

WORK PROGRAMME

2019



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EXECUTIVE SUMMARY

“Healthcare as we know it will probably be seen as medieval in the next two decades”

Peter Hinssen, during EBW18 in Antwerp

BBMRI-ERIC, the Biobanking and BioMolecular Resource Research Infrastructure – European Research Infrastructure Consortium is a unique infrastructure with 20 Member states and one international Organization having joined forces in establishing one of the largest health Research Infrastructures in Europe today. It is the mission of BBMRI-ERIC to establish, operate and develop a pan-European distributed research infrastructure of Biobanks and Biomolecular Resources to facilitate the access to resources as well as facilities and to support high quality biomolecular and medical research. In line with our mission, our new Vision Paper sets out the strategic objectives for the years ahead and provides a guide to design our tactical actions; this edition of the Work Programme is the first of a series that is based on the vision paper and describes measurable actions and deliverables per theme.

BBMRI-ERIC’s vision is to further build and strengthen value-added sustainable biobanking for all stakeholders enabling academia and industry to make new treatments possible

Where last year the focus in communication has been a new and refreshing message from the overall organisation, it is now time to further develop the material and messaging in such a way that also

the National Nodes can use and distribute it. Supporting further awareness by a wider audience in a consistent way is important to increase the numbers of samples being used and truly support both messages: *Making new treatments possible* and Increase *the visibility of biobanks*.

Besides the material itself, also support to the countries in market intelligence on trends, opportunities and potential challenges will be shared monthly. Additionally, dedicated resources will be allocated to position and promote the new Sample Access Help Desk and the various services it can offer to the broader biomedical research field. The Stakeholder Forum build a solid patients/consumer pillar and interactions with governmental stakeholders are optimal. In 2019 BBMRI-ERIC will focus on launching the industry pillar and define a strategy for the creation of the healthcare professionals and researchers pillar. A start will be made with expanding the coalition with other Medical Research Infrastructures and 3 explore the potential to jointly approach several services and increase the impact of our efforts in the public arena, preparing for consolidated services in 2020 and beyond.

The Vision Paper of BBMRI-ERIC describes clearly the need for a service driven approach and the developed services of BBMRI-ERIC are now reaching a mature status to really start this. With the start of

the Sample Access Help Desk we can offer one single entry point for all questions related to getting access to the European samples and associated data, serving the needs of all our stakeholders (incl. clinical, rare disease and for example paediatric communities).

Science is and will be the backbone of all the activities of BBMRI-ERIC. We need to be on top of new trends and developments to act in a timely manner to challenges and opportunities. The various awarded projects like EOSC-Life, EJP-RD, ERIC-FORUM, RI-VIS, EuCanShare, EuCanConnect and ConcePTION can drive these scientific developments that could lead to new dedicated services or a better understanding and background information on the topic itself. In 2019 the governance model of Common Services will transition to maximize efficiency and effectiveness, using the available resources more efficient.

Small changes are made in the budget setup for next year to make it more transparent and easier to monitor, both internally as externally. Similar as in 2018 we will constantly look for additional funding via other roots than via the Member States; via projects, IMI and for example via paid services for non-members/observers. This is the only option to grow and further build BBMRI-ERIC and its impact to the biobank and healthcare community.

In closing I would like to thank the dedicated team in Graz, our Members and Observers, the various governing bodies of BBMRI-ERIC and the general public via twitter for their input to this Work Programme for 2019. Let us keep the momentum created in 2018, execute on our vision and be ready for the day after tomorrow.

Erik Steinfeldt

1. MarCom

Making new treatments possible is the ultimate goal of BBMRI-ERIC and its stakeholders, and it is also the new message that started to be communicated widely and consistently in 2018. Increasing the visibility of BBMRI-ERIC further in combination with targeted campaigns to highlight the developed services will be the key focus on 2019. BBMRI-ERIC has already developed a great set of services but can be even more proactive to match them more targeted for potential new users and significantly grow the user-base. Continued effort will be invested in gathering more environmental data to back up the directions forward and share with the National Nodes.

1.1. Communication and Branding

A set of activities will be initiated to manage and monitor all internal and external communication of BBMRI-ERIC to all stakeholders in order to help explain the mission, vision and added value in a cohesive way, aiming at creating a favourable point of view.

Progress will be measured on a monthly basis on specific communication KPI's: number of followers, impressions and engagements.

