

WORK PROGRAMME

2020



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Executive Summary

“No result of the laboratory’s activities which is of theoretical or practical importance shall be kept secret.”

J.C. Jacobsen (1811 -1887) - founder of Carlsberg

Personalized medicine and biobanking are closely tied, hence the future of healthcare depends also on the collection, preservation and sharing of human samples and data. At BBMRI-ERIC, the Biobanking and Biomolecular resources Research Infrastructure – we enable biomedical research by providing access to the largest biobanking directory in the world. Biobanking is one of the gears in the personalized medicine machine: biobanks don’t just drive research, they enable it. Is biobanking the key to using personalized medicine to cure cancer? It’s not the only one, but one of many key factors that are all needed to develop a truly revolutionary oncological personalized medicine panorama. Given these environmental circumstances we need to work together and build partnerships; a single gear will not get very far. Thus the central theme in the Work Programme 2020 is consolidation.

BBMRI-ERIC is a unique infrastructure with 19 Member states and one international joining 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 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 second 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

In the last 18 months a great deal of resources and focus were invested in communication to build the brand of BBMRI-ERIC and increase the visibility of European biobanks. A start has been made to share the developed marketing and communication tools with the National Nodes, but this should be further intensified. Due to several successful applications for H2020 project funding, where BBMRI-ERIC specifically leads the outreach activities a significant number of events are planned in the next months. In collaboration with other RI’s, ERICs and consortia, a more impactful message can be spread and increase the visibility in face-to-face meetings. In addition to *Making new treatments possible* and *Increase the visibility of biobanks* a new claim will be added to also cover the population biobanks: *Enabling research to drive prevention*. 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.

To make sure BBMRI continues in the right direction, we will continue to rely on the advice and guidance of our Stakeholder Forum. We pride ourselves on the role patients have in BBMRI-ERIC’s decision making process, but more can be done in terms of practical actions produced by the HQ in partnership with our excellent patient advocates. In 2020 we will attempt to create more concrete actions together with the patients’ pillar, including the national nodes.

2019 was the year that BBMRI opened itself up to industry. The new pillar of the Forum, dedicated to industry stakeholders, is now operative. There are important low-hanging fruit to collect in this collaboration (starting from an increased visibility of the Directory), but the long-term mission to be carried over 2020 and beyond is to change the culture of collaboration between industry and biobanking, and to reach a more sustainable and fruitful collaboration. Finally, in 2020 we will complete the Forum with its last pillar, dedicated to healthcare professionals. An internal work of understanding must underpin this endeavour, which will also hopefully strengthen the relationship between BBMRI HQ and its national nodes.

The Vision Paper of BBMRI-ERIC describes clearly the need for a service-driven approach, and in 2020 BBMRI-ERIC will continue to build and support the developed services. The significant increase in the number of requests to the Directory / Negotiator as well as the ELSI helpdesk show that the start made in 2019 to launch these services was successful, but there is plenty of room for improvement regarding the awareness and further growth of end users (including clinical, rare disease and for example paediatric communities). Quality is already on a high level and can act as both role model internally as well as in further strengthening the services offering with other Medical Infrastructures.

Digital science will become increasingly important in the years ahead. Science is and will remain the backbone of all the activities of BBMRI-ERIC, where we need to prepare and execute the opportunities surrounding the digitalization of healthcare. The various awarded projects like EOSC-Life and EJP RD can drive these scientific developments that could lead to new dedicated services or a better understanding and background information on the topic itself. In 2020 the Common Service IT will be refreshed and reorganized to maximize efficiency and effectiveness.

The loss of France as member state will have a significant impact on the budget and has resulted in some strategic cost-cutting. The good news is that several European and Asian countries have shown their interest in joining as Member or Observer in 2020. Continuous efforts will be made to secure the addition of new countries. Similar to 2019 we will constantly look for additional funding via other routes 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 on 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 for their input to this Work Programme for 2020. Let us be open in sharing and working together to further increase our impact for the patient and truly make new treatments possible.

