017 delivered information technology tools will be maintained and supported in production. Further development will focus on improvements of access facilitation and data harmonization, producing components necessary for fine grained searches for sample sets and data sets. User training is an ongoing integral part of information technology infrastructure operations. Common Service IT will also support implementation of Key Performance Indicators, which are part of Workstream 8.12 – Assessment and Improvement of BBMRI-ERIC (page 53).

e-Infrastructure funding. The majority of software development in 2017 will be funded through Work Package 3 of the H2020 project ADOPT BBMRI-ERIC (page 60), while remaining development and operations will be funded from the Common Service IT core budget. The core budget is used for operating and supporting deployed software, including defect fixes and minor functionality enhancements requested by users.

⁶ The User Forum focuses on ensuring the usability of the IT-tools intended for researchers, it is not to be mistaken for the Stakeholder Forum (forum for exchange to take into account the perspectives and concerns of key stakeholders such as patient organisations and industry) or the European Biobank Forum (platform for information exchange for emerging biobank countries, especially population based biobanks).

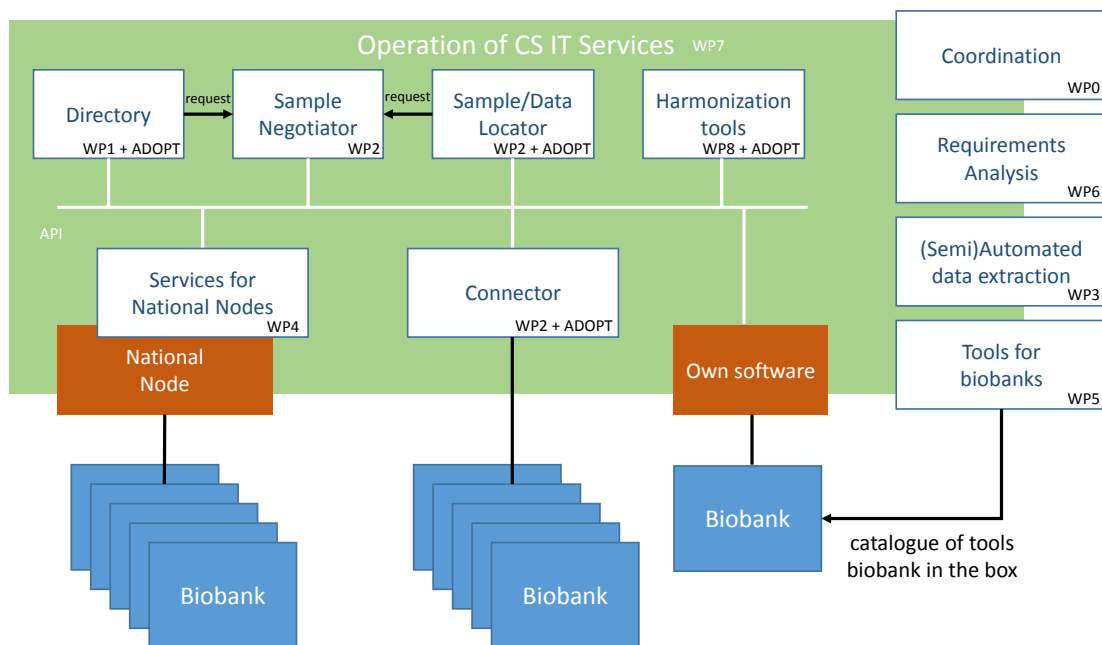


Figure 2: Structure of the Common Service IT and its relation to Work Package 3 of ADOPT BBMRI-ERIC. WP n denotes Work Package n of the Common Service IT.

1.1 Workstream: Development

1.1.1 Objectives

In 2017, this Workstream will focus on maintenance of already deployed tools as well as new developments:

- **Development of BBMRI-ERIC Directory 4.0.** This follows the BBMRI-ERIC Directory 3.0 released in 2016 (see Figure 3), providing an aggregate view of biobanks, biobank networks, and sample collections, allowing users to identify biobanks that may potentially host samples/data of interest. Directory 4.0 will expand support for explicit semantics and translation among different ontologies, thus allowing for interoperability among multiple commonly used standards such as ICD-10 and SNOMED CT.
- **Maintenance of Sample/Data Negotiator 1.0.** This is a tool to facilitate access to the samples and data by simplifying and improving efficiency of many-to-many communication between biobankers (service providers) and researchers (consumers). Development of lesser extent, such as refinement of request form structure, is expected based on user feedback and observation of user behaviour.
- **Development toward Sample/Data Locator 1.0.** This tool will allow researchers to use the *federated search* for sets of samples and/or data. The federated search mechanism

ism means that search queries are distributed to the biobanks using a so-called “Connector” component installed inside participating biobanks and allows biobankers to retain full control over the individual responses to the queries. 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, based on the BBMRI-ERIC Security and Privacy Architecture.⁷

Based on the Common Service IT plan, the Connector for Sample/Data Locator is to be released in 2017, allowing for gaining knowledge with its early deployment in advanced biobanks, while the complete Sample/Data Locator 1.0 release is planned for 2018. The Connector is also expected to be used for automated extraction of highly aggregated anonymous data into the BBMRI-ERIC Directory, in order to improve data quality and frequency of updates.

- **Maintenance and further development of BIBBOX.** This aims to assist biobanks and National or Organisational Nodes by providing a set of integrated open-source tools covering common workflows of biobanks. BIBBOX will be upgraded to version 2.0, bringing the integrated open-source components to their latest versions and enhancing their portfolio. This activity utilizes outcomes of the H2020 project B3Africa (page 61), in particular developments of the Bika Laboratory Information Management System (LIMS)⁸ for the needs of biobanks. BIBBOX 2.0 toolset is also expected to integrate the developed Connector component of the Sample/Data Locator.
- **Upgrading semantic and data harmonization services.** These are maintained as a part of IT middleware in the Common Service IT. Relying on Metadata Repository for identifying data in different ontologies (e.g., ICD-10, SNOMED CT, Unified Medical Language System (UMLS)), tools to store data harmonization recipes and perform the actual harmonization, will be implemented. This will also reuse outcomes of the H2020 project CORBEL (page 64) and past BioMedBridges and BioSHaRE projects.
- **Extending and ontologising of biobank-specific data models.** This includes MIABIS 2.0 Core and other upcoming components of MIABIS, see Work Plan 6 – Biomedical Imaging (page 38) for imaging component.

Analysis of users’ needs and evaluation of IT services. This is a continuous process started in 2016, implemented mainly via the User Forum of Common Service IT. The results are used both for the development of new services, as well as input for considering retirement of services that are no longer useful. This activity provides critical input into management of the Common Service IT and adjustments of mid-term and long-term plans based on analysis of developing needs of users.

⁷ Petr Holub and Common Service IT. *Security and Privacy Architecture*. Sept. 2016. DOI: 10.5281/zenodo.159444. URL: <https://doi.org/10.5281/zenodo.159444>.

⁸ <https://www.bikalims.org/>

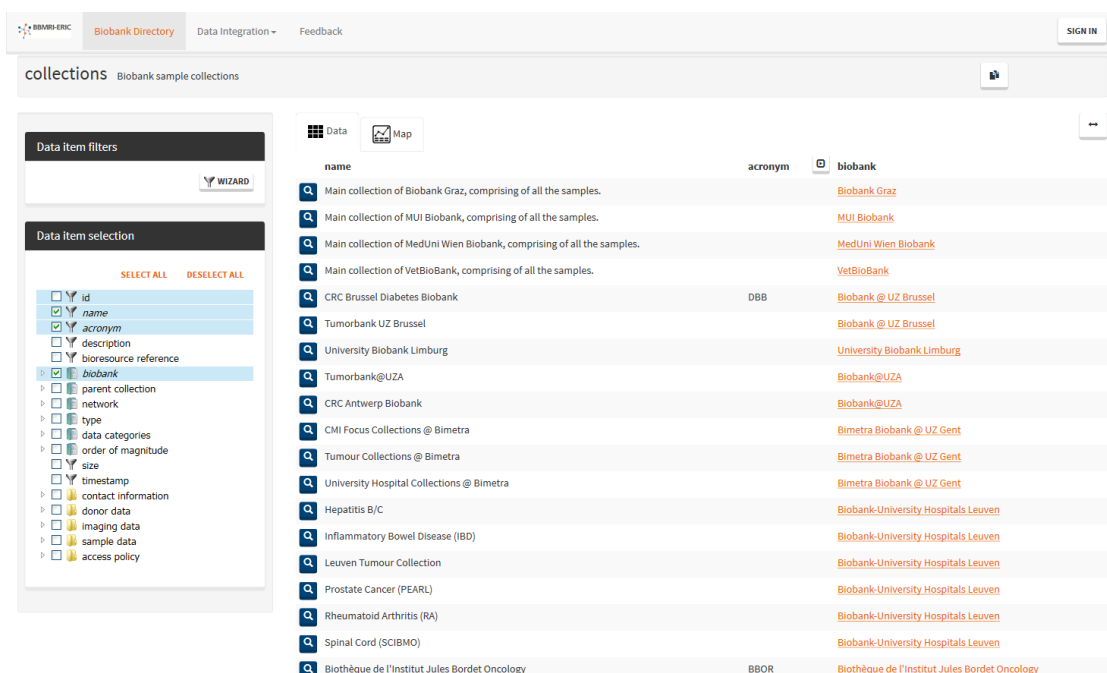


Figure 3: BBMRI-ERIC Directory 2.5
<http://bbmri-eric.eu/bbmri-eric-directory>

1.1.2 Expected Outcomes and Time Plan

Expected outcome	Q1	Q2	Q3	Q4
1. BBMRI-ERIC Directory maintenance and development, version 4.0 release				
2. BBMRI-ERIC Directory 3.0 maintenance and data curation				
3. BBMRI-ERIC Directory 4.0 maintenance and data curation				
4. Development of Connector for Sample/Data Locator				
5. Maintenance of Connector for Sample/Data Locator				
6. BIBBOX version 2.0 release, integrating reference Connector implementation				
7. Common Service IT User Forum based evaluation of services				
<i>Foreseen outcomes 2018–2019:</i> Continuous analysis of user needs and existing services, Sample/Data Locator 1.0, extensions for querying genomic data, BIBBOX 3.0, Directory 5.0.				

1.1.3 Responsible Parties

- Headquarters: Senior IT/Data Protection Manager, Common Service IT.
- National or Organisational Nodes: indirectly via contributing to Common Service IT and H2020 project ADOPT BBMRI-ERIC.
- Projects: ADOPT BBMRI-ERIC (page 60).

1.2 Workstream: Operations

1.2.1 Objectives

In the course of 2017, we will take over results of design and development activities from 2015–2017 and sustain their operations. These will include:

- **Operations of the common IT infrastructure of BBMRI-ERIC.** This primarily covers the hardware infrastructure with virtualisation support to host all other IT services. Selected common collaborative tools are directly supported, including authentication and authorization infrastructure, mailing lists, and shared web sites.
- **Operations of Directory⁹ 3.0 and 4.0**, including supporting National or Organisational Nodes and biobanks in curating their data published in the BBMRI-ERIC Directory.
- **Operations of Sample Negotiator¹⁰ 1.0.**
- **Hosting and operations of tools for National or Organisational Nodes.** This is part of Common Service IT Work Package 5 – this is based on requests of National or Organisational Nodes and closely coupled to the analysis of user needs in Workstream 1.1 – Development (page 12).
- **Operations of Helpdesk for BBMRI-ERIC.** This is used both inside the Common Service IT as well as outside of it—for Common Service ELSI and for rare diseases related activities in ADOPT BBMRI-ERIC, see also Workstream 8.8 – Rare Diseases (page 51). Helpdesk operations include technical operation and support of Request Tracking system,¹¹ mailing lists and wiki.¹²
- **Hosting and operations of selected FP7 project BBMRI-LPC IT tools and services**, see Work Plan 5 – Cohorts (page 35).

⁹ <http://bbmri-eric.eu/bbmri-eric-directory>

¹⁰ <http://negotiator.bbmri-eric.eu/>

¹¹ <https://helpdesk.bbmri-eric.eu/>

¹² <https://helpdesk-wiki.bbmri-eric.eu/>

User support and training. This will be run as a part of the infrastructure operations. It includes:

- training of operational IT staff (Work Package 7 of Common Service IT), with a focus on compliance with Security & Privacy Architecture of BBMRI-ERIC,¹³
- IT developer training for quality assurance and security of the developed systems,
- user training on deployed services of Common Service IT (in particular BBMRI-ERIC Directory and Sample/Data Negotiator), and
- user training on internal BBMRI-ERIC IT tools such as Request Tracking (RT) system to support reliable tracking of users' requests, as well as remote learning tools for efficient knowledge dissemination (wiki, etc.).

Training activities will be coordinated with Workstream 7.2 – Education and Training (page 44).

1.2.2 Expected Outcomes and Time Plan

Expected outcome	Q1	Q2	Q3	Q4
1. Operations of Directory (3.0/4.0)				
2. Operations of Negotiator (1.0)				
3. Operations of common BBMRI-ERIC IT infrastructure				
4. Operations of Helpdesk for BBMRI-ERIC				
5. User support				
6. Training activities (IT developers, IT administrators, users)				
<i>Foreseen outcomes 2018–2019: Operations of the deployed tools and system, ongoing training activities for users and system administrators.</i>				

1.2.3 Responsible Parties

- Headquarters: Senior IT/Data Protection Manager, Common Service IT.
- National or Organisational Nodes: – (indirectly via contributing to Common Service IT).
- Projects: –

¹³ Holub and Common Service IT, *Security and Privacy Architecture*.