Owner	Deliverable	Timing
HQ	- Further develop corporate identity to ensure all communication channels and material, such as the website, logos, newsletter, letterhead, business cards, presentations, posters, booths, rollups, conference material, etc., feature a consistent design	Q1-4
	- Organize a "Communication Day" with representatives from all National/Organisational Nodes in Graz	Q2
	- Increase the Newsletter attractiveness	Q1-4
	- Develop websites and perform outreach activities for new projects in which BBMRI-ERIC is leading or co-leading the outreach WP, joined activities with EATRIS-ECRIN	Q1-4
	- Continuous improvement of social media network: Twitter, LinkedIn	Q1-4

1.2. Environment Research

The external environment of BBMRI-ERIC contains all the conditions and forces that influence the strategic options and define our competitive situation. BBMRI-ERIC needs to be on top of new 5 trends and developments in order to act in a timely manner to challenges and opportunities. Initiatives to monitor this in a consistent way have started in 2018 and are now ready to be extended and deployed to benefit a wider audience. Environment Research will benefit both Marcom and Public Affairs-Stakeholder engagement activities. Progress will be made on KPI's that measure the biweekly updates and the number of follow up activities that are created.

Owner	Deliverable	Timing
HQ	<ul style="list-style-type: none"> - Restructure Policy & Foresight Taskforces - Merge the tasks forces in one (Strategy & Partnership Taskforce); - Define new mission, vision and objectives for the Taskforce including interactions with HQ, National Nodes, Stakeholder Forum and external actors; - Create a unique total workflow for intelligence gathering and information sharing within BBMRI-ERIC, led by the Taskforce. 	Q1 Q1-4 Q1-2
	<ul style="list-style-type: none"> - Nominate representative for the Strategy and Partnership Task Force 	Q1

1.3. Marketing

Communication, branding and environment research are instrumental in marketing the developed services that are offered by BBMRI-ERIC to the National Nodes. This shall truly increase the visibility and valorisation of their biobanks and samples. Special focus in 2019 will be the services approach, supported with the sample access helpdesks. Each campaign will be monitored with similar KPI's as the overall BBMRI-ERIC strategy in combination with detailed statistics per communication channel (social media, mail, podcasts etc).

Owner	Deliverable	Timing
HQ	<ul style="list-style-type: none"> - Develop overall promotion strategy procedure for the sample access services. - Develop self-assessment and collateral - Identify key opinion leaders for support QM, IT, ELSI - Launch awareness campaign per service - New Campaign on Rare Diseases inclusion - Support National Nodes with the marketing of country specific strengths 	Q1-2 Q1 Q2 Q1, Q3 Q2, Q4 Q2, Q4

1.4. Public Relations

In addition to the internal developed material, also the regular media channels will be used to get the overall message across. Press releases to media and posts on social media/blogs can support the communication with the stakeholders and the general public in an effective way with relatively low investment. Central themes will be biobanking in general, GDPR, personalised medicine etc.

Here it is important to measure the effectiveness of press releases, blogs and posts on a monthly basis.

Owner	Deliverable	Timing
HQ	- Enrich the existing monitoring system and newsletter (link with 1.2 Environment Research and 2.2. Public Affairs) and broaden the BBMRI audience (dedicated monitoring newsletters to Management Committee, Assembly of Members).	Q1-2
	- Foster the visibility of the Stakeholder Forums (liaise with 2.1 Stakeholder Forum), by involving Stakeholder Forum members in the production of communication material (news, blogpost, social media etc.).	Q1-4
	- Develop and improve liaison with press at national/international level with support of National Nodes	Q1-4
	- Set up new BBMRI-ERIC press kit, incl services approach and Vision Paper	Q1
	- Offer press kit support to National Nodes	Q1-4
National Nodes	Suggest case studies, support with press contacts	Q1-2

1.5. Events and Promotions

Face to face contact is still very important to discuss and present the added value a Research Infrastructure can bring and its scientific achievements. Significant amount of resources will be dedicated for meetings to bring the various stakeholders together at live events to learn, share and discuss experiences. This workstream will focus on organizing these events like the Europe Biobank Week and biobank visits. A new initiative to have a National Biobank Day in all the member states on a specific joined date will be started in 2019.

The number of visitors, their background and feedback scores will be measured per event and combined to see and analyse trends.