1. Marketing & Communications

One of the goals of BBMRI-ERIC is to increase the visibility of European Biobanks in the Member States, which requires alignment between many actors in the biobank ecosystem. BBMRI-ERIC can only be successful if we establish effective two-way communication with the many stakeholders: we need to listen, understand the needs and strategies of our stakeholders and also communicate the progress of the services, what biobanks and their collections have to offer and the opportunities created by resulting research output, i.e. success stories. These efforts are all supported in our Marketing and Communication activities, and in 2020 we will continue to build and strengthen the community based on the strategy we started two years ago.

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 KPIs: number of followers, social media “impressions” and engagements.

| Owner | Deliverable | Timing |
|-------|---|---------|
| HQ | <ul style="list-style-type: none">- 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- 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- Continuous improvement of social media network: Twitter, LinkedIn via social media management account | Ongoing |

1.2 Environment Research

The European elections in 2019 kickstarted a process of important changes at the EU and national levels that are re-shaping the strategic objective of science policy across the continent. Now more than ever BBMRI requires efficient gathering and sharing of key information that must inform decision-making at HQ and on the national level. BBMRI started to systematically monitor information sources (EU & national legislations, EU institutions’ websites, stakeholders’ press releases, journals articles, etc.) in 2018. Our news monitoring initiative continued throughout 2019 but must adapt to new challenges: a stronger two-way communication must be implemented between the new Policy Task Force and national nodes, to increase the impact of environmental research and the funnel for the collection of key information. Environment Research will benefit both Marcom and Public Affairs-Stakeholder engagement activities.

| Owner | Deliverable | Timing |
|----------------|---|--------|
| HQ | <ul style="list-style-type: none"> - Implement the new Strategy & Partnership Task Force proposed in 2019 - Reform the monitoring services, to produce more usable newsletter/reports for HQ/MC/AoM | Q1-Q2 |
| National Nodes | Nominate representatives to the Strategy & 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 2020 will be the complete value chain of biobanking. Our standard message on sample access will be reinforced combined with specific aspects of the Directory and Negotiator in order to promote their use. Each campaign will be monitored with similar KPIs as the overall BBMRI-ERIC strategy in combination with detailed statistics per communication channel (social media, email, podcasts, etc.).

We will capitalize on hot issues in the media such as GDPR, where we can show our expertise. Our FAQ paper on the GDPR is the most searched-for document on our website; we will promote it periodically through social media and at events.

In order to help our member biobanks we will initiate a monthly communications call with our National Nodes (to which they can send a dedicated communications staff member or any representative) to coordinate our communication and marketing efforts, as well as to better highlight the strengths of each NN and their biobanks. Highlighting particular collections of member biobanks will be a priority. In turn, we will ask the biobanks to better publicize their involvement in BBMRI.

| Owner | Deliverable | Timing |
|-------|--|--------|
| HQ | - Initiate marketing campaign around the Directory/Negotiator targeting both biobanks and researchers, including Biobank/Collection of the Month and continuing the Impact Stories on the BBMRI-ERIC blog. | Q1 |
| | - Coordinate the continuous marketing of materials we have produced that remain relevant (webinar recordings, published materials, etc.) | Q1-Q4 |
| | - Plan monthly communications calls with National Nodes | Q1-Q4 |

1.4 Public Relations

In addition to the internally developed material, the regular media channels will also be used to get the overall message across. Press releases to media and posts on social media/blogs can support the communication with 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 | <ul style="list-style-type: none"> - Produce content (blogpost, social media post, press releases, position papers...) in partnership with Stakeholder Forum members (patients, industry, healthcare professionals) to highlight key challenges and increase the Forum's visibility. - Enrich the existing monitoring system and newsletter (link with Environment Research and Public Affairs) and broaden the BBMRI audience (dedicated monitoring newsletters to Management Committee, Assembly of Members). | <p>Q1 – Q4</p> <p>Q1-Q4</p> |
|----|---|-----------------------------|

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 (in the case of BBMRI-ERIC, through the use of our members' samples and data for research and publications). Significant 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 events like the Europe Biobank Week and biobank visits.