1.3 Workstream: Interface to Other e-Infrastructures and IT-related Projects

1.3.1 Objectives

BBMRI-ERIC collaborates closely with other e-Infrastructures and projects in order to develop services that are needed by BBMRI-ERIC but outside of its primary scope:

- **Development and deployment of federated (distributed) Authentication and Authorization Infrastructure (AAI).** This is essential for working with privacy-sensitive human data as outlined in BBMRI-ERIC Privacy & Security Requirements document.¹⁴ Initial implementation will utilize the Virtual Organization Platform as a Service (VO-PaaS) provided by GÉANT, while BBMRI-ERIC will work with other partners in Authentication and Authorisation for Research and Collaboration (AARC)¹⁵ and upcoming H2020 project AARC2 (page 58) project to provide higher level of identity assurance. Coordination of Authentication and Authorization Infrastructure (AAI) activities across biomedical infrastructures is implemented as a part of Work Package 5 of the H2020 project CORBEL (page 64).
- **Standardization of provenance information for sharing both biological material and data.** This is important for reproducible and meaningful data processing and integration and includes compliance with FAIR principles.¹⁶ This will be pursued in the ISO Technical Committee (ISO/TC) 276 Working Group 5, and is very likely to continue in 2018 because of the length of the standardization process.
- **Finalization of BBMRI Competence Centre.** This is led by BBMRI-ERIC in the H2020 project EGI-Engage (page 66), which is the major project implemented by the European Grid Infrastructure (EGI). BBMRI Competence Centre utilizes outcomes of the BiobankCloud project (finished in 2015) for cloud-based processing of privacy-sensitive data subject to multi-tenancy access control. The goal is to deploy computing pipelines for less-sensitive data on both public and hybrid clouds, and also the pipelines for sensitive data on private clouds. Another aspect is exploration of ingesting 3rd party provided cloud infrastructure, into logically private clouds.
- **Development of long-term data stewardship/curation strategies,** with the objective of improving consistency across various research domains. It will be explored within the H2020 project EOSCpilot (page 67) project as a part of piloting phase of European Open Science Cloud and also assumes tight collaboration with Research Data Alliance

¹⁴Petr Holub et al. *Security and privacy requirements and secure storage architecture*. Delivered as Milestone M6.2 document of EGI- Engage. Mar. 2016. DOI: 10.5281/zenodo.161551. URL: <https://doi.org/10.5281/zenodo.161551>.

¹⁵<https://aarc-project.eu/>

¹⁶Mark D. Wilkinson et al. "The FAIR Guiding Principles for scientific data management and stewardship". In: *Scientific Data* 3.160018 (2016). URL: <http://www.nature.com/articles/sdata201618>.

(RDA) and Group of European Data Experts (GEDE). BBMRI-ERIC's role is to represent the needs of medical research.

1.3.2 Expected Outcomes and Time Plan

Expected outcome	Q1	Q2	Q3	Q4
1. BBMRI Competence Centre in EGI-Engage project (EGI-Engage)				
2. Development of interoperable provenance information schemes in collaboration with ISO/TC 276 Working Group5				
3. Collaboration with RDA, GEDE and EUDAT				
4. Implementation and enhancements of federated AAI in collaboration with GÉANT AARC/H2020 project AARC2 and H2020 project CORBEL				
<i>Foreseen outcomes 2018–2019: Activities related to European e-Infrastructures and to European Open Science Cloud (EOSC).</i>				

1.3.3 Responsible Parties

- Headquarters: Senior IT/Data Protection Manager.
- National or Organisational Nodes: BBMRI Competence Centre in EGI-Engage: BBMRI.at, BBMRI.nl, BBMRI.it, BBMRI.cz, BBMRI.se.
- Projects: ADOPT BBMRI-ERIC (page 60), EGI-Engage (page 66), CORBEL (page 64), B3Africa (page 61), EOSCpilot (page 67), PhenoMeNal (page 69), AARC2 (page 58).

2 Work Plan: Quality

A biobank shall have validated Standard Operating 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, 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, as shown in Figure 4. BBMRI-ERIC provides guidance to establish and improve an appropriate Quality Management System (QMS) for biobanks of human derived materials.

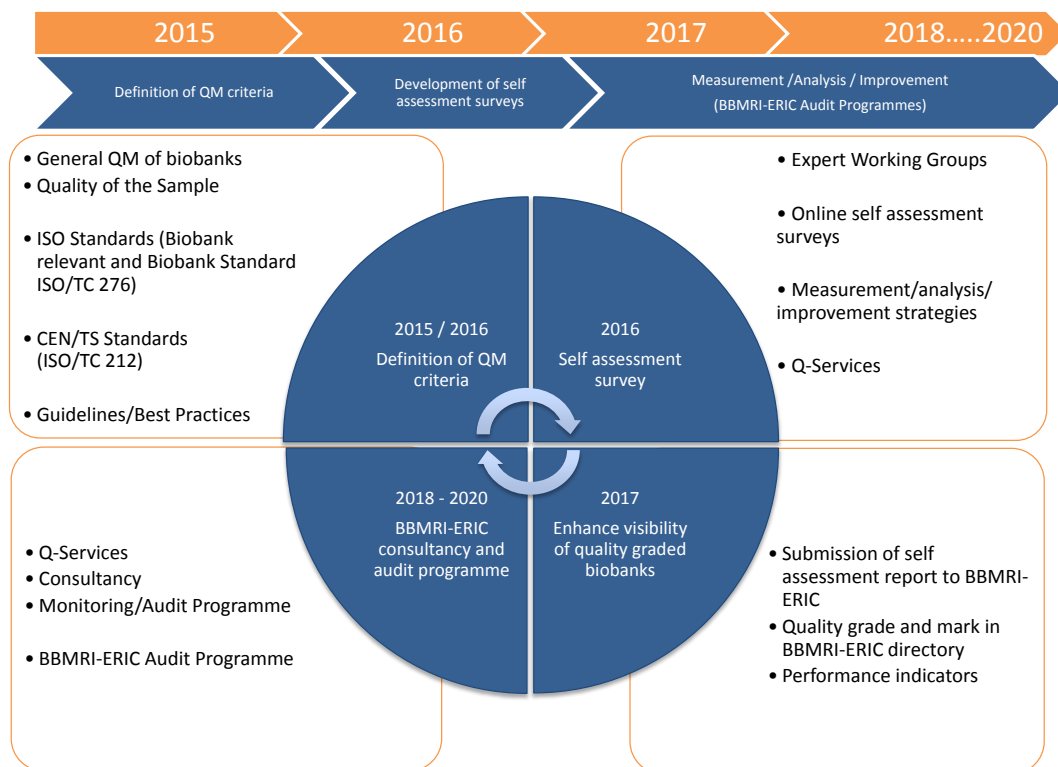


Figure 4: Key Pillars of Quality Management Infrastructure Developments

2.1 Workstream: Quality Self-Assessment and Audit Systems

In 2016, this Workstream focused on the improvement of the biobank Quality Management System (QMS) and especially on the quality of the sample, to foster scientific excellence, and safeguard interoperability. For this reason BBMRI-ERIC established 5 Expert Working Groups joined by more than 80 participants of 17 National or Organisational Nodes. The main focus was the development of appropriate self-assessment surveys for CEN Technical Specifications (CEN/TS) and QMS. The self-assessment surveys were built on a modular basis.

2.1.1 Objectives

In 2017, the main objectives are as follows:

- **Enhancing visibility of biobanks and sample collections in BBMRI-ERIC Directory (introducing a BBMRI-ERIC Quality Grade).** In 2017, biobanks may complete the self-assessment surveys and submit them to BBMRI-ERIC. The survey results can be informative for individual biobanks to improve their specific procedures and processes. BBMRI-ERIC will foster biobanks to provide evidence of samples meeting the CEN/TS and QMS criteria specified in the BBMRI-ERIC self assessment surveys.

In a first step, biobanks (respectively the comprehensive collections and their samples/data) complete and submit the survey to BBMRI-ERIC together with a statement of compliance signed by the respective biobank manager. Second, BBMRI-ERIC reviews the completed survey; The BBMRI-ERIC Quality Grade follows the given “shall/should” criteria defined in the survey based on the respective CEN/TS. If the biobank can prove that the defined set of samples fulfil “shall” requirements, it indicates the compliance of pre-examination processes as intended in the specific CEN/TS. Finally, biobanks that fulfil the criteria of the self-assessment survey will receive recognition by being flagged¹⁷ in the BBMRI-ERIC Directory as compliant to the specific CEN/TS. This will place the biobanks on the European map and makes the Directory a powerful tool enabling the researchers to find high-quality biobanks throughout Europe. Hence, BBMRI-ERIC promotes those biobanks who are able and willing to give access to high quality samples/data. This is an added value and service for both biobanks and their users.

- **Concept development of a BBMRI-ERIC Audit Programme.** Many biobanks today commit themselves to constantly improve their internal biobanking procedures. While some biobanks, respectively associated laboratories, hold a certification or accreditation certificate, others make efforts to implement quality standards. In order to assist biobanks in their aim for excellence, BBMRI-ERIC develops a concept paper

¹⁷ Flagged as, e.g., “Conforms to CEN/TS 16826-1:2015 Specifications for pre-examination processes for snap frozen tissue – Part 1: Isolated RNA”.

on an Audit Programme for the benefit of the biobankers. With the Audit Programme concept paper,¹⁸ BBMRI-ERIC aims to provide quality consultancy, internal audit services, and evaluation of labour costs related to the services. BBMRI-ERIC offers this as a service to support biobanks in their efforts to reach certification and accreditation by authorized national qualification bodies.

Broad support of the BBMRI-ERIC Audit Programme by the biobanking community is crucial. Especially, as this service may touch upon, the not always shareable, confidential areas and/or unique selling proposition of the biobanks. If successful, this may lead to a further harmonisation of procedures and processes across the BBMRI-ERIC Member States. An Expert Working Group¹⁹ shall draft the Audit Programme concept paper in a consensual manner. Ultimately, the BBMRI-ERIC Audit Programme concept paper aims to address relevant biobanking consultancy, as well as, audit services and shall elaborate on the potential benefits of sustainability and competitiveness of biobanks.

- **Contribution to International Standard Developments:** BBMRI-ERIC continues in the function of an Observer Liaison to the international standard developments of ISO/TC 276²⁰ Biotechnology as well as ISO/TC 212²¹ Clinical laboratory testing and *in vitro* diagnostic test systems (started April 2015).

In this capacity BBMRI-ERIC, exercises active knowledge exchange (ISO ↔ BBMRI-ERIC ↔ BBMRI-ERIC community), calls for comments to ongoing document developments of ISO, rationalises comments to the BBMRI-ERIC family as regard the ISO, shares documentation whenever available (ISO ↔ BBMRI-ERIC ↔ BBMRI-ERIC community) and attends ISO Working Group Meetings as well as ISO/TC Plenary Meetings.

- **BBMRI-ERIC Expert Working Groups:** In 2017, BBMRI-ERIC continues with the Expert Working Groups that serve as a platform for efficient communication between biobanking experts of the Member States aiming to support close collaboration and knowledge exchange for improvement of quality in the biobanks: information and knowledge transfer by web-based conferences in 6–8 week intervals, shares new developments from H2020 project SPIDIA4P (page 72), and introduces new standard developments from the ISO/TC 276 and ISO/TC 212.

¹⁸Based on ISO 19011:2011 Guideline for auditing management systems and in part ISO/IEC 17021-1:2015 Conformity assessment – Requirements for bodies providing audit and certification of management systems.

¹⁹A call for experts will be launched either to be incorporated into the existing Expert Working Group 5 for QMS or work as its own Expert Working Group 7.

²⁰ISO/TC 276 constituted following Working Groups: WG1 Terminology, WG2 Biobanks and bioresources, WG3 Analytical methods, WG4 Bioprocessing, WG5 Data Processing and integration.

²¹ISO/TC 212 WG 4 develops published CEN/TS to International Organization for Standardization (ISO) Standards: ISO Committee Draft (ISO/CD) 20166 FFPE RNA, ISO/CD 20165 FFPE proteins, ISO/CD 20164 FFPE DNA, ISO/CD 20186 Blood cellular RNA, ISO/TC 212 ISO/CD 20185 Isolated genomic DNA, ISO/CD 20091 Isolated ccf DNA, ISO/TC 212 ISO/CD 20184 FT isolated RNA, ISO/CD 20167 FT isolated proteins

Expert Working Group 1: Pre-examination processes for snap frozen tissue handling with the intent to isolate RNA and proteins.

Expert Working Group 2: Pre-examination processes for FFPE tissue handling with the intent to isolate RNA and proteins and DNA. This group will team up with the the BBMRI.it established Working Group for Archived Tissues Workstream 8.4 – Archived Tissues (page 49).

Expert Working Group 3: Pre-examination processes for venous whole blood handling with the intent to isolate cellular RNA, genomic DNA and circulating Cell-free DNA from plasma. This group will team up with the the BBMRI.it established Working Group for Liquid biopsies Workstream 8.5 – Liquid Biopsies (page 49).

Expert Working Group 4: Pre-examination processes for urine, venous whole blood serum and plasma for the intend to measure metabolomics. This group will team up with BBMRI-LPC (page 62) proficiency testing.

Expert Working Group 5: General quality management for biobanks.

Expert Working Group 6 (to be established through an open call for experts): Immortalised Cell Lines authentication of established and primary cell lines and human tissues. This group teams up with the BBMRI.it established group for Immortalised Cell lines Workstream 8.6 – Immortalised Cell Lines (page 50).