Owner	Deliverable	Timing
HQ	- Latina America workshop in Brazil, January '19	Q1
	- #EBW19 (8-11 October 2019) Lübeck (D)	Q3
	- Kick-off meetings in new projects EOSCLife, EUCanShare, ERIC-Forum	Q1-2
	- Collaboration for events organised by/with ISBER and ESBB	Q2-3
	- National Biobank Day	Q2
National Nodes	- Support Europe Biobank Week with programme	Q1-3
	- Open biobanks for stakeholders to visit	Q2-4

HQ	<ul style="list-style-type: none"> - Kick off meeting of the industry pillar - Further develop the Stakeholder Engagement Experts Task Force <ul style="list-style-type: none"> - Create a knowledge base of best practices for National Nodes to use; - Provide training to NN on stakeholder engagement; - Launch an annual National Biobank Day in partnership with National Nodes and SF members. 	Q2 (EBW19) Q1-4
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2.2. Public Affairs

2019 will bring important changes in the panorama of EU policy, to which BBMRI-ERIC must be ready to adapt. The installation of the new Commission, the elections of the European Parliament and the negotiation for the next Framework Programme require BBMRI-ERIC not only to be reactive, but also proactive. The objective for 2019 is to consolidate BBMRI-ERIC policy position, by creating a stronger policy narrative based on the new Vision. At the same time, BBMRI-ERIC can consolidate its leadership on the GDPR implementation (code of conduct), explore more the European Open Science Cloud and open up to new policy files.

Timing is everything, focus will be on the response times to public consultation and timely executing of strategy in getting new members onboard.

Owner	Deliverable	Timing
HQ	<ul style="list-style-type: none"> - Enrich and update the database of key (internal/external) contacts using Salesforce (liaise with 1.2 Environment Research). - Establish BBMRI-ERIC as a leading biomedical RI within the EU research policy framework (ERIC Forum, ICRI...). - Produce and promote BBMRI-ERIC policy positions on relevant issues at EU and international level: <ul style="list-style-type: none"> - Reply to public consultations, focus on European organizations; - Produce own policy paper, when appropriate. 	Q1-4 Q1-4 Q1-4

2. Stakeholders and Partners

2.3. Strategic Partnerships

For the successful implementation of BBMRI-ERIC Vision it is necessary to seamlessly integrate BBMRI-ERIC services with other, complementary services, by expanding the number of formal collaboration BBMRI-ERIC has, and deepen the level of cooperation. Increasing our collaboration with other RIs will decrease isolation and fragmentation of efforts. Most importantly, such renewed alliance will increase the impact of the activities significantly and minimize waste of precious resources.

The process of expanding our partnerships shall go hand in hand with the enlargement of BBMRI-ERIC membership, to make sure than more and more biobanks and researchers can profit of our services.

Owner	Deliverable	Timing
HQ	<ul style="list-style-type: none"> - Deepen the collaboration with EATRIS and ECRIN: <ul style="list-style-type: none"> - Explore the creation of joint services - Explore scenarios for establishment of a longterm collaboration framework 	Q1-3
	<ul style="list-style-type: none"> - Consolidate the collaboration with ESBB <ul style="list-style-type: none"> - Strategic workshop with ESBB to discuss plans for future collaboration (besides the Europe Biobank Week) 	Q1-4
	<ul style="list-style-type: none"> - Continue and consolidate the collaboration with ISBER <ul style="list-style-type: none"> - Negotiations and planning of Global Biobank Week 2020 	Q1-4
	<ul style="list-style-type: none"> - Enlarge BBMRI-ERIC Membership <ul style="list-style-type: none"> - Produce country profiles to identify possible new members; - Prioritise action in 1-2 countries; - Produce strategies in partnership with local biobanking communities. 	Q1-4
	<ul style="list-style-type: none"> - Strengthen strategic partnership with National Nodes and Members <ul style="list-style-type: none"> - Produce a new BBMRI-ERIC value proposal for existing and new Members, based on a survey to NN focused on mapping key requirements by which each Member will evaluate BBMRI-ERIC - Support NN in building a strategy to tap onto European Structural and Investment Funds and other capacity building opportunities. 	Q1-4

INCREASING THE **VISIBILITY** OF BIOBANKS AND SAMPLE COLLECTIONS



3. Services and Tools

The Vision Paper of BBMRI-ERIC describes clearly the need for a service driven approach and the developed services of BBMRI-ERIC are now reaching a mature status to really start this. A new approach that can accelerate the pathway from laboratory discoveries to diagnostics and treatments. This does require integration in the real-life practice of academic and industry researchers, to ensure that they become a real building block in the road towards new treatments. In addition, it is then crucial to operate towards a service-oriented total workflow model, serving the needs of all our stakeholders (incl. clinical, rare disease and for example paediatric communities).