We have created feedback forms for our National Nodes to rate Europe Biobank Week 2019 in order to improve their experience in 2020. The MARCOM team is compiling a list of strategies to make EBW more advantageous for our National Nodes. Additional investments will be made in training and communication together with the National Nodes prior to EBW in order to have one strong message, to prevent misunderstanding within the community.

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 | <ul style="list-style-type: none"> - Execution of Europe Biobank Week 2020 - #EBW2020 in Sofia - Collaboration for events organised by/with ISBER and ESBB - BBMRI-ERIC and NN's fundraising event | <p>Q3</p> <p>Q3-Q4</p> <p>Q3</p> |
| National Nodes | <ul style="list-style-type: none"> - Support Europe Biobank Week with programme and booths - Open biobanks for stakeholders to visit | <p>Q3</p> <p>Q1-Q4</p> |

2 Stakeholders and Partners

2.1 Stakeholder Forum

The launch of the industry pillar of the Stakeholder Forum in 2019 marked a key development for BBMRI-ERIC's strategy: it provides access to expertise and knowledge that is key to develop and adapt our services to fit the future of personalised medicine. In 2020, the industry pillar must be consolidated and start producing actionable suggestions for the practical improvement of biobank/industry relationships.

In 2020, we will launch the healthcare professionals pillar of the Stakeholder Forum, which will bring BBMRI-ERIC closer to the representatives of those medical professionals working side-by-side with biobankers.

Finally, the patients pillar will reach full maturity in 2020: as the most developed stakeholder collaboration BBMRI has, it will continue to build on the past year's success to implement concrete actions to educate patients and support biobankers in the daily communication with participants.

The newly created Stakeholder Experts Engagement Task Force connects the Forum to BBMRI national nodes. In 2020, the Task Force will build on the basis of the plan made by Gauthier Chassang and Francesco Florindi in 2019.

| Owner | Deliverable | Timing |
|-------|--|--------|
| HQ | <ul style="list-style-type: none"> - Expand industry pillar membership, to include more companies and other industry sectors (medtech, data companies, CROs...) - Produce a BBMRI-industry position paper on the collaboration between biobanks and industry, in partnership with EFPIA, EBE and other umbrella organisations. - Produce an industry pillar work programme (in partnership with EFPIA, EBE, MedTech and other umbrella organisations) - Launch the healthcare professionals' pillar of the Stakeholder Forum - Produce a work programme for the patients' pillar including: education resources for NN regarding biobanking, co-created with the patients' pillar, drawing from the expertise of BBMRI NN - Consolidate the BBMRI Stakeholder Experts Engagement Task Force <ul style="list-style-type: none"> o Produce and implement a work programme for 2020 - Liaise the Task Force with all the Forum pillars | Q1-Q3 |

2.2 Public Affairs

The understanding of BBMRI's role in European research is increasing. EU institutions and stakeholders across the continent realize more and more the importance of BBMRI and our contribution to research and policy-making. To preserve such status and increase its impact it is imperative to give continuity and consolidate BBMRI public affairs activities. In 2020, monitoring related to public affairs and the importance of the BBMRI-ERIC network of excellent scientists and stakeholders must remain at the core of our policy tactics.

| Owner | Deliverable | Timing |
|-------|--|--------|
| HQ | <ul style="list-style-type: none"> - 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). - Foster the visibility of the Stakeholder Forums (liaise with 2.1S Stakeholder Forum), by involving Stakeholder Forum members in the production of communication material (news, blogpost, social media etc.). | Q1-Q4 |