Expert Working Group 7 (to be established through an open call for experts): The main task of this group is the consensus-based development of a BBMRI-ERIC Audit Programme concept paper. Working Group is to be established through an open call for experts in case it is needed (see Concept development of a BBMRI-ERIC Audit Programme on page 20).

2.1.2 Expected Outcomes and Time Plan

Expected outcome	Q1	Q2	Q3	Q4
1. Enhance visibility of quality graded biobanks and sample collections in BBMRI-ERIC Directory				
2. Concept development of Audit Programme				
3. Contribution to international standard developments				
4. Maintain Expert Working Group				
<i>Foreseen outcomes 2018–2019:</i> Continue 1–4 with a particular focus on the implementation (if consensus is reached) of the BBMRI-ERIC Audit Programme.				

2.1.3 Responsible Parties

- Headquarters: Director General, Quality Manager.
- National or Organisational Nodes: experts, quality managers, and auditors of all nodes.
- Projects: ADOPT BBMRI-ERIC (page 60), SPIDIA4P (page 72), BBMRI-LPC (page 62) proficiency testing.

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

To consider the ethical, legal, and social issues (ELSI) related to biobanking and research infrastructure activities, by providing top-level expertise as well as involving the stakeholders' points of view in the development process of BBMRI-ERIC's tools, services or policies.

3.1 Workstream: Common Service ELSI

The proper consideration of 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 Common Service ELSI came into operation on the 1st February 2015 and comprises experts from across all BBMRI-ERIC member states.

3.1.1 Objectives

The Common Service ELSI offers support on ethical, legal and societal issues related to biobanking activities. In 2016, task forces have been formed refining specific topics along the objectives and timely needs of BBMRI-ERIC—e.g., General Data Protection Regulation (GDPR).

In 2017, this includes:

- **Task Force International Organisations' Policy Assessment and Monitoring:**
Aims to continue to coordinate joint replies to relevant public consultations on the European level; including the input of National Nodes and stakeholders as well as liaising regularly with key organisations, especially the Council of Europe, WMA, OECD, and the European Commission (DG JUSTICE, DG SANCO, DG RESEARCH, DG CONNECT) to promote key challenges and concerns of biobankers in a comprehensive manner. This activity continuously requires building excellent relations with the respective organisations.

- **Task Force EU General Data Protection Regulation:** Aiming to offer practical interpretation and guidance on new legislation, especially in relation to how the General Data Protection Regulation is expected to apply to biobanks—e.g., Frequently Asked Questions (FAQ) V1.0,²² this task force also explores, prepares and negotiates a Code of Conduct²³ in collaboration with the specific task force on that matter (see next paragraph).
- **Task Force Code of Conduct:** This task force develops a Code of Conduct, which shall be validated by the European Commission as a legal and practical means for implementing and complying to the GDPR and facilitating EU and third country cross-border data exchange by 2018. The Code of Conduct will be drafted in collaboration with the Task Force GDPR and requires the inclusion of relevant national and European stakeholders in the drafting process such as the BBMRI-ERIC Stakeholder Forum, patient organisations, the National or Organisational Nodes of BBMRI-ERIC, and the Biological and Medical Sciences Research Infrastructures focused on health research using synergies with the H2020 project CORBEL (page 64), etc. This shall ensure the input and needs of the various stakeholders are taken into account from an early stage in order to give strength and coherence to the initiative when implemented in practice. The goal is to submit the Code of Conduct in Q4 2017 to the European Commission.
- **Task Force Rule Making in US:** On 8th September 2015, the US Department of Health and Human Services together with 15 other federal departments and agencies issued the Notice of Proposed Rulemaking (NPRM), a proposal to revise the regulations—informally called the *Common Rule*—governing the ethical conduct of research involving humans. The *Common Rule* has changed little since inception in 1991, while the research landscape has changed radically. The revision aims to better protect human subjects involved in research, while facilitating valuable research and reducing burden, delay, and ambiguity for research investigators. The basic concern of this proposal was to establish a risk-based ethical review process in medical research, so that, for example, high-risks should be given more careful attention while low risk research could follow a more simplified protocol. This task force investigates if the US proposal is something that could be suggested also in Europe with a particular focus on how it might affect biobank and registry research.
- **Task Force Societal Issues:** In building on the expertise with public and patient engagement activities, such as deliberate workshops, focus groups, or citizen panels in the National Nodes, BBMRI-ERIC aims to pool expertise, good practices and insights together to draw practical conclusions about biobanking as a societal concern. It is furthermore planned to develop best-practice models as well as engagement scripts for how biobanks can engage with different publics at stake (such as more general

²²Jasper Bovenberg et al. *The EU General Data Protection Regulation - Answers to Frequently Asked Questions* 1.0. May 2016. DOI: 10.5281/zenodo.164631. URL: <https://doi.org/10.5281/zenodo.164631>.

²³Articles 40 and 41 of the GDPR.

publics and specific ones). The objective is thus to facilitate comparison of and mutual learning from discourses and organizational contexts across Europe, and provide guidance to countries where public engagement activities have not yet been addressed with success. These activities aim to focus on both societal understanding (e.g., beliefs, attitudes and rationales of patients and publics) of biomedical research and, in this context, engagement (e.g., ways and means through which engagement of patients/citizens/publics and social actors takes place). This will be done by providing:

- (a) a baseline review of published articles and experiences (Q1 2017),
- (b) basic model-scripts, comparative survey templates on attitudes/rationales in order to facilitate comparative understanding as well as a how-to-guide for societal engagement in biobanking for researchers (Q2–3 2017),
- (c) piloting a high public impact action with the cancer community (Q1–4 2017), and
- (d) a dedicated conference session (Q3–4 2017).

Together with ECPC, this task force explores co-producing an engagement script (biobanking 2.0), an empowerment programme in research biobanking and an informed consent matrix tailored for research biobanks with oncological patients. Also, an awareness-raising event at the European Parliament is foreseen. Executed in the context of the H2020 project ADOPT BBMRI-ERIC (page 60, case study: colon cancer), some work will be done in close collaboration with the BBMRI-ERIC Stakeholder Forum (esp. PATIENT chapter) and shall promote ongoing individual activities of patient advocacy groups. Societal engagement activities on a larger pan-European scale require further resources and funding, consequently identifying potential partners and calls shall be a key priority in 2017.

- **ELSI tools:** Improving tools to support biobankers in their daily work²⁴ (e.g., WIKI legal,²⁵ hSERN,²⁶ BioMedBridges' Legal Assessment Tool²⁷) was already an objective in 2016: A questionnaire sent to ELSI tool users/biobankers/researchers in the context of the ADOPT BBMRI-ERIC (page 60) and CORBEL (page 64) H2020 projects concluded that such tools are desired and should be user-friendly, sustainable and contain up-to-date information useful in daily practice. One tool is preferred by the users over links to many different ones. Such a tool is in development in the BBMRI-ERIC Intranet (working title: "ELSI playground") and internally tested. In 2017, it will be a key priority to implement this tool for public usage.
- **Task Force for Sharing and Access to Data and Human Biospecimens:** With the specific objective to promote responsible, effective and equitable access to samples

²⁴ Murat Sariyar et al. "Sharing and Reuse of Sensitive Data and Samples: Supporting Researchers in Identifying Ethical and Legal Requirements". In: *Biopreservation and biobanking* 13.4 (2015), pp. 263–270.

²⁵ http://www.bbmri-wp4.eu/wiki/index.php/Main_Page

²⁶ <http://www.hs-ern.eu/>

²⁷ <http://hhu2.at.xencon.de:8080/lat/>

and data, this Task Force aims at providing general guidance for access policies (ultimately, controlled-access to data sets and samples is always granted by the biobanks but facilitated by BBMRI-ERIC). This activity has to take into account ongoing and previous work and practical experiences of projects (e.g. RD-CONNECT, BBMRI-LPC, ADOPT BBMRI-ERIC) as well as international documents (e.g., OECD Principles and Guidelines for Access to Research Data from Public Funding, the Toronto Statement, and more recently the Global Alliance for Genomics and Health's White Paper). To achieve this goal, it will liaise with the Common Service IT and other task forces wherever necessary. In 2016, the task force commented on the BBMRI-ERIC Framework Document "Specifying the Access Criteria and Procedures When Requesting Samples/Data Access Facilitated by BBMRI-ERIC" that was developed in the context of the project ADOPT BBMRI-ERIC and will continue to do so when starting the implementation of the access procedure in 2017.

- **ELSI Helpdesk** It implements a federated ELSI Helpdesk,²⁸ which was conceptualised in 2016 with the aim to provide practical, usable, reliable, verifiable and sustainable guidance on ethical, legal and societal issues. Customized help is offered and is primarily intended to serve researchers/biobankers of BBMRI-ERIC Member States. In general, the service should be publicly available and free of charge for BBMRI-ERIC members. The content for the ELSI Helpdesk will largely stem from the results of the ELSI task forces (e.g., FAQ). Extensive customized support, however, may lead to the implementation of a cost-recovery model. The maturity of the ELSI Helpdesk is to be assessed based on the requests received until Q3 2017.

Continued activities include:

- inform and update existing services, databases (e.g., expert database), tools, publications and research results, surveys and workshops and organising educational and informative webinars,
- organise ELSI team (2/year) and task force meetings as well as workshops on ELSI aspects (e.g., conference sessions in the context of the Global Biobank Week); wherever feasible, meetings take place virtually; Jour fixe and Board of Directors meetings are held regularly via phone,
- provide ethical review for BBMRI-ERIC coordinated research proposals,
- adapt (if needed) the Ethics Check in order to make it a sustainable and efficient service for users based on the assessment results of 2016 (based on the evaluation in the context of the ADOPT BBMRI-ERIC, colon cancer case study of Work Package 3, and

²⁸ In order to ensure the best service for biobankers and researchers, the Headquarters explores in how to best set up a user-friendly single entry point on the BBMRI-ERIC website. Similar to IT and rare diseases, it uses the request tracking system set up by the Common Service IT.

- ensure continued representation of BBMRI-ERIC as observer in international organisations with ELSI impact on biobanking and biomolecular resources and intensify collaboration with societies such as P³G or ELSI2.0.²⁹

The Common Service ELSI is primarily intended to provide tools and expertise, as well as knowledge and experience sharing for the benefit of researchers/biobankers of the member countries of BBMRI-ERIC. It works in close collaboration with the BBMRI-ERIC Stakeholder Forum (especially Code of Conduct and societal issues) and the Common Service IT (especially in the context of tool implementation and Helpdesk conceptualisation).

3.1.2 Expected Outcomes and Time Plan

Expected outcome	Q1	Q2	Q3	Q4
1. International Organisations' Policy Assessment and Monitoring				
2. GDPR				
3. Code of Conduct				
4. Societal Issues				
5. ELSI tools				
6. Sharing and Access				
7. ELSI Helpdesk				
8. Workshops and face to face ELSI team meetings				
<i>Foreseen outcomes 2018–2019:</i> Adapt and improve the work described in the Task Forces based on feedback from service/tool users (esp. National Nodes/biobankers). Validate GDPR Code of Conduct, intensify public engagement activities and ELSI stakeholder relations.				

3.1.3 Responsible Parties

- Headquarters: Common Service ELSI, Senior Project Manager/Chief Policy Officer, Communication Officer, Stakeholder Forum.
- National or Organisational Nodes: feedback by all nodes.
- Projects: ADOPT BBMRI-ERIC (page 60), CORBEL (page 64).
- Others: EUREC, national Data Protection Authorities, Biological and Medical Sciences Research Infrastructures (BMS RIs), European Patients' Academy (EUPATI).

²⁹<https://elsi2workspace.tghn.org/>

3.2 Workstream: Stakeholder Forum

Stakeholders can affect or be affected by an organisations actions, objectives and policies. For BBMRI-ERIC, it is thus of high strategic importance to learn about the perspectives, concerns and interests of key stakeholders such as patient organisations, industry, learned societies and user communities. Learning about stakeholders' perspectives requires constant interaction and engagement and is best achieved by comprehensive consultation and a continuous communication flow. Having stakeholders on board early in the process eliminates huddles early on and remains an ongoing activity. This process may seem time-consuming at first but, in the long run, results in a research infrastructure that is supported by its stakeholders and its user community from the start of operation. Consequently in 2016, the Stakeholder Forum has been set up following a participatory governance model and shall be put on a broader basis with proper resources in 2017.

3.2.1 Objectives

In 2016, it was required to re-conceptualise the Stakeholder Forum. It now consists of organisational chapters (vertical) and thematic topics (horizontal, see Figure 5).