3.1. Set up of Sample Access Helpdesk

Main service of BBMRI-ERIC is providing access to samples and their data for the various researchers, scientists and potentially industry. Access that can be given by self-service or via the new Sample Access Helpdesk where the aim is to have one single point of entry for the relevant biobank questions, requests for samples and introduction to potential biobanks or international partners. This new setup requires close cooperation between the various disciplines internally and externally, strongly involving the National Nodes. During the transition period towards this new helpdesk setup, the various topics are still separately described

Owner	Deliverable	Timing
HQ	- Retreat with National Nodes to discuss common services goals and expectations	Q1-2
	- Create real split between Services and R&D	Q2
	- Total workflow approach, incl break down of silos	Q2-3
	- Setup of Sample Access Helpdesk	Q2
National Nodes	- Actively participate in Retreat	Q1-2
	- Nominate experts for Sample Access Help Desk	Q1

3.2. Quality

The BBMRI-ERIC biobanks are ready to enter the “Window of Opportunity” to position themselves as “the source” of high-quality sample providers. A practiced quality management system based on international standards is a key enabler for science that one trusts. A cornerstone in this development is the provision of an International Standard for Biobanking (ISO 20387:2018) and a collection of Technical Specifications for appropriate sample handling procedures (CEN/TS and ISO/TS) which will bring the biobank community into a new era of scientific research and development. BBMRI-ERIC will focus in 2019 on providing services for QM improvements and performance evaluation.

3.2.1. Empower researchers to successfully implement quality measures

Crucial for trusted scientific output of research (academia and industry) is the sound implementation of quality measures, indispensable for the development of personalized medicine solutions, medical devices and diagnostics. Empowering researchers through information (Knowledge Hub), training education (Training & Support) and review (Pre-Auditing) initially focussing on the Members and Observers. Outside Europe the services can be obtained for a cost recovery fee.

Owner	Deliverable	Timing
HQ-QM	<p>Knowledge Hub</p> <ul style="list-style-type: none"> - Provision of BBMRI.QM webinars (public) - Provision of BBMRI.QM training on relevant standards - Maintenance of the QM service and tools (see also R&D) <p>Training & Support</p> <ul style="list-style-type: none"> - In-house and online trainings on Biobanking Standard (ISO20387) and Sample handling Standards (CEN/TS, ISO) - Provision of BBMRI.QM training on relevant standards <p>Auditing</p> <ul style="list-style-type: none"> - BBMRI-ERIC Self-Assessment Surveys - BBMRI-ERIC Audits - Provision of BBMRI.QM training on Auditing Systems 	Q1-4
National Nodes	<ul style="list-style-type: none"> - Support and promote BBMRI.QM Services - Nominate technical Experts for BBMRI.QM Services 	Q1-4

3. Services and Tools

3.2.2. Introduction of the performance evaluation

Those biobanks, collections and samples meeting the high-quality demands according to European and International Standards, can qualify for a Quality-Grade in the BBMRI-ERIC Directory. Quarterly the National Nodes will receive and update on BBMRI-ERIC SAS utilisation performance indicators.

Owner	Deliverable	Timing
HQ-QM	- Q-Grade according to BBMRI-ERIC Self-Assessment (SAS)	Q1-4
National Nodes	- Promote and support BBMRI-ERIC Q-Grading - Encourage biobanks to utilize BBMRI-ERIC SAS and undergoing review processes.	

3.2.3. Performance evaluation

Auditing is essential to verify the existence of objective evidence showing conformance to required processes, to assess how successfully processes have been implemented, and are also necessary to provide evidence concerning reduction and elimination of problem areas. Our Pre- Audit Program support biobanks with a hands-on management tool for achieving continual improvement in their organization.

A) Pre-Auditing the "Quality Management Systems and General requirements for biobanking" according to ISO 20387:2018 and ISO 9001:2015, is an onsite service. This service is provided on request and might lead to a Q-Label in the BBMRI-ERIC Directory.

B) Pre-Auditing "Collection/Sample handling processes" according to CEN/TS and ISO/TS, is a remote pre-audit service. This service is based on submitted reports of BBMRI-ERIC Self-Assessment Surveys and might lead to a Q-Label in the BBMRI-ERIC Directory. Onsite audit service will be provided on request (See also R&D)

Owner	Deliverable	Timing
HQ-QM	- Conduct performance evaluation on A) and B)	Q1-4
HQ-QM and National Nodes- QM	- Conduct performance evaluation on A) and B) in accordance with HQ-QM to safeguard harmonisation	Q1-4

3.3. CS IT

BBMRI-ERIC offers IT support to improve the visibility and findability of biobanks to increase the use of the stored material and its data, in a privacy respecting manner.