2.3 Strategic Partnerships

For the successful implementation of the BBMRI-ERIC Vision it is necessary to seamlessly integrate BBMRI-ERIC services with other, complementary services, by expanding the number of formal collaborations BBMRI-ERIC has, and increase the level of cooperation with other research infrastructures (RIs). 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"> - Consolidate the collaboration with EATRIS and ECRIN: <ul style="list-style-type: none"> o Plan and implement the creation of joint services o Consolidate the strategic framework for a long-term collaboration o Launch a website to provide information on the BBMRI-EATRIS-ECRIN collaboration and its goals | Q1-Q3 |
| | <ul style="list-style-type: none"> - Consolidate the collaboration with ESBB <ul style="list-style-type: none"> o Strategic workshop with ESBB to discuss plans for future collaboration (besides the Europe Biobank Week) during Sofia scouting trip | Q2 |
| | <ul style="list-style-type: none"> - Enlarge BBMRI-ERIC Membership <ul style="list-style-type: none"> o Produce country profiles to identify possible new members; o Prioritise action in 1-2 countries; Spain, Slovakia, Lithuania, Croatia, Ireland o Explore potential in Japan and Russia | Q1-Q4 |

| | | |
|--|---|--|
| | <ul style="list-style-type: none"> ○ Produce strategies in partnership with local biobanking communities | |
|--|---|--|

3 Services and Tools

The transition of BBMRI-ERIC to a reliable service provider for biomedical researchers in Europe kicked off with a review of our core services – Quality, IT and ELSI – to bring them to a mature stage in 2019. Good results were achieved, especially regarding the number of users of the Directory and Negotiator. In 2020 it is important to keep growing the number of users and ultimately increase the number of samples that are used for research. Our Quality Management services are designed to guide biobanks and laboratories step by step towards excellence via three pillars: the knowledge hub, training & support, and auditing. Impressive results were achieved with 88 completed Self-Assessment Surveys, the addition of 15 collections with a Q-mark to the Directory and a series of 14 webinars with an average of approximately 50 participants each. Being recognized not only within the Member States, but also in projects on this topic such as ConcePTION (IMI call on breastmilk) and SPIDIA4P is a clear indication that we are on the right track and can lead the global discussion on quality of samples and biobanking. In 2020 we will continue to strengthen the services and monitor these on a monthly basis to document growth and trends.

3.1 Expand Sample Access Helpdesk

The main service of BBMRI-ERIC is providing access to samples and their data for the various researchers, scientists and, potentially, industry. Access 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 | <ul style="list-style-type: none"> - Retreat with National Nodes to discuss common services goals and expectations - Create real split between Services and R&D - Total workflow approach, including breakdown of silos between QM, IT and ELSI - Further development of Sample Access Helpdesk - Annual helpdesk meeting, funded through projects | Q1-Q2 Q2 Q2-Q3 Q2 |
| National Nodes | <ul style="list-style-type: none"> - Actively participate in Retreat - Nominate experts for Sample Access Help Desk | Q1-Q2 Q1 |

3.2 Quality

The BBMRI-ERIC biobanks are ready 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; iso.org) and a collection of Technical Specifications for appropriate sample handling procedures (CEN/TS and ISO), which will bring the biobank community into new era of scientific research and development. BBMRI-ERIC will focus even more in 2020 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. BBMRI will focus on 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 | Knowledge Hub: <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) Training & Support <ul style="list-style-type: none"> - In-house and online trainings on Biobanking Standard (ISO 20387) and Sample-handling Standards (CEN/TS, ISO) - Provision of BBMRI.QM training on relevant standards - Continue the BBMRI.QM Work Groups a) for pre-analytical sample processing, research driven and biobanking relevant, b) defining a strategy for structured research on biobank samples and procedures Auditing <ul style="list-style-type: none"> - BBMRI-ERIC Self-Assessment Surveys - BBMRI-ERIC Audits - Provision of BBMRI.QM training on Auditing Systems | Q1-Q4 |
| National Nodes | <ul style="list-style-type: none"> - Support and promote BBMRI.QM Services - Nominate technical experts for BBMRI.QM Services | Q1-Q4 |

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 an update on BBMRI-ERIC SAS utilisation performance indicators.