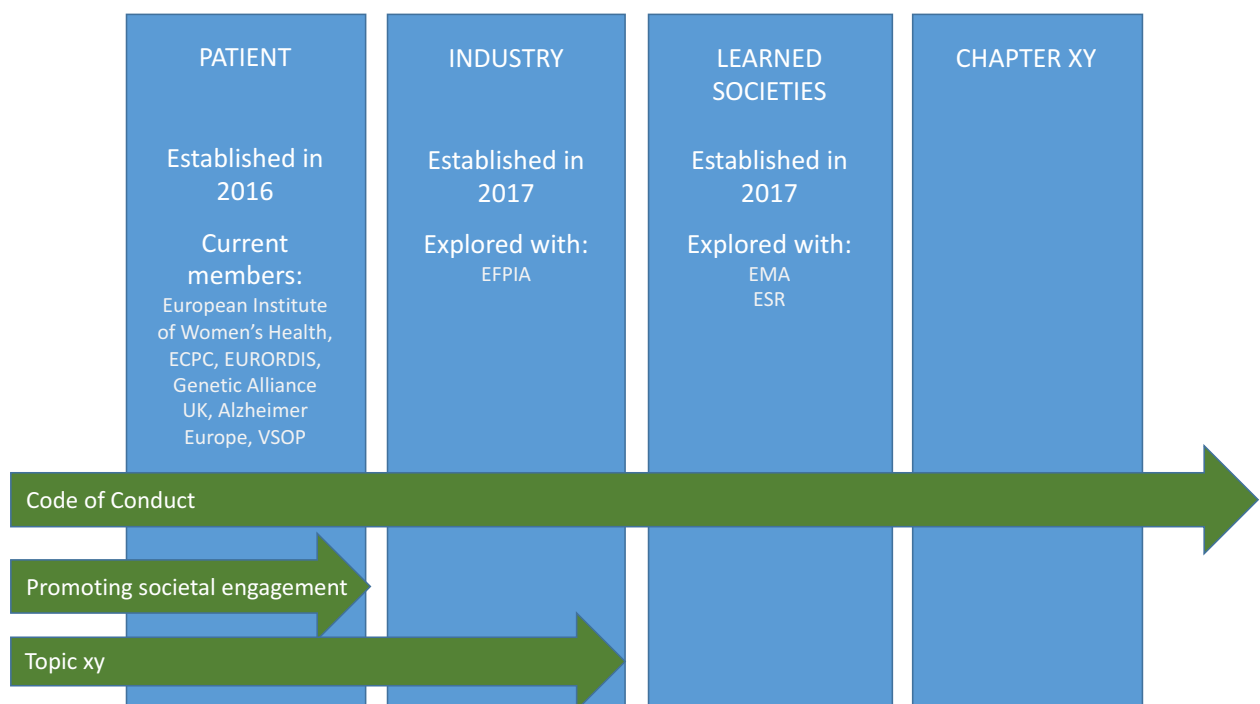


Figure 5: Stakeholder Forum: organisational chapters and thematic topics.

The Stakeholder Forum is designed as a timely and dynamic platform of exchange building on a participatory governance. The thematic topics in question will determine if one, some or all organisational chapters of the Stakeholder Forum will meet in smaller, topic-specific workshops. Topics will be identified in a consultative manner with the stakeholders and selected based on their timeliness and urgency. An annual meeting shall bring stakeholders and the BBMRI-ERIC community together. To achieve this level of participation, the role of an Engagement Officer is introduced as a full-time position in Q3. He/she is expected to have high-level experience in liaising with various stakeholders from multiple fields and has to be comfortable to engage in the scientific context in which BBMRI-ERIC operates and, in particular, understands and empathises with the cause of patient advocacy. Previous experience in stakeholder engagement and science communication is considered an advantage, as well as in-depth knowledge in one of the scientific fields that BBMRI-ERIC represents. The key responsibilities further include liaising on stakeholder issues with BBMRI-ERIC governance bodies as appropriate, including required documentation and communication. The Engagement Officer has an advocacy role within and outside of BBMRI-ERIC and is key in achieving the strategic goal of BBMRI-ERIC to know of and address the concerns of its multiple stakeholders appropriately.

In 2016, the focus was on setting up the patient chapter. The interest of industry and learned societies was explored and allowed the launch of these respective chapters in 2017. The chairperson of the Stakeholder Forum shall be a patient advocacy group representative and by this function by default a member of the BBMRI-ERIC Scientific and Ethical Advisory Board (SEAB).

3.2.2 Expected Outcomes and Time Plan

Expected outcome	Q1	Q2	Q3	Q4
1. Appointment of Engagement Officer				
2. Identify & engage potential Stakeholder Forum participants				
3. Set up Industry Chapter				
4. Set up Learned Societies Chapter				
5. Task specific meetings				
6. Stakeholder Meeting				
<i>Foreseen outcomes 2018–2019: Increase outreach to stakeholders by various means (tailored to audience) and set up further chapters, topics if required.</i>				

3.2.3 Responsible Parties

- Headquarters: Senior Project Manager, Engagement Officer, Chair of the Stakeholder Forum, Stakeholder Forum.
- National or Organisational Nodes: feedback by all nodes.
- Projects: ADOPT BBMRI-ERIC (page 60), CORBEL (page 64), SPIDIA4P (page 72).
- Others: EUREC, national Data Protection Authorities, BMS RIs, Innovative Medicines Initiative (IMI), stakeholders (to be identified).

4 Work Plan: Biomolecular Resources

Scientists engaged in biobank-based research need access to information about relevant and state-of-the-art techniques and reagents. In this Work Plan, BBMRI-ERIC will develop a Biomolecular Resources Service that will support, inform and guide European scientists in academia and industry about questions concerning technologies for collection and analysis of biobank samples. The aims of the Biomolecular Resources Service are to assist preparation for, and early adoption of, emerging technologies of relevance, and to identify best practices and support harmonisation of methods, together with proper documentation, to promote international collaboration. Ultimately, the Biomolecular Resources work links with Work Plan 2 – Quality (page 19) in attempt to stimulate the use of quality standards in different domains such as samples/data including provenance, such that the centers for biomolecular resources, biobanks and researchers are able to work with well-defined fit-for-purpose materials and data in the future.

4.1 Workstream: Biomolecular Resources Service

4.1.1 Objectives

The aims of this Biomolecular Resources Service is to coordinate and connect the services and expertise in the area of biomolecular resources that are spread over different locations in Europe. An appointee, Biomolecular Resources Officer, at the BBMRI-ERIC headquarters shall coordinate these actions to establish a network of experts in the field of biomolecules to work towards utilisation and sustainability of the available resources. This enables BBMRI-ERIC to enhance the awareness of technologies and broad access to various, state-of-the-art and beyond, techniques for biospecimen analysis. Hence, the role of the appointee is to work closely together with the European academicians, industry and quality experts (for both samples and data) of BBMRI-ERIC to facilitate access to aligned technical solutions for the user community.

The specific objectives of the Biomolecular Resources Service are:

- appointment of the Biomolecular Resources Officer;
- establishment and facilitation of the operation of an expert network in the field of biomolecular resources in Europe,

- organising meeting(s) (T/C, webinar, workshop) with the experts of the network to discuss, follow and evaluate the developments in the field of biomolecules,
- defining the users and mapping the user needs, jointly with Work Package 6 of ADOPT BBMRI-ERIC (page 60),
- organisation of training events related to biomolecular technologies, and
- assess the principles of coordination of purchase conditions for biobanking related equipment and reagents.

4.1.2 Expected Outcomes and Time Plan

Expected outcome	Q1	Q2	Q3	Q4
1. Appointment of the Biomolecular Resources Officer				
2. Establishment of a network of experts in the field of biomolecular Resources in Europe				
3. Organising meeting(s) (T/C, webinar, workshop) with the expert network				
4. Defined Biomolecular Resources users and user needs				
5. Organisation of the first training event related to biomolecular technologies				
<i>Foreseen outcomes 2018–2019: Maintaining the expert network and focusing on continuing 3 and 5.</i>				

4.1.3 Responsible Parties

- Headquarters: Director General, EU Project Manager, Quality Manager, Biomolecular Resources Officer.
- National or Organisational Nodes: Experts of all nodes.
- Projects: BBMRI-LPC (page 62), ADOPT BBMRI-ERIC (page 60).

4.2 Workstream: Technology Watch

4.2.1 Objectives

In order to ensure broad access to advance, unique and emerging technologies as well as reagents in the field of biomolecules, the Technology Watch Work Stream aims to map, eval-

uate and align the available technologies for biomolecular resources for the needs of the users (e.g., in terms of costs, availability, speed, quality). These actions stimulate the harmonisation processes, increase the amount of accessible molecular information from samples, and provide insights for improved analysis methodologies in the field of biomolecules. Current, continuous and comprehensive views into biomolecular technologies benefit the discovery process of new disease biomarkers and drug targets and enhance the general level of understanding of the disease mechanisms. This work will be done in collaboration with the Workstream 8.2 – Biomarkers Verification and Validation Models (page 48).

The objectives are:

- evaluation and mapping of existing and future technologies for biomolecules against the user needs defined in Workstream 4.1 – Biomolecular Resources Service (page 32),
- provision of regular reports on new/upcoming technologies,
- provision of reports from internal evaluation studies,
- setting up an evaluation platform for new biomolecular processes and protocols – links with Work Plan 2 – Quality (page 19), and BBMRI-LPC (page 62).

4.2.2 Expected Outcomes and Time Plan

Expected outcome	Q1	Q2	Q3	Q4
1. Initiation of the work on mapping and evaluating the existing technologies for biomolecules				
2. Setting up an evaluation platform for new biomolecular processes and protocols				
<i>Foreseen outcomes 2018–2019: Maintaining and updating the platform upon user needs.</i>				

4.2.3 Responsible Parties

- Headquarters: Director General, EU Project Manager, Biomolecular Resources Officer, Quality Manager.
- National or Organisational Nodes: Experts of all nodes.
- Projects: ADOPT BBMRI-ERIC (page 60), BBMRI-LPC (page 62).

5 Work Plan: Cohorts

Over the recent decades, Large Prospective Cohorts with samples linked to extensive exposure and lifestyle information as well as adequate follow-up times have been established in Europe. These collections, particularly when pooled, provide a valuable resource for many research questions from rare to chronic disease aetiology and prevention. In 2013, the multinational FP7 project BBMRI-LPC (page 62) was established to consolidate the European large prospective cohort and research community. BBMRI-LPC aims at facilitating transnational access to samples and health data in large European follow-up studies, thereby increasing their utilisation. BBMRI-ERIC is a participant of the BBMRI-LPC project and will ensure that developed concepts and solutions are sustainably integrated within BBMRI-ERIC wherever feasible through this Work Plan, Workstream 1.1 – Development (page 12), Workstream 4.2 – Technology Watch (page 33) and Workstream 7.3 – Global Biobank Week (page 45). During the course of BBMRI-LPC, relevant knowledge has been gained about the access procedure across multiple cohorts in Europe. This experience shall be used optimally to help BBMRI-ERIC in its aim to facilitate access, and to encourage collaborative transnational research projects in the future.

5.1 Workstream: Catalogues

5.1.1 Objectives

BBMRI-LPC has developed two catalogues: (a) a catalogue of cohorts³⁰ and (b) a detailed catalogue of variables that is adapted to the specific needs of large prospective cohorts containing information on questionnaire data, physical measures, lab data from basic recruitment and previous research as well as follow-up assessments for specific diseases.³¹ The goal of this Workstream is to incorporate agreed upon catalogue tools into BBMRI-ERIC IT operations in collaboration with Workstream 1.2 – Operations (page 15).

³⁰<http://www.bbmri-lpc-biobanks.eu/catalogue.html>

³¹<http://bbmri-lpc.iarc.fr/mica/?q=variable-search>

Expected outcome	Q1	Q2	Q3	Q4
1. Finalization of the hand-over strategy for the BBMRI-LPC catalogues				
2. Integration of agreed upon BBMRI-LPC catalogues into BBMRI-ERIC IT infrastructure				
<i>Foreseen outcomes 2018–2019:</i> Operations of agreed upon catalogues within Common Service IT. Seeking further opportunities in strengthening the network of cohorts across Europe to facilitate collaborative research.				

5.2 Workstream: A Biobank Cost Calculator

5.2.1 Objectives

The BBMRI-LPC Cost Calculator³² (Figure 6 on the next page) is a tool that enables biobanks to calculate their biobanking associated costs. This shall help them to determine a price strategy for their samples, data and services (e.g., access costs). The cost calculator has been designed for population based cohorts and biobanking in clinical studies. It has a modular design and a process-oriented basis, meaning it takes you through the whole chain from survey/study preparation to delivery of samples and data. First experiences indicated that it takes about an hour to complete if all required information is available at the time of completing the survey.

The objective for BBMRI-ERIC is to:

- Collaborate with BBMRI-LPC (Work Package 4: IARC, HMGU) on testing the Cost Calculator for both population-based and clinical biobanks (focus on usability/practicability).
- Integration into BBMRI-ERIC (hosting and operating) to guarantee sustainability of the Cost Calculator (based on testing and usability assessment).

5.2.2 Expected Outcomes and Time Plan

Expected outcome	Q1	Q2	Q3	Q4
1. Testing Cost Calculator				
2. Hosting and operating				
<i>Foreseen outcomes 2018–2019:</i> Hosting and operations.				

³²<https://epi.helmholtz-muenchen.de/tools/calc/>

Cost Calculator

for calculating biobanking costs



[Infos](#)
[General](#)
[Survey Costs](#)
[Sampling](#)
[DNA Extraction](#)
[Sample Storage](#)
[Sample Retrieval](#)
[Proband Data](#)
[Processes](#)
[Summary](#)
[Formula](#)

Personnel costs

Per hour cost according to qualification level

please indicate the per hour cost (gross cost including overhead costs for personnel if applicable) for a person with the following professional level

A: high	<input type="text"/>	academic	G1
B: middle	<input type="text"/>	requiring dedicated education	G2
C: low	<input type="text"/>	without special education	G3

Overheads

Overhead costs (percentage)	<input type="text"/>	what is the percentage of overhead costs you apply ?	G4
Depreciation (years)	<input type="text"/>	how many years of depreciation do you commonly calculate?	G5
Maintenance (percentage per year)	<input type="text"/>	what is the percentage of gross costs you calculate maintenance costs with in general?	G6

Miscellaneous

Currency unit	<input type="text"/>	which currency unit do you use?	G7
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[Save](#)
[Load](#)
[Print](#)

Impressum - BBMRI-LPC Cost Calculator v0.7:
 Dr. Gabriele Anton
 Helmholtz Center Munich, Institute of Epidemiology II
 Ingolstädter Landstraße 1, D-85764 Neuherberg

Figure 6: BBMRI-LPC Cost Calculator <https://epi.helmholtz-muenchen.de/tools/calc/>

5.2.3 Responsible Parties

- Headquarters: European Project Manager, Senior IT/Data Protection Manager.
- National or Organisational Nodes: all nodes (esp. feedback by researchers/biobanks for usability assessment).
- Projects: BBMRI-LPC (page 62).