3.3.1. Core IT Services

Several tools are developed and operated to support researchers in finding material also enabling effective communication between the parties involved. Tools to support newly established biobanks or biobanks lacking sufficient IT systems are also offered. Monthly the number of users, views, requests and positive responses will be measured.

Owner	Deliverable	Timing
Common Services - IT	<p>Directory</p> <ul style="list-style-type: none"> - operations and maintenance - support of NNs in providing/updating data - LifeScience AAI integration - outreach <p>Negotiator</p> <ul style="list-style-type: none"> - operations and maintenance - LifeScience AAI integration <p>Locator</p> <ul style="list-style-type: none"> - operations and maintenance - supporting pilot biobanks in connecting via Connectors <p>Authentication & Authorization Infrastructure (AAI)</p> <ul style="list-style-type: none"> - operations and maintenance - simplification of procedures for users <p>BIBBOX</p> <ul style="list-style-type: none"> - support of biobanks in adopting BIBBOX tools <p>CRC-Cohort</p> <ul style="list-style-type: none"> - hosting and curating data set - enriching data with digital pathology data sets - enhancements of analytical tools for checking data quality - implementation of Connector for the CRC-Cohort <p>MIABIS</p> <ul style="list-style-type: none"> - development of new components (SOP metadata, domain-specific extensions to sample/donor data, etc.) 	Q1-4

3. Services and Tools

Owner	Deliverable	Timing
Common Services – IT	Interoperability Forum <ul style="list-style-type: none"> - Directory API - Genomic data querying API - Locator - continuing current activities of API standardization (aka Connector loading API and federated querying API) 	Q1-4
Common Services – IT	BBMRI-ERIC Helpdesk <ul style="list-style-type: none"> - maintenance Operational IT infrastructure <ul style="list-style-type: none"> - support for failover transfers between CNR (Italy) and BBMRI-ERIC backup facility hosted in Austria - CS IT User Forum development to help with alignment of users' needs to the design and development of CS IT products - recruiting additional representatives of users – especially academic and industrial researchers - focus studies on usability of Directory, Negotiator, Locator + Connector, AAI, Helpdesk 	Q1-4 Q2-4 Q1-4

3.3.2. Support

Various initiatives to support the National Nodes with IT will be started or continued.

Owner	Deliverable	Timing
Common Services – IT	BBMRI-ERIC Helpdesk <ul style="list-style-type: none"> - maintenance Operational IT infrastructure <ul style="list-style-type: none"> - support for failover transfers between CNR (Italy) and BBMRI-ERIC backup facility hosted in Austria - CS IT User Forum development to help with alignment of users' needs to the design and development of CS IT products - recruiting additional representatives of users – especially academic and industrial researchers - focus studies on usability of Directory, Negotiator, Locator + Connector, AAI, Helpdesk - Training days onsite to increase the number of users with the various tools. 	Q1-4 Q2-4 Q1-4

3.4. ELSI Services

The BBMRI-ERIC ELSI Service provides support on ethical, legal and societal issues related to biobanking. It relies on a network of experts, who are in various degrees linked to the National Nodes and are organized in several task forces. The vision and aim are to provide available, feasible, practical, usable, reliable, verifiable and sustainable ELSI guidance for our customers.

Owner	Deliverable	Timing
Common Services - ELSI	<ul style="list-style-type: none"> - Maintain and improve ELSI Helpdesk (custombased) and Knowledge Base (self-serving tool), ensure accuracy of information provided. Preparing it to transition towards one Sample Access Help Desk - Provide Ethics Check Service for Proposals - Implement education & training activities for biobankers, researchers, National Nodes - Connect National Help Desks 	Q1-4
National Nodes	<ul style="list-style-type: none"> - Nominate/update members or contributing experts to ELSI team - Provide info on national ethical, legal, and societal aspects, - Provide input to task forces (e.g. public consultations) - Connect with BBMRI-ERIC Sample Access Helpdesk 	Q1-4

3.5. Rare Diseases

In 2018 significant efforts were made to explore the potential of including services around Rare Diseases within BMMRI-ERIC and had a positive outcome. The deliverables created within project RD-Connect can be hosted as true services now the project is ended. The RD-Connect Registry and Biobank Finder are to be integrated to allow flow of information. A study is needed to see if the tool and current RD biobank area of the BBMRI-ERIC Directory can be merged or complemented.