| Owner | Deliverable | Timing |
|----------------|---|--------|
| HQ-QM | <ul style="list-style-type: none"> - Q-Grade according to BBMRI-ERIC Self-Assessment (SAS) | Q1-Q4 |
| National Nodes | <ul style="list-style-type: none"> - Promote and support BBMRI-ERIC Q-Grading - Encourage biobanks to utilize BBMRI-ERIC SAS and undergoing review processes. | Q1-Q4 |

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 to provide evidence concerning reduction and elimination of problem areas. Our Pre-Audit Program supports 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 can potentially lead to a Q-Label in the BBMRI-ERIC Directory.

B) Pre-Auditing “Collection/Sample Handling Processes” according to CEN/TS and ISO is a remote pre-audit service. This service is based on submitted reports of BBMRI-ERIC Self-Assessment Surveys and can potentially 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-Q4 |
| HQ-QM and National Nodes-QM | - Conduct performance evaluation on A) and B) in accordance with HQ-QM to safeguard harmonisation | Q1-Q4 |

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 / Operations

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. The number of users, views, requests and positive responses will be measured monthly.

| Owner | Deliverable | Timing |
|----------------------|--|--------|
| Common Services – IT | Directory <ul style="list-style-type: none"> - operations and maintenance - support of NNs in providing/updating data - outreach Negotiator <ul style="list-style-type: none"> - operations and maintenance - Authentication & Authorization Infrastructure (AAI) - operations and maintenance CRC-Cohort <ul style="list-style-type: none"> - hosting and curating data set MIABIS <ul style="list-style-type: none"> - development of new components (SOP metadata, domain-specific extensions to sample/donor data, etc.) | Q1-Q4 |

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|--|--|--|
| | Interoperability Forum <ul style="list-style-type: none"> - continuing current activities of API standardization (aka Connector loading API and federated querying API) | |
|--|--|--|

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 | Q1-Q4 |

3.4 ELSI Services

In order to provide support on ethical, legal and societal issues (ELSI), we operate on the basis of a federated model, in partnership with a network of experts from academia and practice from across both our National Nodes and project partners. Focus areas are identified by the National Nodes, specified at the annual ELSI team meeting and realised by the task forces. The vision is to deliver reliable, practical and sustainable services and state-of-the-art research for the immediate benefit of the community. This includes monitoring regulations, developing practical guidelines as well as providing customised assistance and trainings.

| Owner | Deliverable | Timing |
|----------------------------|---|--------|
| ELSI Services and Research | ELSI Knowledge Base <ul style="list-style-type: none"> - develop practical guidelines (e.g. FAQs) by translating research outputs into guidance ELSI Helpdesk <ul style="list-style-type: none"> - promote national helpdesks and services - provide a platform for knowledge exchange across helpdesks Ethics Check <ul style="list-style-type: none"> - review the compulsory Ethics Self-Assessment section during the application phase ELSI Policy Monitoring <ul style="list-style-type: none"> - monitor ELSI-related issues in biobanking, and influence relevant policy and regulatory developments at the European level ELSI Trainings <ul style="list-style-type: none"> - implement training activities in collaboration with projects and National Nodes (e.g. webinars, workshops) | Q1-Q4 |

| | | |
|----------------|---|-------|
| National Nodes | Task Forces and Helpdesks - nominate members or contributing experts - provide info on national ethical, legal and societal issues - contribute to task forces and helpdesk requests | Q1-Q4 |
|----------------|---|-------|

4. Research and Development

There is still a very active debate within the community on the role that research should take within Research Infrastructures. In 2020 BBMRI-ERIC will actively participate in several H2020 and IMI projects to share and build expertise on MarCom, ELSI, IT and Quality that can enable researchers in their journey to discover new unexplored paths. Research is the backbone of the community and as research infrastructure there will be continued support from BBMRI-ERIC. All activities planned in this domain will be funded through projects, since the main objective of the funders is to develop services, as described in chapter 3. This distinction needs further discussion between the various governing bodies within BBMRI-ERIC and will be part of the activities.