6 Work Plan: Biomedical Imaging

In March 2014, the European Society of Radiology (ESR) established a dedicated working group, namely the ESR Working Group on Imaging Biobanks with the task of monitoring the existing imaging biobanks in Europe. Its goal 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.³³

Collaboration of BBMRI-ERIC with Research Committee of ESR, European Imaging Biomarkers Alliance (EIBALL), European Institute for Biomedical Imaging Research (EBIR), and the Head of European/International Affairs was started in April 2015 when ESR showed persuasively that imaging biobanks are essential and should be linked with biobanks. European Society of Radiology would also like to motivate centres that are already part of a National or Organisational Node of BBMRI-ERIC to connect imaging data to their biobanks. Additionally, several IT-related issues were addressed: e.g., how DICOM standards are useful for the exchange of medical images and if the MIABIS models provide a potential basis for the modelling of imaging biobanks. As a next step, the first workshop took place in October 2015.³⁴ A Memorandum of Understanding (MoU) between ESR and BBMRI-ERIC to conduct joint activities has been signed on 11th November 2015.

During 2016, a dedicated working group was set up as part of MIABIS called MIABIS-Imaging, to focus on developing metadata standard representing the imaging biobanks in the BBMRI-ERIC Directory. This group delivered a data model and performed a prototype integration of sample/data from ESR into the BBMRI-ERIC Directory 3.0. The preliminary results of this effort have also been presented at the Europe Biobank Week,³⁵ and a more detailed paper is foreseen to be published 2017–2018.

³³ European Society of Radiology. “ESR Position Paper on Imaging Biobanks”. In: *Insights into imaging* 6.4 (2015), pp. 403–410.

³⁴ (back-to-back with the European Society of Radiology Management in Radiology Annual Meeting in Barcelona) to elaborate in-depth on all topics as well as to bring together experts from different biobanks using images.

³⁵ Petr Holub and Bernard Gibaud. *Biobanks and Imaging: the Bioinformatic Challenge, from MIABIS to DICOM*. Presentation at Europe Biobank Week 2016. 2016.

6.1 Workstream: Imaging Biobank Integration into BBMRI-ERIC Directory

6.1.1 Objectives

- Integration of imaging data in the BBMRI-ERIC Directory, focusing on updates of European Society of Radiology (ESR) imaging biobanks.
- Extensions of the MIABIS-compliant metadata description model to support digital pathology imaging. The MIABIS-Imaging working group will be revived for this purpose in 2017, with focus on digital pathology representatives.
- Implementation of the digital pathology imaging extensions into BBMRI-ERIC Directory 4.0, together with preliminary data from selected advanced biobanks.

6.1.2 Expected Outcomes and Time Plan

Expected outcome	Q1	Q2	Q3	Q4
1. Imaging data integration in BBMRI-ERIC Directory 3.0/4.0.				
2. Development of extensions needed for the digital pathology.				
<i>Foreseen outcomes 2018–2019: Deeper integration of imaging into findability and accessibility services (Negotiator, Locator).</i>				

6.1.3 Responsible Parties

- Headquarters: Senior IT/Data Protection Manager, Common Service IT.
- National or Organisational Nodes: –
- Projects: ADOPT BBMRI-ERIC (page 60).
- Others: ESR, the European Imaging Biomarkers Alliance, the European Institute for Biomedical Imaging Research, the European Society of Pathology.

6.2 Workstream: Imaging e-Infrastructure

The purpose of the imaging e-infrastructure is to integrate into the BBMRI data universe bioimage data coming from multiple sources. The initial efforts will concentrate on images coming from radiology and digital pathology, with the first a part of the ongoing collaboration between ESR and BBMRI-ERIC (based on the foundations of the joint MoU), and the latter the result of experiences and data sources already present in BBMRI-ERIC. It is expected that this will provide the needed infrastructure for further development in radiomics and equivalent approaches for digital pathology.

Imaging e-infrastructure is based on radiomics, a new -omic science defined as the conversion of images to higher-dimensional data and the subsequent mining of these data for improved decision support. It has been initiated in oncology studies, but it is applicable to all diseases and it can be performed with all diagnostic images procedures.

Image features are extracted from volumes of interest, which can be either entire tumours or defined sub-volumes within tumours, known as habitats. It is a new field, and there are substantial challenges to its implementation in a clinical setting.

Radiomics has grown as basic research. Recently the interest is focused in clinical research. It is potentially useful in the diagnosis of common and rare diseases and can be used in decision support of personalized medicine. Clinical radiomics applications' should increase precision in diagnosis, prognosis, prediction of therapy response and, therapeutic assessment.

6.2.1 Objectives

The objectives include:

- definition of SOPs for image processing methods on extraction of radiomics and digital pathology data and linking them to the biobank data, in order to achieve consistency and interoperability across European biobanks,
- initial development of metadata model describing imaging biomarkers and allowing linking to biobank (meta)data and clinical (meta)data, in order to improve interoperability and findability of biomarker resources,
- analysis of ELSI issues related to sharing imaging and biomarker data,
- colorectal cancer will be used as disease model, consistent with one of the main objectives of H2020 project ADOPT BBMRI-ERIC (page 60).

6.2.2 Expected Outcomes and Time Plan

Expected outcome	Q1	Q2	Q3	Q4
1. Definition of SOPs for image processing methods on extraction of radiomics and digital pathology data and linking them to the biobank data.				
2. First version of metadata model describing imaging biomarkers and allowing linking to biobank (meta)data and clinical (meta)data.				
3. Analysis of ELSI issues related to sharing imaging and biomarker data.				

6.2.3 Responsible Parties

- Headquarters: Senior IT/Data Protection Manager, DG, Common Service ELSI.
- National or Organisational Nodes: BBMRI.at (digital pathology), BBMRI.it (digital imaging e-infrastructure), BBMRI.cz, BBMRI.ee, BBMRI.fi, BBMRI.nl, BBMRI.uk.
- Projects: ADOPT BBMRI-ERIC (page 60).
- Others: ESR, pathology societies.

7 Work Plan: Outreach

To promote the success, achievements and services of BBMRI-ERIC and its National or Organisational Nodes requires proactive communication and engagement activities (internal/external; local/national/European/global) as well as educational and training measures tailored to fit the needs of the biobanking community and its stakeholders.

7.1 Workstream: Communication

Consolidates Workstreams 10.3, 10.4, 10.5 of the Work Programme 2016.

7.1.1 Objectives

BBMRI-ERIC's communication and media relations aim at delivering timely and customised information to its user community and stakeholders in building on the following key elements:

- its public website (discerning tailored sections for researchers, industry, citizens, patients, member states) and the Intranet (archival and exchange platform), see Figure 7,
- media engagement (esp. press releases and briefings),
- public and internal information campaigns: the new media (Twitter, LinkedIn), the monthly e-Newsflash (using MailChimp with 5,000+ subscribers), and mailing lists,
- graphical design and promotional material (including leaflets, posters, brochures, presentations, roll-ups,...),
- informational thematic webinars (organised quarterly on specific topics such as quality, ELSI, IT), and
- the periodical magazine "Biobanks Europe" (print copy and PDF download).

These communication tools, means and strategies are continuously adapted to fit the needs of the various audiences of BBMRI-ERIC ranging from biobankers to policy makers and the media. Consequently, public and stakeholder engagement activities are defined in close collaboration with the Common Service ELSI and the Stakeholder Forum and include awareness raising on both the European and national policy maker level. Ultimately, news and

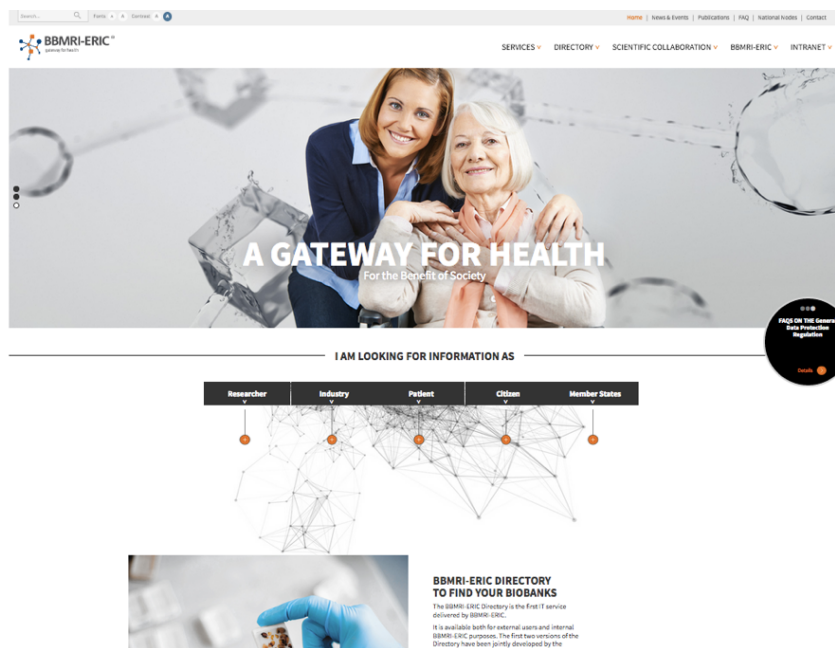


Figure 7: BBMRI-ERIC website received a major update during 2016.
<http://www.bbmri-eric.eu/>

achievements from the National or Organisational Nodes are promoted to the European biobankers. Relevant information and updates from P³G and similar societies are shared accordingly.

7.1.2 Expected Outcomes and Time Plan

Expected outcome	Q1	Q2	Q3	Q4
1. Public Website & Intranet				
2. Intranet				
3. Media Engagement				
4. Information campaigns (e.g., Twitter)				
5. Promotional material				
6. Thematic webinars				
7. Magazine "Biobanks Europe"				
<i>Foreseen outcomes 2018–2019:</i> Continue activities as specified above but tailored further for specific user groups in collaboration with the National or Organisational Nodes and the Stakeholder Forum.				

7.1.3 Responsible Parties

- Headquarters: Finance and Communication Assistant, Communication Officer, Senior Project Manager.
- National or Organisational Nodes: Communication officers of all nodes.
- Projects: ADOPT BBMRI-ERIC (page 60), CORBEL (page 64), B3Africa (page 61).

7.2 Workstream: Education and Training

Education and training are the backbone of a knowledge-based society. The mission of this Workstream is to jointly develop an education and training policy framework for bio-bank employees in Europe and beyond, through the Working Party Education & Training Policy established in BBMRI-ERIC in 2014. It delivers a European curriculum, findability and accessibility of courses and training. This Workstream is cross-linked with the tasks and deliverables of the H2020 projects Rltrain (page 71) and CORBEL (page 64) Work Package 8.

Additionally, Headquarters organises and/or facilitates education and training activities on IT, ELSI, quality and biomolecular technologies through webinars. This is done in collaboration with the respective Common Services, with a main aim to disseminate and wherever possible, harmonise the solutions/services of the National or Organisational Nodes.

7.2.1 Expected Outcomes and Time Plan

- Policy Framework for biobank employees (Working Party education and training Policy)
- Executive Master Curriculum for Research Infrastructure managers (RItrain)
- Content of training sessions for Research Infrastructure operators (CORBEL)
- European Master Curriculum for biobankers (jointly with interested universities)
- Webinars (education and training on ELSI, IT, quality)

Expected outcome	Q1	Q2	Q3	Q4
1. Policy Framework				
2. European Master Curriculum				
3. Education and training webinars				
<i>Foreseen outcomes 2018–2019: Executive Master Curriculum, continue 1–3</i>				

7.2.2 Responsible Parties

- Headquarters: Administrative Director, Communication Officer.
- National or Organisational Nodes: –
- Projects: RItrain (page 71), CORBEL (page 64) Work Package 8.
- Others: EUPATI.

7.3 Workstream: Global Biobank Week

Builds on Workstream 9.1 of the Work Programme 2016.

In the course of 2016, BBMRI-ERIC and ESBB were joined by ISBER in their strategic alliance to jointly organise one singular biobanking conference per year, which will take place on 13th – 15th September 2017 in Stockholm, Sweden. It is called the “Global Biobank Week: Towards Harmony in Biobanking” and shall exceed the number of participants of the European Biobank Week 2016, which reached a total audience of 700 participants and 150 industrial partners in Vienna.

Objectives: Every last Monday of the month a telephone conference is scheduled to organise the conference with the support of the following committees: Steering Committee, Programme Committee, the Marketing Committee, Finance Committee and Local Committee.

The Professional Conference Organiser Colloquium is responsible for the actual implementation and coordination of the event.

In 2017, the key actions for organising and implementing the conference are:

- committee work (Programme, Finance, Marketing and Steering Committees), public relations & planning,
- abstract submission deadline, programme & registration,
- Global Biobank Week,
- post-production & planning for 2018.

The Global Biobank Week will continue to feature successful formats and concepts from the previous years such as the Ethics Café, a simple, effective, and flexible format for hosting large group dialogue and the BBMRI Biobank Forum (former: BBMRI-LPC Forum), which serves as a platform for information exchange between countries with advanced population-based cohorts, biobanks and registries and those that are planning to initiate large population-based biobanks.