Owner	Deliverable	Timing
HQ	Maintaining Registry & Biobank Finder, Sample Catalogue	Q1-4

4. Research and Development

BBMRI-ERIC needs to be on top of new trends and developments to act in a timely manner to challenges and opportunities. Besides the earlier addressed Market Research, it is important to work in smaller teams on new innovative approaches that could lead to new dedicated services or a better understanding and background information on the topic itself. In the majority of cases we will use the projects to achieve this. Per topic is described which developments and research activities are planned

4.1. Quality

BBMRI-ERIC is part of new European Standard developments (ISO and CEN) within the Project SPIDIA4P we will expect in the next 2 years nine new Technical Specifications, we will integrate into our Self-Assessment and Auditing Service. Currently BBMRI-ERIC QM Service offers 9 Self-Assessment Surveys on European basis (CEN/TS) this CEN/TS will be updated as ISO Standards. The updates have to be implemented into the BBMRI-ERIC System. The Auditing Service developed by BBMRI-ERIC should be rolled out to the National Nodes. A Pool of Auditing Experts in Biobanking (ISO 20387:2018) and technical Experts for assessing sample quality according to given standards (CEN/TS and ISO/TS) should be build up.

The Quality service is seen of value outside of BBMRI-ERIC, even outside of Europe (e.g. Japan, USA, Middle East) This service is embedded in a total value chain of biomedical research.

Collaboration with medical Research Infrastructures. BBMRI-ERIC already paved the way for collaboration with medical RI's EATRIS and ECRIN (Position paper 13 September 2018). BBMRI.QM can take the leading role in further development of an encompassing Quality Management Service including all RIs.

Owner	Deliverable	Timing
HQ-QM National Nodes QM	Building up auditing expertise within the National Nodes - 3-4 day QM Seminar for National Node-QM (Graz) Promoting cross audits within the National Node - At least 1 cross audit per National Node	Q2-Q3
HQ-QM	A) Collaboration with medical Research Infrastructures re QM Services - Development of a common QM Strategy in medical RIS - Build up collaboration with EATRIS and ECRIN - Invite stakeholders of EATRIS and ECRIN to a conference on harmonized QM Strategy - Draft MoU cooperation plan	

4.2. IT

Researchers looking for samples can already use the CS-IT services mentioned in the previous chapter. Further development and exploration of possibilities is still needed and therefore part of the R&D activities. Especially within EOSC-Life and EJP-RD is strong presence of CS-IT included.

Owner	Deliverable	Timing
CS IT	<p>Directory</p> <ul style="list-style-type: none"> - focus groups analysis to obtain feedback on the user experience using User Forum - updates of user interfaces to improve user experience - incorporation of new MIABIS modules (e.g., SOP metadata) - continuing incorporation of persistent identifiers - FAIR Data Point support and FAIR compliance Negotiator <p>Negotiator</p> <ul style="list-style-type: none"> - exploration of Podium integration (support of sample delivery workflow) - support of National Nodes and networks - support of project database <p>Locator</p> <ul style="list-style-type: none"> - improvements of data model - focus groups analysis to obtain feedback on the user experience using User Forum - usability improvements based on feedback from pilot database <p>Authentication & Authorization Infrastructure</p> <ul style="list-style-type: none"> - operations and maintenance - simplification of procedures for users <p>BIBBOX</p> <ul style="list-style-type: none"> - implementation of complete pipeline as a biobank solution <p>Helpdesk</p> <ul style="list-style-type: none"> - integration with AAI 	Q1-4

4. Research and Development

Owner	Deliverable	Timing
Projects	<p>EOSC-Life</p> <ul style="list-style-type: none"> - FAIRification of data resources from BBMRI - provenance information management standard development - LifeScience AAI development <p>EJP RD</p> <ul style="list-style-type: none"> - development of common data models - development of interoperable APIs for federated querying of available data sets and samples - privacy protection <p>AARC2</p> <ul style="list-style-type: none"> - supporting implementation of LifeScience AAI services provided by eInfrastructures <p>EOSC-Hub</p> <ul style="list-style-type: none"> - policies for FAIR-compliant handling of medical data in EOSC 	Q1-4

4.3. Code of Conduct for Health Research

The aim is to reach a sector-specific code that explains how the GDPR applies in practice. With regards to clinical trials, it will focus on the secondary use of data that are not regulated within the Clinical Trials Directive. Furthermore, the Code has to be comprehensive to non-legal experts. The initiative is led by BBMRI-ERIC in collaboration with representatives from the BMS RIs, patient organizations, public health and the industry. Expectantly, the Code is available for broader public consultation in spring 2019.