4.1 Quality

BBMRI-ERIC is a Liaison organization to the International Organization of Standardization (iso.org). This gives the community the advantage of gathering timely information about new standard developments that are relevant to biobanks and biomedical research. BBMRI.QM services are based on these standards. The insight to new European and international standard developments (CEN and ISO) within the Project SPIDIA4P with expected nine new Technical Specifications in the next year, will be communicated within the community and will be integrated into our Self-Assessment and Auditing Service. Currently BBMRI-ERIC QM Service offers 9 Self-Assessment Surveys on European basis (CEN/TS) and international level (ISO Standards). The updates have to be implemented into the BBMRI-ERIC System.

This knowledge translates into several projects requesting BBMRI.QM services, such as CY-Biobank, EDiReX, ConcePTION, CliniMARK, and led in 2019 to a COST action application "Good Standardization Practice for Biomedical Research - GSPbmr" to be evaluated in 2020.

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) 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.

The mutual collaboration with medical Research Infrastructures can be reinforced. BBMRI.QM has taken the leading role in further development of an encompassing Quality Management Service including all RIs based on the developed strategy of Good Standardisation Practices for biomedical research (GSPbmr).

| Owner | Deliverable | Timing |
|-------|---|--------|
| HQ-QM | Building auditing expertise with National Nodes | Q1-Q4 |

| | | |
|-------------------|--|-------|
| National Nodes QM | <ul style="list-style-type: none"> - QM Seminars / webinars for National Node-QM Promoting cross audits within the National Node - At least 1 cross audit per National Node | |
| HQ-QM | <ul style="list-style-type: none"> - Collaboration with medical RIs regarding QM Services - Roll out common QM strategy in medical RIs (GSPbmr) | Q1-Q4 |

4.2 IT

Common Service IT (CS IT) is expected to be renewed in 2020. The anticipated change in the CS IT is that there will be more focus on the core services (Directory, Negotiator, MIABIS and Interoperability Forum, Helpdesk) to ensure faster advancement of those, at cost of leaving more advanced services up to the activity of National Nodes and their alliances. Hence the Work Programme specifies only the bulk budget for the CS IT and the actual implementation will be based on the results of the Call for Tender.

4.3 ELSI

In order to ensure that ELSI services are state of the art, participation in research projects as well as internal development is required. Tasks specific to research projects are executed in collaboration between Headquarters and National Nodes, typically formalised via Framework Agreements and secondments. The GDPR Code of Conduct Initiative for Health research has broadened teaming up with other health research sector specific codes in order to exchange on GDPR interpretation and using synergies. Given the diverse national derogations, public consultation will not start before the summer of 2020.

| Owner | Deliverable | Timing |
|----------|--|---------|
| HQ | <ul style="list-style-type: none"> - provide support for GDPR compliance - collaborate with ELSI, Quality and IT - develop a GDPR Code of Conduct for Health Research | Q1 – Q4 |
| Projects | <p>CORBEL</p> <ul style="list-style-type: none"> - implement sustainability plan for ELSI support for all BMS RIs - link code of conduct initiative to BMS RIs <p>EOSC-life</p> <ul style="list-style-type: none"> - assess and develop policies, specifications and tools for data management for BMS RIs and EOSC - link code of conduct initiative to open science <p>EUCAN-Connect</p> <ul style="list-style-type: none"> - ensure an ELSI compliant, sustainable governance framework building on assessment of stakeholder needs and monitor GDPR compliance - link code of conduct initiative to Canada, 3rd parties <p>CINECA</p> | Q1 – Q4 |

| | | |
|--|---|--|
| | <ul style="list-style-type: none"> - assess ELSI in relation to EU, Canada & Africa and support GDPR compliance | |
| | <p>EDIREX</p> <ul style="list-style-type: none"> - ELSI guidance/advisory board | |
| | <p>EJP RD</p> <ul style="list-style-type: none"> - ELSI guidance/advisory board - develop and provide rare diseases specific ELSI training | |
| | <p>ID-EPTRI</p> <ul style="list-style-type: none"> - ELSI guidance/advisory board - Identify paediatric specific ELSI needs and how to ensure appropriate service | |
| | <p>CY-Biobank</p> <ul style="list-style-type: none"> - advise and develop ELSI best-practices and processes for biobanking | |
| | <p>DIAMONDS</p> <ul style="list-style-type: none"> - assess ethics management and promote best practice | |