7.3.1 Expected Outcomes and Time Plan

Expected outcome	Q1	Q2	Q3	Q4
1. Committee work, PR, planing				
2. Abstract, programme, registration				
3. Global Biobank Week				
4. Planing 2018				
<i>Foreseen outcomes 2018–2019: Yearly conferences. Target audience: Global biobanking community.</i>				

7.3.2 Responsible Parties

- Headquarters: Director General, Administrative Director, Senior Project Manager, EU Project Manager, Communication Officer.
- National or Organisational Nodes: BBMRI.se.
- Projects: –

8 Work Plan: Continued Activities

This section includes workstreams that continue from previous years without significant changes in their objectives. Hence, they are presented in a condensed format and references to earlier work programmes are made (e.g., Ex Workstream x.x/20xx). Please note that these workstreams are neither in any particular order nor ordered by importance.

8.1 Workstream: Expert Centres

Ex Workstream 10.8/2016

BBMRI-ERIC Associated Expert Centres/Trusted Partners³⁶ are non-profit organisations representing a novel public-private partnership model. They are responsible for the analysis of samples in the country of origin under internationally standardized conditions and for the generation of primary data. BBMRI-ERIC Associated Expert Centres/Trusted Partners integrate pre-competitive public and private research and development activities by providing access not only to biological samples and medical data but also to the broad spectrum of medical and scientific expertise related to the samples and data, and their analysis. In order to guarantee excellence, BBMRI-ERIC evaluates all candidates applying for the status of BBMRI-ERIC Associated Expert Centre/Trusted Partner before their inclusion and approval.

In 2016, CBmed GmbH³⁷ was certified as the first BBMRI-ERIC Associated Expert Centre/Trusted Partner. CBmed GmbH, an Austrian funded competence center, links excellent research infrastructure, scientific expertise, medical knowledge, national and international industry partners for systematic medical biomarker research. After certification of CBmed GmbH in June 2016, an internal audit will take place in June 2017 to monitor the ongoing compliance and continuous improvement. The ATMA-EC consortia is the most recently certified BBMRI-ERIC Associated Expert Centre/Trusted Partner for biomarker research (since October 2016). EXCEMET³⁸ Consortia is an Expert Centre candidate for metabolomics. Further applications may come forth in 2017.

³⁶Andrea Wutte and Jan-Eric Litton. *BBMRI-ERIC-Associated Expert Centres/Trusted Partners V2.0*. Oct. 2015. DOI: 10.5281/zenodo.164634. URL: <https://doi.org/10.5281/zenodo.164634>.

³⁷<http://www.cbmed.org/en/index.php>

³⁸<http://www.excemet.org>

8.2 Workstream: Biomarkers Verification and Validation Models

Ex Workstream 3.6/2016

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 first goal of this workstream is to verify new biomarkers directly in large, multiple retrospective case studies. The work links closely with Workstream 8.1 – Expert Centres (page 47), especially to CBmed/Austria and ATMA-EC/Italy that were certified as BBMRI-ERIC Associated Expert Centres/Trusted Partners in 2016. They are active in biomarker research and molecular analysis. Another topical link is the H2020 project Hercules³⁹ that focuses on finding solutions to drug resistance in high-grade ovarian cancer. The second goal of the workstream is to develop a sampling strategy for biobanks to optimally support biomarker discovery, development and validation—in conjunction with the Work Package 6 of ADOPT BBMRI-ERIC (page 60). Naturally, there will be a collaboration between this workstream and Work Plan 4 – Biomolecular Resources (page 32).

8.3 Workstream: Healthcare Integrated Biobanking

Ex Workstream 3.1/2016

Healthcare integrated biobanks are increasingly important in personalised medicine, biomedical research and in transferring knowledge to health systems. Many countries envision that their biobanks will become integral parts of their health care structures. The networking of healthcare integrated biobanking community with other communities involved in health care can contribute to improved health care management and outcomes.

The aim of this Workstream is to realise the full promise of personalised medicine by facilitating access to large sets of samples and health/disease related data linked to individual patients. For this purpose, a Working Group that deals with issues related to disease-oriented biobanks and ensures liaison across the ADOPT BBMRI-ERIC (page 60) has been set up (43 participants from all National or Organisational Nodes). The Working Group shall continue its liaison activities and foresees to share standard operating procedures and best practices related to frozen tissues, archived tissues and liquid biopsies.

³⁹GA No 667403, launched in Jan 2016 <http://www.project-hercules.eu/> BBMRI-ERIC is not a partner, but has ties with Georgio Stanta from the Centro di Riferimento Oncologico, Aviano (a member of ATMA-EC Consortia – see Workstream 8.1 – Expert Centres (page 47)).

8.4 Workstream: Archived Tissues

Ex Workstream 3.2/2016

In conjunction with Work Plan 2 – Quality (page 19), the goal of this Workstream is to involve the national societies of pathology in order to develop the first European Network of Clinical Archived Tissues with defined rules and activities. To realize this, an Archived Tissue Working Group⁴⁰ has been formed in 2015 with representatives from 10 European countries. Funding has been applied for the network in June 2016 with the Central European project proposal “Improving Clinical Molecular Technology in Health System in Central Europe - Network (CEHealthSy-Net)”⁴¹ an Archived Tissue Working Group continues its networking activities within the European Network of Clinical Archived Tissues.

Another goal of this workstream is to define and diffuse the archived tissue pre-analytical condition and molecular analysis for clinical research. The Quality Expert Working Group 2 (page 22) for quality management for formaline-fixed paraffin-embedded (FFPE) tissues is active and collaborates directly with European Standardization Committee and other working groups within European Society of Pathology and Organisation of European Cancer Institutes. The collaboration shall be continued in relation to accreditation and clinical research methods in archived tissues.

8.5 Workstream: Liquid Biopsies

Ex Workstream 3.3/2016

Information about disease mechanisms can be directly derived from liquid biopsies (circulating tumor/organ cells). For example in cancer, liquid biopsies represent promising approaches for tracking cancer progression and treatment response.

In conjunction with Work Plan 2 – Quality (page 19), the goals of this Workstream are to foster interoperability of liquid biopsy biobanks with defined rules and procedures, and to produce Standard Operating Procedures and Best practices in order to characterize liquid biopsies through robust assay development, technical validation and standardization. A Working Group on human whole blood molecular analyses provides contributions to the evidence based Standard Operation Procedures and gives recommendations for the characterisation of liquid biopsies related to isolated cellular RNA, isolated genomic DNA and isolated cell-free DNA. Further developments on evidence based standards for liquid biopsies will be presented by H2020 project SPIDIA4P (page 72) within the years to come.

⁴⁰Steering Committee of Archived Tissue Working Group: Giorgio Stanta/IT, Kurt Zatloukal (coordinator)/AT, Fatima Carneiro/PT, Manfred Dietel and Michael Hummel/DE, Pieter Riegman/NL, Kostas Stamatopoulos/GR, Olli Carpén/FI, Jostein Halgunset/NO, Noel Gatt/MT, Rudolf Nenutil/CZ

⁴¹Participants: Italy, Austria, Germany, Slovenia, Croatia, Hungary and Czech Republic

SOPs and Best Practices have been produced by BBMRI.it in several topics: blood collection, blood processing for the different molecular analyses (genomic DNA, circulating cell-free DNA, microRNAs, circulating tumor cells using different biomarker-based and unbiased procedures for the isolation of circulating tumour cells), storage and banking, and pre-analytical measurement of factors affecting the evaluation of circulating biomarkers (hemolysis, etc.).

The future steps for the liquid Biopsies Workstream include:

- sharing the SOPs with the National or Organisational Nodes for comments,
- distribution a self-assessment questionnaire on liquid biopsy based on recommendations developed by the Working Group 3 CEN venous whole blood following the discussion of the CEN/TS documents,
- analysing and evaluating the results of the national survey on pre-analytical and analytical procedures for liquid biopsies.

8.6 Workstream: Immortalised Cell Lines

Ex Workstream 3.4/2016

Human and animal cell lines are widely used in basic and translational biomedical research as they constitute a simple representative model system for functional studies and identification of diagnostic tools and therapeutic targets. In conjunction with Work Plan 2 – Quality (page 19), the goal of this Workstream is to increase awareness within the BBMRI-ERIC community about authentication of established and primary cell lines and human tissues to foster reproducible results. Currently, a Working Group⁴² is being composed on human sample authentication in order 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 the Workstream 4.1 – Biomolecular Resources Service (page 32). Agreed SOPs and Best Practices have been produced by BBMRI.it in relation to developing of a new cell line, acquiring a cell line from another laboratory, storage and banking, shipping cell cultures, and cell line misidentification. The next steps include sharing the SOPs with the National or Organisational Nodes for comments, the inclusion of a chapter on cell line quality in the on-line self assessment tool (based upon the agreed SOPs and available Best Practices).

⁴² Led by Barbara Parodi/BBMRI.it, Marialuisa Lavitrano (coordinator)/BBMRI.it and George Gale/BBMRI.mt.

8.7 Workstream: Microbiome

Ex Workstream 3.5/2016

The human microbiome is the collection of all the micro-organisms living in association with the human body and has received major attention worldwide as determinant of health and disease. Reduction in microbiome biodiversity can compromise the human immune system and predispose individuals to many diseases. Several international projects aim at setting up biobanks in this field, hence the collaboration of healthcare integrated biobanks with the community of researchers studying microbiomes, would favour the creation of specialised biobanks for archiving native microbiomes. This would enable future research on the relationships between the microbiome to the health and disease status.

In conjunction with Work Plan 2 – Quality (page 19), the specific goals for this Workstream is to:

- connect the microbiome community with the BBMRI-ERIC community in relation to human health,
- liaise with the SPIDIA4P (page 72),
- set up a MIABIS Working Group to define the sample types and data types relevant for microbiome and include aggregated (metadata-level) description of microbiome biobanks to the BBMRI-ERIC Directory,
- liaise with, for instance, the German Collection of Microorganisms and Cell Cultures (Braunschweig, Germany) and the Center of Microbiome Research (Graz, Austria) and others.

8.8 Workstream: Rare Diseases

Ex Work Stream 5.2/2016

Rare diseases are a large, heterogeneous category, affecting no less than 30 million Europeans. Today many patients with rare diseases still lack accurate diagnosis and appropriate treatments which has a negative impact on survival and quality of life. Transnational efforts are essential to make optimal use of resources. This is more critical for rare diseases than for other disease entities. BBMRI-ERIC considers a Common Service for Rare Diseases, which could provide a long-term home for any valuable initiative in this field. In 2016, steps were taken with the coordinator of RD-CONNECT (page 70), to integrate the RD-Connect Sample Catalogue (a global catalogue of biobanks and registries)⁴³ to the BBMRI-ERIC Directory. Furthermore, within ADOPT BBMRI-ERIC (page 60), the technical functions of a

⁴³<http://catalogue.rd-connect.eu>

helpdesk was started in 2016 with further developments and implementation foreseen in 2017-2018.⁴⁴

The specific goals of the Rare Diseases Workstream are to:

- provide a rare disease biobank section in the BBMRI-ERIC Directory– linked with the Work Plan 1 – e-Infrastructure (page 11),
- further develop the support Helpdesk service⁴⁵ for rare disease biobanks and registries taking into account the current developments within the European Reference Networks,
- continue the coordination activities in the rare disease field (particularly with ADOPT BBMRI-ERIC (page 60), RD-CONNECT (page 70), and the European Reference Networks,
- continue the work on harmonised quality standards for rare diseases – linked with the Work Plan 2 – Quality (page 19),
- establish a governance model for the sustainability of rare disease biobanks.

8.9 Workstream: Infectious Material

Ex Workstream 10.7/2016

The aim of this workstream is to develop a common strategy on how biobanks with infectious material should be integrated into BBMRI-ERIC based on the cooperation with ERINHA⁴⁶ and EVAg.⁴⁷ During 2016, BBMRI-ERIC and EVAg signed an agreement on joint initiatives in relation to exploring the integration options of EVAg into BBMRI-ERIC as a Common Service and common education as well as training interest.

8.10 Workstream: Headquarters

Ex Workstream 10.2/2016

The BBMRI-ERIC Headquarters based in Graz is led by the Director General and is responsible for the executive management of BBMRI-ERIC and the coordination/co-ordination of ADOPT BBMRI-ERIC (page 60), RIttrain (page 71) and CORBEL (page 64). The Headquarters will continue its activities as specified in Article 13 of the BBMRI-ERIC Statutes.

⁴⁴ Work Package 7 in ADOPT BBMRI-ERIC (page 60) - lead: Luca Sangiorgi

⁴⁵ Similar to IT and ELSI, it uses the request tracking system set up by the Common Service IT. In order to ensure the best service for biobankers and researchers, the Headquarters explores in how to best set up a user-friendly single entry point on the BBMRI-ERIC website.

⁴⁶ European Research Infrastructure on Highly Pathogenic Agents, <http://www.erinha.eu/>

⁴⁷ European Virus Archive goes global, <http://www.european-virus-archive.com/>

8.11 Workstream: Scientific Retreat with the BBMRI-ERIC National or Organisational Nodes

Ex Workstream 10.1/2016

The Scientific Retreat features short talks, breakout sessions, and the opportunity for the National or Organisational 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 2017 is foreseen to take place on 16th – 18th May 2017 in Lausanne, Switzerland. It is planned to discuss the preliminary Work Programme 2018 and to identify the focus areas for the years to come.