Owner	Deliverable	Timing
HQ	<ul style="list-style-type: none"> - Lead the Code of Conduct Initiative - Building relationships with DPO representatives 	Q1-4
Projects	<ul style="list-style-type: none"> - Link Code of Conduct Initiative to Canada, 3rd parties (EUCAN) 	Q2-4

4.4. ELSI

Similar as with IT also the ELSI services are available but further developing and expanding is needed, especially in light of GDPR developments. BBMRI-ERIC and National Nodes will partner in several projects (CORBEL, EOSC-Life, CINECA) in relation to Ethical, Legal and Societal issues.

Owner	Deliverable	Timing
HQ	<ul style="list-style-type: none"> - Analysis for offering a certified service for public and private users] (e.g. free/paid, liability issues) - Provide support for GDPR compliance 	Q1-4
Projects	<ul style="list-style-type: none"> - Conceptualize & present sustainability plan for CS ELSI for all BMS (CORBEL) - Policies, specifications and tools for the management of data for biological and medical research (EOSC-life) - Provide Ethical and legal governance framework for transnational data-sharing for EU-Canada (CINECA) - Ensure projects governance framework, dissemination and sustainability (EUCAN) - Contribute to policy/governance development (EO-SC-hub) - ELSI ADOPT BBMRI-ERIC - ELSI guidance (EDIREX) 	Q3 Q1-4 Q1-4 Q1-4 Q1-2 Q3 Q1-4

4.5. Rare Diseases

Currently developments are underway on the implementation of BBMRI-ERIC Negotiator for sample workflow in the context of RD-Connect, based on a project strategic agreement in 2016. The Sample Catalogue is uniquely positioned to provide sample level information for rare disease samples in an open and transparent manner, but access to the samples can be improved by integrating a connector for the BBMRI-ERIC Locator service into the sample catalogue, which would offer a second venue for researchers, who are already familiar with the BBMRI-ERIC infrastructure to discover rare disease samples.

Owner	Activity	Timing
HQ	<ul style="list-style-type: none"> - Integrate the RD-Connect finder with the BBMRI-ERIC directory - Integrate the Sample Catalogue and the Locator - Integration with the BBMRI-ERIC AAI 	Q2-3 Q2 Q3

5. Funding

5.1. Core Budget

In our continuous efforts to improve the readability and transparency of the yearly BBMRI-ERIC budget, a series of changes to the structure of the budget have been made, mostly by reorganizing costs between budget categories, reducing the number of budget sections whilst maintaining a level of detail that is relevant as well as inclusive. In line with our statutes, the budget includes an overarching view of the following 2 years and respects the main underlying principle, namely that the expenditures and income are in balance.

Expenditures

The expenditures are divided into 3 main budget categories:

- 1. Operational costs:** these are costs related to the ongoing support activities of the Central Executive Management Office, as well as all the outreach efforts that are undertaken to make BBMRI-ERIC a visible international organisation, from communications and marketing activities, to meetings and conferences that increase visibility and consolidate the biobanking network. The overall costs that are foreseen for 2019 are € 904.547,00.
- 2. Staff costs:** these are represented in their brutto-brutto form, meaning that all the expenses related to personnel that are required by law are included in the Budget to offer an accurate overview of the staffing costs. In 2019, the staffing costs of BBMRI-ERIC are forecasted to be € 759.550,24.
- 3. Costs related to services:** The main services that are currently incorporated into BBMRI-ERIC's Work Programme are Quality Management, Common Service ELSI and Common Service IT. Costs related to each of these services are displayed in a separate line of the

budget and incorporate personnel costs, meetings are travel costs, tools and material that are vital to the provision of these services.

The total value of the costs associated with these services was calculated in 2019 at € 1.151.522, 58.

Income

As the main source of funding, BBMRI-ERIC relies on the financial contributions of its member states and observers. The value of the yearly contribution is calculated based on the principles that were agreed on during the Assembly Of Member's first session in February 2014, which includes a fixed part and a variable part that is calculated yearly based on the updated GDP figures, as provided by Eurostat and the World bank, and also factors in the total value of the foreseen expenditures, thus ensuring the balance principle.

The total mandatory contributions in 2019 were calculated at € 1.965.204,82.

In addition to the mandatory contributions, the member states are also contributing to the ongoing provision of services through the host country contributions for CS ELSI and CS IT, namely by offering funding to support the presence of an expert in each country who is actively involved in the development and provision of these 2 services.

The forecasted value of the host country contributions in 2019 is € 234.023,00.