4.4 Rare Diseases

During 2019 discussions have started with Euro Biobank on how to start joined efforts in the future. The current steps are foreseen for 2020:

EUROBIOBANK and BBMRI-ERIC will explore the possibility to integrate their efforts with respect to Rare Disease BioBanking into a single Rare Disease Project (RDP) within the structures of BBMRI-ERIC. EUROBIOBANK shall transfer the Brand "EUROBIOBANK" exclusively to BBMRI-ERIC with respect to all its biobanking operations within Europe and outside.

| Owner | Activity | Timing |
|---------|--|--------|
| HQ + NN | <p>The RD activities shall, together with the National Nodes, and through them the National RD patients' organizations, promote the continuity of high standards in an expanded RD Biobank platform by prospectively seeking to recruit patients with RD (according to the orphanet classification & the OMIM descriptors) for organization into Cognate Physio-pathological Pathways) and that are willing to share:</p> <ol style="list-style-type: none"> 1. Suitably consented biological material and health data, 2. A WGS (/n years if from blood) or saliva and blood, 3. One blood / other sample / n years (for metabolic and proteomic profiling) 4. Samples for WGS and health / "omics" data from family (trios) 5. Ethnic WGS controls. | Q2-Q4 |

5. Funding

2020 brings both challenges and new funding opportunities to BBMRI-ERIC, with some of the most noteworthy highlights being the withdrawal of France as a member country and the successful application for several new EU grants. The main goal of BBMRI-ERIC's core funding strategy is to minimise financial risks and maximise the value of our member's contributions. With the withdrawal of France from the consortium, the 2020 annual budget has been subsequently adapted to minimise the financial risk and at the same time achieve the main goals that have been set out for the years ahead. As a result, the 2020 budget represents 81% of the previous year's budget. In defining the 2020 budget we have also considered other factors that constitute relevant global issues, such as environmental concerns, thus reducing the funding allocated to travelling.

In line with our statutes, the annual budget also 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

There are 3 main cost categories, based on BBMRI-ERIC main activities:

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 2020 are € 778.000.

| Operational costs | 2020 | 2021 | 2022 |
|--|------------|------------|------------|
| rent, maintenance, equipment, consumables | 211.000,00 | 215.500,00 | 210.500,00 |
| consulting, subcontracting, legal advice | 83.000,00 | 86.000,00 | 89.000,00 |
| marketing and communications | 42.000,00 | 52.000,00 | 52.000,00 |
| annual conference (E/GBW) | 400.000,00 | 410.000,00 | 410.000,00 |
| travel and meetings | 42.000,00 | 79.500,00 | 79.500,00 |
| total: | 778.000,00 | 843.000,00 | 841.000,00 |

2. Staff costs: the budget included the brutto-brutto costs, also known as true cost of employment, which refer not only to actual salaries but also all the legal financial obligations that are inherent to the employment relationship, such as taxes and social security contributions, employee severance fund and mandatory health insurances. The core budget will fund approximately half of the 2020 staffing costs, with the remaining costs being covered through the EU funds. The 2020 staffing costs have been forecasted to be €550.700.

| Staff costs (7,3 FTE) | 2020 | 2021 | 2022 |
|--|------------|------------|------------|
| salaries, social security contributions, insurances | 550.700,00 | 560.612,60 | 570.703,63 |