8.12 Workstream: Assessment and Improvement of BBMRI-ERIC

Ex Workstream 8.1/2016

In 2016, BBMRI-ERIC has delivered a listing (“cookbook”) of possible performance measures⁴⁸ at the Pan-European, National or Organisational Node level and biobank level. In this listing, a subset of performance measures have been proposed as future BBMRI-ERIC key performance indicators. Which ones to be selected is still a consensus to be reached in 2017. For the biobank-level key performance indicators, the work in ADOPT BBMRI-ERIC (page 60) is relevant.

8.13 Workstream: Fundraising Activities

Ex Workstream 10.9/2016

BBMRI-ERIC continues its activities to allocate additional funding for its core activities (e.g., H2020). BBMRI-ERIC may participate in research project consortia as coordinator, participant/contributor or associated organisation that supports research consortia with a letter of intent. BBMRI-ERIC is non-discriminatory as regards to the scope of the project, whether scientific or infrastructural. BBMRI-ERIC will assess each project application within its Management Committee, which consists of the Director General of BBMRI-ERIC, the Directors of the National or Organisational Nodes and the Directors of the Common Services. As a general principle, BBMRI-ERIC encourages the inclusion of one or more National or Organisational Nodes, depending on the specific aims of the proposed project or their areas of expertise (e.g., rare diseases, cancer).

⁴⁸Petr Holub et al. *Performance Indicators for BBMRI-ERIC*. Oct. 2016. DOI: 10.5281/zenodo.159416. URL: <https://doi.org/10.5281/zenodo.159416>.

In addition, the BBMRI-ERIC Working Group Financial Workflows will continue (a) to simplify the Linked Third Party agreement which enables National or Organisational Nodes to participate in H2020 applications and (b) to explore if and how National or Organisational Nodes can benefit from BBMRI-ERIC's VAT-exemption to purchase equipment and services.

Ultimately, within 2017, BBMRI-ERIC has to come up with a sustainability strategy, especially for the time when the H2020 project ADOPT BBMRI-ERIC (page 60) ends. It is clear that sustainability cannot be reached by project funding alone but requires considerable thought on cost-recovery models for services that exceed the basic services, especially to BBMRI-ERIC members.

9 Core Budget

The budget tables for 2017 are included in the separate document “Budget 2017” and provide full transparency for both estimated expenses as well as membership fees for 2017, 2018 and 2019. As it is difficult to predict which countries might join during 2019, the budget outlook 2019 is broadly based on the outlook 2018. Also, the current gross domestic product (GDP) data has to be used for the calculation of future annual contributions and requires an actualisation in the following years’ budgets. For the Work Programme 2018, it will be possible to provide a better estimation for 2019.

Table 9.1: Core budget table.

<i>Core Budget</i>	2016 approved [€]	2016 Q1–3 actual [€]	2017 applied [€]	2018 expected [€]	2019 expected [€]
<i>Earnings</i>	2,136,104	1,647,398	2,213,220	2,232,027	2,178,298
<i>Expenditures</i>	–2,136,104	–1,284,336	–2,213,220	–2,232,027	–2,178,298

The figures in column “2016 Q1–3 actual” (January to September 2016) are the actual numbers of this year. Two countries, namely Cyprus and France, have paid their contribution only during October 2016 and are therefore not included in this table. Details are shown in the budget tables in the separate document AoM/8/9.

For the purpose of this version of the budget (version 1; details in document AoM/8/9) submitted, it is important to mention that one country, namely Greece, has not yet paid (as of 24th October 2016) their annual contributions for the years 2014–2016. Also, Turkey has not paid its contribution for 2016 (as of 24th October 2016). The invoices to Latvia and Poland were issued only recently following the decision of the Finance Committee; Poland, on the one hand, “upgraded” its membership only recently from Observer to Member, hence the final annual payment will be smaller than originally expected. Latvia, on the other hand, joined as Member and not Observer as estimated, consequently there is some increased earning from this part. It can be expected that they will pay in time before the end of the calendar year. Despite promising signs from two countries to join during 2016, Portugal and Ireland have not yet submitted their requests for admission. For Ireland, however, the request for admission is still expected this year. In conclusion, the final figures will only be known by the end of this year.

The assumptions behind the proposed budget 2017 are as follows:

- Two more countries had declared their will to join during 2017, namely Slovenia (Member) and Lithuania (Observer). They are included in the budget 2017. We have positive signals also from other countries (Denmark, Hungary, Spain, and Portugal), but have excluded these from our calculations as, very likely, they will join only at a later stage. *As contingency plan in case the mentioned countries are not requesting membership we can shift during this year some of the expenses from the H2020 project ADOPT BBMRI-ERIC to the Core Budget. In addition, we have the overheads of other EU projects ("indirect costs") also in reserve.*
- The Common Service ELSI budget estimates are based on the originally approved ELSI application from 2014, increased by the expenses of the ELSI experts from the new Members. The Common Service IT budget estimates are based on the figures from the approved application 2015, updated with no additional costs and only some minor shifts within individual personnel time distribution by the CS IT Directorate.
- As shown in previous budget requests for 2016 and 2015, a large number of grant applications with BBMRI-ERIC participation have been granted. BBMRI-ERIC is the primary recipient of funding within these applications (€2,387,628 is foreseen as pre-finance payment or actual payments during 2017). There are substantial amounts foreseen for Linked Third Parties (National or Organisational Nodes) and other partners, namely €1,636,994 during 2017. The expenses for the Stakeholder Forum Secretariat do not appear under Common Service any longer as it will be established within Headquarters in Graz and thus appear below Headquarters expenses. It is foreseen to have one full-time Engagement Officer to start mid-2017 for the Secretariat. The other additional post, the Biomolecular Resources Officer will also start only mid-2017 and is currently covered by EU funding only. This can be seen in the detailed budget tables on pages 3–4 of AoM/8/9 document, "staff Headquarters". Therein you also see that it is not intended to open a lawyer position within the next years. One can also easily identify the split of expenses for the two employees who are currently in maternity leave and their replacements. Important to stress in this chapter is that EU projects are substantially co-funding core budget activities of especially the Common Service ELSI and Common Service IT.
- On page 5 of the budget tables, one will also identify the slightly increased expenses for contracting, which is mainly due to the extra expenses for the approved consulting role of the Director General during second half of next year. Otherwise, the expenses for travel to be paid by the core budget will be reduced during 2017 using EU grants for these expenses.
- In terms of earnings, the submitted draft budget 2017 of €2,213,220 is split into hosting country contributions of €268,820 (this is for Headquarters in Graz, and the Common Services respectively) and membership contributions of €1,895,237, as can be seen in the tables of document AoM/8/9. As in previous years, this results in an overall decrease of membership fees for most countries, and a slight increase for some. It

is important to recall that the annual contribution is calculated on a GDP relevant formula. This means that the economic development of different countries is mirrored and adapted in relative terms to the annual contribution.

BBMRI-ERIC has a series of internal regulations in place, which are part of our Operations Handbook, the basis for the travel policy.

10 Projects Active

10.1 AARC2 (H2020)

Authentication and Authorisation For Research and Collaboration

Topic: H2020-EINFRA-2016 **Type of Action:** RIA **Duration:** 24

Start date: 1st May 2017 (expected) **Grant agreement:** 730941

Web: (not yet available)

Total request Grant by Consortium: €2,999,893.75

Total request Grant by BBMRI-ERIC: €39,590.00

Linked Third Parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: Development of Levels of Assurance for authentication suitable for biomedical research applications.

Status: score 12 (threshold 10)/under negotiation at the time of preparing Work Programme 2017

Abstract: *Lead by GÉANT:* The goal of AARC2 is to design an AAI framework to develop interoperable AAI, to enable researchers to access the whole research and infrastructure service portfolio with one login. AARC2's objectives are:

1. enable federated access in research communities participating in AARC2
2. assist research communities to map their requirements to concrete service offerings
3. support research (e-)infrastructures to implement the integrated architecture and policies frameworks developed by AARC project
4. offer different trainings to adopt AARC/AARC2 results
5. enhance the integrated architecture

AARC2 objectives will be achieved by:

- Piloting selected research community use-cases (SA1)
- Showcasing ready-to-use AAI solutions and pilot results to infrastructures (SA1–NA2)
- Developing a virtual Competence Centre where infrastructure representatives and AARC2 team discuss AARC2 results deployment and approaches to use-cases (all WPs)
- Promoting federated access and adoption of AARC2 results via training and outreach (NA2)
- Expand support for new technologies and policies (JRA1 and NA3).
- Follow a user-driven approach: development driven by use-cases and continuous community feedback on AARC2 work. Relevance to the work programme:

- AARC2 will work with existing e-infrastructures and ESFRI projects to deploy and enhance (JRA1) the integrated AAI (built on eduGAIN and federated access) delivered by AARC (obj1-Development of a pan-European identity federation)
- Use-cases that meet integration (accessing services offered by multiple e-infrastructures) and data-rich aspects included in AARC2 (SA1). AARC2 will work to enable federated access and to map the use-cases to existing AAI services and policy frameworks (obj2-Stimulate AAI services supporting communities in the data-rich era)
- AARC2 will liaise with security groups, NRENs and infrastructures to address best practices in cybersecurity and assurance (see NA3). (obj3-Deliver an integrated infrastructure)

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

10.2 ADOPT BBMRI-ERIC (H2020)

implemEntation and OPeration of the gateway for healTh into BBMRI-ERIC

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

Start date: 1st October 2015 **Grant agreement:** 676550

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

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

Total request Grant by BBMRI-ERIC: €3,786,840.00 (Common Service IT, Common Service ELSI)

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

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

10.3 B3Africa (H2020)

Bridging Biobanking and Biomedical Research across Europe and Africa

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

Start date: 1st July 2015 **Grant agreement:** 654404

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

Total request Grant by Consortium: €201,250.00

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

Linked Third Parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: contacts to Africa, ELSI activities will be informative for the work of the Common Service ELSI

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

10.4 BBMRI-LPC (FP7)

Biobanking and Biomolecular Resources Research Infrastructure – Large Prospective Cohorts

Topic: INFRA-2012-1.1.9 **Type of Action:** CP&CSA **Duration:** 57 months

Start date: 1st February 2013 **Grant agreement:** 313010

BBMRI-ERIC as a full partner: 1st April 2014

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

Total request Grant by Consortium: €8,000,000

Total request Grant by BBMRI-ERIC: €14,552 (Common Service IT, Common Service ELSI)

Linked Third Parties/BBMRI-ERIC Framework Agreement: none

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

Status: score 13.5 (threshold 10)/accepted

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 Universität Graz Meduni Graz (MUG); Karolinska Institutet (KI); Genome Re-

search 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'analisi Genomica-Fundacio Centre De Regulacio Genomica (CNAG-CRG); Cambridge Protein Arrays Ltd (CPA); Pecs Tudomanyegyetem – University of Pecs (UP); The Research Institute of The McGill University Health Centre (RI MUHC); Legal Pathways Bv (LEGAL PATHWAYS); Islensk Erfdagreining EHF (DECODE); Terveiden 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 Technischen 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); University of Bristol (UBRIS); BBMRI-ERIC; Universita' Degli Studi di Milano-Bicocca (UNIMIB).

10.5 CORBEL (H2020)

Coordinated Research Infrastructures Building Enduring Life-science services

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

Start date: 1st September 2015 **Grant agreement:** 654248

Web: <http://www.corbel-project.eu/>

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

Total request Grant by BBMRI-ERIC: €1,900,093.00 (including 3rd parties)

Linked Third Parties/BBMRI-ERIC Framework Agreement:

(1) bbmri.nl /LUMC €454,340.08, (2) bbmri.fi/THL €80,500.00, (3) bbmri.no/NIPH,NTNU €80,500.00, (4) bbmri.ee/UTARTU €80,500.00, (5) bbmri.at/MUG €177,850.00

Benefit/tasks for BBMRI-ERIC: Co-Coordinated by BBMRI-ERIC; WP3: case studies (National Nodes); WP5: Access; WP7: Common Service ELSI; WP9: Training

Status: score 11 (threshold 10)/accepted

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

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

10.6 DRYNET (H2020)

Setting an interdisciplinary/sectorial/international research network to explore dry storage as an alternative strategy for cells/germplasm biobanking

Topic: MSCA-RISE-2016

Type of Action: MSCA-RISE

Duration: 48

Start date: 1st May 2017 (expected)

Grant agreement: 734434

Web: (not yet available)

Total request Grant by Consortium: €765,000

Total request Grant by BBMRI-ERIC: €54,000

Linked Third Parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: Workshop for BBMRI-ERIC and possibility to invite researchers within Marie Skłodowska-Curie Fellowships (Japan, France, Hungary).

Status: score 14.3 (threshold 10.5)/under negotiation at the time of preparing Work Programme 2017

Abstract: *Lead by Università degli studi di Teramo:* The number of biobanks for diagnostic/clinical/biodiversity preservation purposes is increasing exponentially, representing an economic burden for the EU. Cryopreservation is the only cells/gametes long-term repository method. Liquid nitrogen storage is expensive though, requires dedicated facilities, is hazardous, carries pathogens and has high carbon footprint. DRYNET objective is to set an inter-sectorial/multidisciplinary/international network between EU academic (5), SME (3), the BBMRI-ERIC, and international partners (Japan/Thailand), with the aim of sharing know-how & expertise to lay down the theoretical and early empirical basis for the dry storage of cells/germ plasm. DRYNET merges the partner's expertise, theoretical/ biophysical/ mathematical modelling, cellular/ molecular/ insect biology, embryology, mechanical engineering into a coherent approach towards dry storage of cells/germ plasm. International/inter-sectorial secondments, with meeting/workshop/summer school will be primary tools to implement our strategy for biobanking. Outreaching activities will guarantee public awareness of the project. DRYNET's relies on water subtraction to induce a reversible block of metabolism, a survival strategy available in nature (anhydrobiosis). The work plan foresees the exploitation of natural xero-protectants, loaded/expressed in gametes/cells, before drying. DRYNET will bring a simplification of current practices, with cost and carbon footprint reduction, for the maintenance/shipping of biobanks. DRYNET will generate young scientists with transferable skills, ensuring career prospect in academia/industry. DRYNET strengthens the international/sectoral network between different disciplines, ensures long-term sustainability of the project, and boosts European competitiveness in biobanking.