In 2019, as a Quality Management service, the provision of on-site trainings/audits was envisaged as a service provided to the biobanks, however, from a financial perspective, this has been included in the 2019 budget as a cost-recovery scheme in order to avoid increasing the mandatory country contributions, with the intention

of including it in the scope of the overall BBMRI-ERIC funding and providing it as a free service to the biobanks that are part of the BBMRI-ERIC network.

The total value of this service was forecasted in 2019 at € 160.000,00.

A third source of income comes from the organisation of the yearly conference, the European/Global Biobank Week. Through registration and exhibition space fees, the forecasted income generated for the 2019 conference is calculated at € 50.000,00.

BBMRI-ERIC also generates small amounts of income from subcontracting office spaces and some paid/reimbursed invitations as speaker-lecturer for some members of staff.

The total forecasted value of the expenditures and income in 2019 is € 2.814.390,82.

On the next page an overview is given in table form.

Operational costs	2018 (approved)	2019	2020	2021
rent, maintenance, equipment, consumables	-203.732,0	-246.818,00	-217.997,00	-217.997,00
consulting, subcontracting, legal advice	-80.000,00	-111.000,00	-111.000,00	-111.000,00
marketing and communications	-50.000,00	-52.000,00	-52.000,00	-52.000,00
annual conference (E/GBW)	-410.000,00	-400.000,00	-400.000,00	-400.000,00
travel and meetings	-67.000,00	-93.500,00	-97.500,00	-94.000,00
total:	- 810.732,00	- 903.318,00	- 888.497,00	- 884.997,00

5. Funding

Staff costs	2018 (approved)	2019	2020	2021
salaries, social security contributions, insurances	-744.716,00	-759.550,24	-714.915,00	-714.915,00
total:	-744.716,00	-759.550,24	-714.915,00	-714.915,00

Services (incl. Personnel and development costs)	2018 (approved)	2019	2020	2021
QM	-10.500,00	-244.944,00	-244.944,00	-244.944,00
CS ELSI	-373.226,00	-277.897,58	-277.897,58	-277.897,58
CS IT	-523.771,00	-525.000,00	-550.000,00	-550.000,00
SHF	-93.681,00	-103.681,00	-103.681,00	-103.681,00
total:	-990.678,00	-1.151.522,58	-1.176.522,58	-1.176.522,58

Total expenses	2018	2019	2020	2021
total:	-2.546.126,00	-2.814.390,82	-2.779.934,58	-2.776.434,58

Membership contributions	2018	2019	2020	2021
Austria	64.926,20	64.301,50	63.479,68	66.390,50
Belgium	72.742,30	73.425,60	72.413,00	75.999,60
Bulgaria		30.484,1	30.369,45	30.775,60
Cyprus	6.617,00	6.638,30	6.624,95	6.672,2
Czech Republic	44.431,40	45.453,60	45.025,96	46.540,8
Estonia	22.370,80	22.514,30	22.461,77	22.648,00
Finland	49.426,60	49.764,50	49.246,70	51.080,80
France	279.492,20	281.152,20	275.795,86	294.767,60
Germany	378.236,10	386.654,10	379.091,60	405.877,30
Greece	45.509,20	45.139,50	44.718,39	46.210,00
Italy	216.894,40	218.172,50	214.133,07	228.440,30
Latvia	22.828,10	22.901,40	22.840,75	23.055,60
Malta	21.071,70	21.175,90	21.151,36	21.238,40
Netherlands	104.364,50	106.412,30	104.709,96	110.739,70
Norway	66.076,90	64.590,90	63.763,02	66.695,30
Poland	74.006,60	75.386,30	74.332,73	78.064,50
Sweden	77.167,40	77.901,50	76.795,34	80.713,40
Switzerland	27.851,90	28.292,90	27.858,15	29.398,10
United Kingdom	304.166,80	304.955,00	299.100,91	319.835,60
Turkey	32.950,30	33.887,70	33.335,92	35.290,30
IARC	6.000,0	6.000,0	6.000,0	6.000,0
total membership contributions	1.917.131,35	1.965.204,82	1.933.248,58	2.046.434,58
Other income	2018	2019	2020	2021
Host country contribution	158.831,00	231.523,00	231.523,00	110.000,00
other earnings (including EBW):	470.163,00	457.663,00	455.163,00	460.000,00
QM/Audit onsite training (cost recovery)	0	160.000,00	160.000,00	160.000,00
Total other income:	628.994,00	849.186,00	846.686,00	730.000,00
Total income:	2.546.125,35	2.814.390,82	2.779.934,58	2.776.434,58



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