



BBMRI-ERIC[®]
Biobanking and
BioMolecular resources
Research Infrastructure

WORK PROGRAMME 2018

www.bbmri-eric.eu

EXECUTIVE SUMMARY AND 2018 GOAL TREE

'A customer is someone who has not found a better alternative yet'

Nirmalya Kumar

The way biobanks see it, researchers have no alternative than to connect and partner up with them when looking for high-quality samples and associated data. In other words, researchers cannot go find a better alternative because there is none. The researchers themselves, however, are often convinced that there are many alternatives to biobanks, which is mainly due to the fact that sample collections hosted by biobanks lack visibility, findability, and accessibility or simply because researchers have a strong desire to have their own collections of specific material.

In order to bridge this gap between biobanks, the research community and the different stakeholders, BBMRI-ERIC's goal for 2018 will be to build and strengthen value-added, sustainable biobanking. This ambitious goal and its various sub-goals, laid out on the following pages, can only be achieved if the BBMRI-ERIC team in Graz, the National Nodes, and the various biobanks join efforts.

To gain a better understanding of who we actually serve, communication and dissemination will play a central role in 2018. Focussing on these activities will allow us to respond better to different requirements and tackle the challenges ahead. However, it will also help us map the environment in which we operate and identify areas in which we need to adapt or where we can place ourselves in an even stronger position. To that end, we will gather information that will then be fed back to the National Nodes in order for them to benefit as well.

The various services offered by BBMRI-ERIC will be continuously improved and expanded, while also creating additional awareness. Quality Management will continue to expand its Self-Assessment Survey, launch a quality grade and develop a concept paper for an audit programme. The Common Service IT will focus on improving and supporting the Directory, the Negotiator, the Connector, and BIBBOX, with the Locator due for a first release across five member states. The Common Service ELSI will centre its efforts around a number of services and support, including optimising the recently launched Help Desk, adapting the Ethics Check and drafting the Code of Conduct.

In order to maintain the leading position of BBMRI-ERIC and its Members and Observers, it is absolutely crucial to explore new, innovative ideas in more detail. To that end, there will be small working groups to analyse the potential and added value of these innovations and developments for the wider community. These working groups will also be designed to give advice on risks and investment in necessary resources while exploring whether this could be something to develop into a specific BBMRI-ERIC service.

Finally, strategic efforts concerning funding will be intensified in 2018. By actively monitoring market developments, we can detect upcoming calls at an early stage and take action. Additionally, BBMRI-ERIC will start to explore fundraising activities outside of the regular H2020 projects, relying, among other things, on input from the Stakeholder Forum.

Last but not least, I would like to thank the team in Graz as well as our Members and Observers and the various governing bodies of BBMRI-ERIC for their input to this Work Programme for 2018. I look forward to working with all of you to deliver on our commitments.

Erik Steinfelder – Director General

GOAL TREE

Overall goal: Building and strengthening value-added, sustainable biobanking for all stakeholders

HQ

- Support National Nodes in building and strengthening sustainable biobanking by delivering services and tools
- Embrace diversity and inclusion and continue to intensify and expand coalitions
- Increase visibility by leveraging new value proposition into scientific success
- Deliver on commitments, supported by defined KPIs

National Nodes

- Advance biobanks and resources locally by implementing the Work Programme
- Drive utilisation of samples, facilitated by digital science focus
- Embrace additional funding

Projects

- Continue to carry out active projects
- Promote participation of Member State biobanks, taking advantage of specific strengths

Funding

- Meet or exceed our financial commitments

Achieving these goals and monitoring them should put us in a strong position, giving potential Members a reason to join.

CONTENTS

Executive Summary and 2018 Goal Tree	3
Goal Tree	5
1 MarCom	7
1.1 Communication and Branding	7
1.2 Environment Research	7
1.3 Marketing	8
1.4 Public Relations	8
1.5 Events and Promotional Activities.....	8
2 Stakeholders	9
2.1 Stakeholder Forum	9
2.2 Public Affairs.....	9
2.3 Policy Monitoring	10
2.3 Management Tools.....	10
3 Services and Tools	11
3.1 Quality	11
3.1.1 Data Quality ad Quality Grade of Biobanks and Collections.....	11
3.1.2 Introduction of the Performance Evaluation.....	12
3.2 CS IT	13
3.2.1 Core IT Services.....	13
3.2.2 Upcoming IT Services	15
3.2.3 Support	15
3.3 CS ELSI.....	16
4 Innovation and Development	18
4.1 Technology Watch	18
4.2 Microbiome	18
4.3 Rare Diseases.....	19
4.4 Continued Activities.....	19
5 Funding	20
5.1 Core Budget	20
5.2 Fundraising Activities.....	22
6 New Projects	23
6.1 EDIREX	23
6.2 EOSC-hub	25
6.3 CETOCOEN Excellence	26
6.4 ID-EPTRI	27

1 MARCOM

Marketing and communication are essential for BBMRI-ERIC when it comes to sharing updates, achievements and news. In this chapter, several initiatives will be laid out that will focus on spreading messages in a more coherent and controlled way.

1.1 Communication and Branding

Several activities will be launched in order to manage and monitor all of BBMRI-ERIC’s internal and external communication. The aim is to explain our mission, vision and added value in a cohesive way, creating a favourable point of view.