List of Participants: Università degli studi di Teramo, Università degli studi di Cagliari, Universidad de Burgos, AVANTEA srl, BioTalentum TUDASFEJLESZTO KFT, Institute of Agrobiological Sciences, NARO, Chulalongkorn University, IMAGENE, Biobanks and BioMolecular resources Research Infrastructure Consortium (BBMRI-ERIC)

10.7 EGI-Engage (H2020)

Engaging the EGI Community towards an Open Science Commons

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

Start date: 1st May 2015 **Grant agreement:** 654142

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

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

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

Linked Third Parties/BBMRI-ERIC Framework Agreement:

BBMRI.cz, BBMRI.se, BBMRI.nl

Benefit/tasks for BBMRI-ERIC: BBMRI Competence Centre in WP6 (SA2) Knowledge Commons; cross-border procurement in WP2

Status: score 15 (threshold 10)/accepted

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

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

10.8 EOSCpilot (H2020)

The European Open Science Cloud for Research Pilot Project

Topic: INFRADEV-04-2016 **Type of Action:** RIA **Duration:** 24

Start date: 1st February 2017 (expected) **Grant agreement:** 739563

Web: (not yet available)

Total request Grant by Consortium: €9,953,067.50

Total request Grant by BBMRI-ERIC: €78,405.00

Linked Third Parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: Development and piloting of policies of medical data sharing as a part of European Open Science Cloud.

Status: score 11.5 (threshold 9)/under negotiation at the time of preparing WP2017

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

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

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

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

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

List of Participants: Science And Technology Facilities Council, CSC-Tieteen Tietotekniikan Keskus Oy, Max-Planck-Gesellschaft Zur Forderung Der Wissenschaften Ev, European Molecular Biology Laboratory, Surfsara BV, Stichting EGI, Centre National De La Recherche Scientifique CNRS, Karlsruher Institut Für Technologie, The University of Edinburgh, Stichting Liber, Trust-It Services Limited, Athena Research And Innovation Center In Information Communication & Knowledge Technologies, Jisc Lbg, Partnership For Advanced Computingin Europe Aisbl, Consiglio Nazionale Delle Ricerche, Istituto Nazionale di Fisica Nucleare, Stiftung Deutsches Elektronen-Synchrotron Desy, Istituto Nazionale di Geofisica e Vulcanologia, Barcelona Supercomputing Center – Centro Nacional De Supercomputacion, Georg-August-Universitat Gottingenstiftung Offentlichen Rechts, Koninklijke Nederlandse Akademie Van Wetenschappen – KNAW, ICOS ERIC, GEANT Vereniging, Istituto Nazionale di Astrofisica, Biobanks And Biomolecular Resources Research Infrastructure Consortium (BBMRI-ERIC), European Spallation Source ERIC, Natural Environment Research Council, European X-Ray Free-Electron Laser Facility GmbH, ECRIN European Clinical Research Infrastructure Network, The University of Manchester United, Pin Soc.Cons. A R.L. – Servizi Didattici e Scientifici Per l'Universita di Firenze, Commissariat A L Energie Atomique Et Aux Energies Alternatives, Consorzio Interuniversitario Cineca

10.9 PhenoMeNal (H2020)

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

Topic: H2020-EINFRA-1-2014

Type of Action: RIA

Duration: 36 months

Start date: 1st September 2015

Grant agreement: 654241

Web: <http://phenomenal-h2020.eu/>

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

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

Linked Third Parties/BBMRI-ERIC Framework Agreement: none

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

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 exposure 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 à l'énergie atomique et aux énergies alternatives, Institut national de la recherche agronomique, SRI International, The Governors of the University of Alberta/University of Alberta

10.10 RD-CONNECT (FP7)

RD-Connect: An integrated platform connecting registries, biobanks and clinical bioinformatics for rare disease research

Topic: FP7-HEALTH-2012-INNOVATION

Type of Action: SP1 Collaboration

Duration: 72

Start date: 1st November 2012

Grant agreement: 305444

BBMRI-ERIC as a full partner: 1st April 2015

Web: <http://rd-connect.eu/>

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

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

Linked Third Parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: Set and implement quality standards for rare disease biobanks, contribution to the biomaterial sharing work, incorporate new biobanks, develop synergies among BBMRI-ERIC and RD-Connect training activities, investigate sustainability options.

Status: score 13.5 (threshold 10)/accepted

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

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

10.11 RItrain (H2020)

Research Infrastructures Training Programme

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

Start date: 1st September 2015 **Grant agreement:** 654156

Web: <http://ritrain.eu/>

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

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

Linked Third Parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: Coordinated by BBMRI-ERIC. Definition of required competences in distributed RIs throughout the lifecycle of an RI, from the initiation preparatory phase through to operational maturity.

Status: score 11.5 (threshold 10)/accepted

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

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

10.12 SPIDIA4P (H2020)

SPIDIA for Personalized Medicine – Standardisation of generic Pre-analytical procedures for Invitro DIAGNOSTICS for Personalized Medicine

Topic: SC1-HCO-02-2016

Type of Action: CSA

Duration: 48 months

Start date: 2017 (expected)

Grant agreement: 733112

Web: (not yet available)

Total request Grant by Consortium: €1,999,972.50

Total request Grant by BBMRI-ERIC: €100,673.75 (Headquarters Quality Service)

Linked Third Parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: standards to biobanks and reference centres, education and training programmes, industry-academia stakeholder workshop

Status: score 14.5 (threshold 10)/accepted

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

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

Glossary

AAI Authentication and Authorization Infrastructure. 17, 18, 58, 59

AARC Authentication and Authorisation for Research and Collaboration. See <https://aarc-project.eu/> and GÉANT, 17, 18

BBMRI-ERIC Associated Expert Centre/Trusted Partner Non-profit public-private partnership organisations, see Workstream 8.1 – Expert Centres.

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BBMRI-ERIC Directory Information service by BBMRI-ERIC, providing highly aggregated data about the biobanks and their collections of biological material and data. Previously also known as BBMRI Catalogue. 9, 11–16, 20, 22, 38, 39, 51,

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BIBBOX “Biobank in a Box” (BIBBOX) is an integrated software toolset as a part of reference information technology tools for biobanks. 13, 14,

61

BMS RI Biological and Medical Sciences Research Infrastructure. 28,

31

CEN European Committee for Standardization (Comité Européen de Normalisation), <http://www.cen.eu/>. 20, 50, 73

CEN/TS Technical Specification by CEN,

<https://www.cen.eu/work/products/TS/Pages/default.aspx>. 20, 21,

50

Common Service A Common Service means a facility of BBMRI-ERIC according to Article 15(1) according to the Statutes.. 44, 51, 53

Common Service IT Common Service on Information Technologies (IT). 7, 11–16, 27, 28, 36, 39, 52, 56, 60, 62, *see* Common Service

Common Service ELSI Common Service on Ethical, Legal, and Societal Issues. 7, 15, 24, 28, 41, 42, 56, 60–62, 64, *see* Common Service

DG CONNECT The European Commission Directorate General for Communications Networks, Content & Technology,

<https://ec.europa.eu/digital-single-market/en/dg-connect>.

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DG JUSTICE The European Commission Directorate-General for Justice and Consumers, <http://ec.europa.eu/justice/>,

http://ec.europa.eu/justice/mission/index_en.htm.

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DG RESEARCH The European Commission Directorate-General for Research and Innovation, <http://ec.europa.eu/research/>. 24

DG SANCO The European Commission Directorate-General for Health and Food Safety, <http://ec.europa.eu/health/>, http://ec.europa.eu/dgs/health_food-safety/index_en.htm. 24

DICOM Digital Imaging and Communications in Medicine (DICOM) is a standard for handling, storing, printing, and transmitting information in medical imaging. It includes a file format definition and a network communications protocol. 38

Director General The Director General is responsible for management of BBMRI-ERIC. 6, 23, 75

ECPC European Cancer Patient Coalition, <http://www.ecpc.org/>. 4, 26

EGI-Engage EGI-Engage project. <https://www.egi.eu/about/egi-engage/>, 18

ELSI ethical, legal, and social issues. 8, 24, 26–28, 40–42, 44, 45, 56, 61

EOSC European Open Science Cloud. 18

ESBB European, Middle Eastern & African Society for Biopreservation and Biobanking, <http://esbb.org/>. 45

ESFRI The ESFRI, the European Strategy Forum on Research Infrastructures, is a strategic instrument to develop the scientific integration of Europe and to strengthen its international outreach. https://ec.europa.eu/research/infrastructures/index_en.cfm. 59

ESR European Society of Radiology. 38–41

EUDAT European data infrastructure, <https://www.eudat.eu/>. 18

EUPATI European Patients' Academy, <https://www.eupati.eu/>. 28, 45

EUREC The EUREC is a network that brings together already existing national Research Ethics Committees (RECs) associations, networks or comparable initiatives on the European level. <http://www.eurecnet.org>. 28

FAQ Frequently asked questions. 25, 27

FFPE Formaline-fixed paraffin-embedded (type of archival tissue). 49

GDPR General Data Protection Regulation. 24, 25, 28

GEDE Group of European Data Experts in RDA, <https://rd-alliance.org/groups/gede-group-european-data-experts-rda>. 18, *see* RDA

Global Biobank Week Annual biobanking conference, continuation of HandsOn Biobanks and Europe Biobank Week. It is planned 13th – 15th September 2017 in Stockholm, Sweden. 27, 45, 46

GÉANT The GÉANT Association, <http://www.geant.net/>. 17, 18, 73, 76

Headquarters also called Central Executive Management Office of BBMRI-ERIC. It is located in Graz and supports the Director General in performing the managerial functions. 1, 15, 16, 18, 23, 27, 28, 31, 33, 34, 37, 39, 41, 44–46, 52, 56, 72

ICD-10 International Classification of Diseases, 10th revision, provided by World Health Organization (WHO). See <http://www.who.int/classifications/icd/en/>. 12, 13

IMI Innovative Medicines Initiative, <https://www.imi.europa.eu/>. 31

ISBER International Society for Biological and Environmental Repositories, <http://www.isber.org/>. 45

ISO International Organization for Standardization (ISO), <http://www.iso.org/>. 21, 75

ISO/CD Committee Draft of ISO. 21, *see* ISO

ISO/TC Technical Committee of ISO. 17, 18, 21, *see* ISO

LIMS Laboratory Information Management System. 13

MIABIS Minimum Information About Biobank data Sharing (MIABIS), community standard for representing biobanks and their contents. See <https://github.com/MIABIS/miabis/wiki>. 38, 39, 51

MoU Memorandum of Understanding. 38, 40

National or Organisational Node National Nodes means an entity, not necessarily with legal capacity, designated by a Member State, that coordinates the national Biobanks and Biomolecular Resources, and links its activities with the pan-European activities of BBMRI-ERIC. Organisational Node means an entity, not necessarily with legal capacity, designated by an intergovernmental organisation that coordinates the Biobank(s) and Biomolecular Resources of the organisation, and links its activities with those of the pan-European infrastructure, BBMRI-ERIC. 6, 7, 10, 11, 13, 15, 16, 18, 20, 23, 25, 28, 31, 33, 34, 37–39, 41–46, 48, 50, 53, 54, 56

NPRM The Notice of Proposed Rulemaking (NPRM) is a public notice issued by law when one of the independent agencies of the United States government wishes to add, remove, or change a rule or regulation as part of the rulemaking process. <http://www.gpo.gov/fdsys/pkg/FR-2015-09-08/pdf/2015-21756.pdf>. It follows the Advance Notice of Proposed Rulemaking (ANPRM, in relation to the *Common Rule* it closed in 2011), which is used by an agency as a vehicle for

obtaining public participation in the formulation of a regulatory change before the agency has done significant research or investigation on its own.

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NREN National Research and Educational Network. 59

OECD Organisation for Economic Co-operation and Development,

<https://www.oecd.org/>. 24

P³G Public Population Project in Genomics and Society, <http://www.p3g.org/>. 28,

43

QMS Quality Management System. 19–21

RDA Research Data Alliance, <https://rd-alliance.org/>. 17, 18, 74

SNOMED CT Clinical health terminology by The International Health Terminology

Standards Development Organisation (IHTSDO). See

<http://www.ihtsdo.org/snomed-ct>. 12, 13

SOP Standard Operating Procedure. 19, 40, 41, 50, *see* QMS

Stakeholder Forum Stakeholder Forum provides a platform for stakeholder of

BBMRI-ERIC, e.g., patient advocacy groups, learned societies, and industry.

Stakeholder Forum is distinct from BBMRI-LPC Forum (see Workstream 7.3 – Global Biobank Week). 8, 25, 26, 28–31, 42, 44

UMLS Unified Medical Language System. An ontology which unifies key terminology, classification and coding standards, and associated resources to promote creation of more effective and interoperable biomedical information systems and services, including electronic health records. See

<https://www.nlm.nih.gov/research/umls/>. 13

VOPaaS Virtual Organization Platform as a Service provided by GÉANT.

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WHO World Health Organization. 75

WMA World Medical Association, <https://www.wma.net/>. 24

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