3. Services: The main services that are currently incorporated into BBMRI-ERIC's Work Programme are Quality Management, ELSI Service and Common Service IT. The forecasted budget includes staff costs as well as development and implementation costs and costs related to the provision of these services. The total value of the costs associated with these services was calculated in 2020 at € 945.398,53.

| Services (incl. Personnel and development costs) | 2020 | 2021 | 2022 |
|--|------------|------------|------------|
| QM (including 1,5 FTE) | 126.919,23 | 128.753,77 | 130.621,34 |
| ELSI (including 2,5 FTE) | 317.308,48 | 334.108,48 | 334.108,48 |
| CS IT | 400.000,00 | 400.000,00 | 400.000,00 |
| SHF(including 1 FTE) | 101.161,83 | 120.100,00 | 120.100,00 |
| total: | 945.389,53 | 982.962,25 | 984.829,82 |

Income

The total mandatory contributions in 2020 are forecasted at €1.705.833,53.

In addition to the mandatory contributions, Austria, as the host member country of BBMRI-ERIC pay a yearly contribution of €100.000. Member states are also contributing to the ongoing provision of services through the host country contributions for the ELSI Services 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. In 2020, CS IT will see a renewed tender process, thus host country contributions have been excluded as such from the budget, pending the outcome of the tender. The forecasted value of the host country contributions in 2020 is € 102.093.

A third source of income comes from the organisation of the yearly conference, the European Biobank Week. Through registration and exhibition space fees, the forecasted income generated for the 2020 conference is calculated at roughly € 50.000,00. BBMRI-ERIC also generates small amounts of income from subcontracting office spaces to the Austrian National Node, BBMRI.at, and some paid/reimbursed invitations as speaker-lecturer for some members of staff.

| Membership contributions | 2020 | 2021 | 2022 |
|--------------------------|------------|------------|------------|
| Austria | 67.503,69 | 71.198,95 | 72.896,55 |
| Belgium | 75.176,65 | 79.538,98 | 81.543,05 |
| Bulgaria | 30.916,58 | 31.430,96 | 31.667,27 |
| Cyprus | 6.674,26 | 6.732,88 | 6.759,81 |
| Czech Republic | 46.985,29 | 48.896,69 | 49.774,78 |
| Estonia | 22.708,90 | 22.944,41 | 23.052,60 |
| Finland | 50.658,88 | 52.889,65 | 53.914,47 |
| France | - | - | - |
| Germany | 396.221,36 | 428.495,18 | 443.321,84 |
| Greece | 45.670,25 | 47.467,31 | 48.292,88 |
| Italy | 222.539,64 | 239.713,64 | 247.603,42 |
| Latvia | 23.115,11 | 23.385,93 | 23.510,35 |
| Malta | 21.297,02 | 21.409,78 | 21.461,59 |

| | | | |
|---------------------------------|--------------|--------------|--------------|
| Netherlands | 109.774,88 | 117.145,18 | 120.531,10 |
| Norway | 65.265,53 | 68.766,20 | 70.374,41 |
| Poland | 78.079,26 | 82.693,95 | 84.813,94 |
| Sweden | 79.103,79 | 83.807,55 | 85.968,47 |
| Switzerland | 28.185,37 | 29.983,74 | 30.809,92 |
| United Kingdom | 297.401,14 | 321.083,58 | 331.963,34 |
| Turkey | 32.555,94 | 34.734,29 | 35.735,03 |
| IARC | 6.000,00 | 6.000,00 | 6.000,00 |
| <hr/> | | | |
| Total membership contributions | 1.705.833,53 | 1.818.318,85 | 1.869.994,81 |
| Host country contribution: | 102.093,00 | 102.093,00 | 102.093,00 |
| Other earnings (including EBW): | 466.163,00 | 466.163,00 | 466.163,00 |
| <hr/> | | | |
| Total other income: | 568.256,00 | 568.256,00 | 568.256,00 |
| | 2020 | 2021 | 2022 |
| <hr/> | | | |
| Total expenditures/income | 2.274.089,53 | 2.386.574,85 | 2.438.250,81 |