Owner	Deliverable	Timing
HQ team Graz	<ul style="list-style-type: none"> - Create corporate identity manual to ensure all communication channels and material, such as the website, letterhead, business cards, presentations, posters, booths, etc., feature a consistent design - Create Communications Working Group with representatives from all National/Organisational Nodes - Create Marcom calendar 	Q1 Q1 Q1
National Nodes	<ul style="list-style-type: none"> - Nominate representative to join Communications Working Group 	Q1

1.2 Environment Research

BBMRI-ERIC's strategic options and competitive situation are defined by external factors. That is why we need to be on top of new trends and developments in order to respond to challenges and opportunities in a timely manner. Environment Research will draw from both Marcom and public affairs/stakeholder engagement activities.

Owner	Deliverable	Timing
HQ team Graz	<ul style="list-style-type: none"> - Set up Environment Research Task Force - Give all National Nodes quarterly update on market landscape - Develop procedure for calls/tenders - Establish effective monitoring system, integrating public affairs monitoring (see work plan stakeholders, task 2.2, including Engagement Officer’s tasks, International Organisations Policy Task Force contribution) 	Q1 Q1 – Q4 Q2
National Nodes	<ul style="list-style-type: none"> - Nominate representative to join Environment Research Task Force 	Q1

1.3 Marketing

The services and products BBMRI-ERIC provides to the National Nodes need to be promoted in order to increase the visibility and valorisation of their partner biobanks and samples.

Owner	Deliverable	Timing
QM	<ul style="list-style-type: none"> - Develop self-assessment and collateral - Identify key opinion leaders for support - Launch QM awareness campaign 	Q1 Q2 Q2, Q4
CS IT	<ul style="list-style-type: none"> - Develop collateral for Directory, Locator and Negotiator, Bibbox and cost calculator - Identify key opinion leaders for support - Launch CS IT awareness campaign 	Q1 Q2 Q3
CS ELSI	<ul style="list-style-type: none"> - Develop ELSI Helpdesk collateral - Identify key opinion leaders for support - Launch CS ELSI and services awareness campaign 	Q1 Q2 Q3

1.4 Public Relations

Public Relations entails press releases for the media and social media/blog posts in order to communicate with stakeholders and the general public. The idea is to spread news on biobanking, the GDPR etc.

Owner	Deliverable	Timing
HQ team Graz	<ul style="list-style-type: none"> - Set up BBMRI-ERIC press kit - Offer press kit support to National Nodes - Support National Nodes in sharing and promoting case studies - Align with Marcom calendar 	Q1 Q2 Q2-Q4 Q1-Q4
National Nodes	<ul style="list-style-type: none"> - Suggest case studies 	Q1

1.5 Events and Promotional Activities

Bringing various stakeholders together at live events to share experiences and learn from each other is essential for the further development of biobanking and for successful research. This workstream will focus on organising events such as Europe Biobank Week and biobank visits.

Owner	Deliverable	Timing
HQ team Graz	<ul style="list-style-type: none"> - Europe Biobank Week - Europe Biobank Tour 	Q1-Q3 Q2 – Q4
National Nodes	<ul style="list-style-type: none"> - Support Europe Biobank Week with programme - Open biobanks for stakeholders to visit 	Q1-Q3 Q2-Q4

2 STAKEHOLDERS

BBMRI-ERIC’s stakeholders can affect or be affected by our actions, objectives and policies. The Stakeholder Forum will provide a platform for consultation and discussion for all stakeholders. In this chapter, the various activities related to our stakeholders are laid out.

2.1 Stakeholder Forum

The Stakeholder Forum is BBMRI-ERIC’s main platform to engage with stakeholders. Based on the outcome of the Stakeholder Workshop held at Global Biobank Week 2017, we can now start to map all key BBMRI-ERIC stakeholders from all key player clusters (governmental, patients/consumers, industry, healthcare professionals etc.). With the mapping exercise as a starting point, our focus for 2018 will be on reinvigorating the work of the Stakeholder Forum and launching the “industry pillar”.

Owner	Deliverable	Timing
HQ team Graz	<ul style="list-style-type: none"> - Map BBMRI-ERIC stakeholders - Develop BBMRI-ERIC stakeholder engagement strategy - Enlarge patient – citizen pillar of the Stakeholder Forum - Launch industry pillar of the Stakeholder Forum - Establish Stakeholder Engagement Task Force composed of engagement officers from National Nodes - Map ELSI needs of (all) users 	Q1-Q4 Q1-Q2 Q1 Q1 Q1-Q2 Q1-Q2
National Nodes	<ul style="list-style-type: none"> - Nominate representative to Stakeholder Engagement Task Force 	Q1
Projects	<ul style="list-style-type: none"> - Provide Engagement Officer with information needed to complete and continuously update stakeholder map 	Q1-Q4

2.2 Public Affairs

BBMRI-ERIC can and should build bridges now, and be ready to engage with the new European Parliament and College of Commissioners after the elections in May 2019. At the same time, BBMRI-ERIC can consolidate its leadership with regard to the implementation of the GDPR (Code of Conduct), explore the European Open Science Cloud further and open up to new policy files.

Owner	Deliverable	Timing
HQ team Graz	<ul style="list-style-type: none"> - Update list of key European and international decision makers - Touch base with existing EU/international decision makers relevant to BBMRI-ERIC - Position BBMRI-ERIC within the programme of the EU Presidencies (BG, AT; prepare for RO, FI, HR troika) - Attract new Members 	Q1 – Q3 Q1-Q4 Q1-Q4 Q1-Q4

2.3 Policy Monitoring

An effective monitoring system will be set up in close collaboration with the Marcom team to provide the HQ and National Nodes with regular updates on European and international public affairs in the area of research and health, focussing on what is most relevant to biobanking.

Owner	Deliverable	Timing
HQ team Graz	<ul style="list-style-type: none"> - Establish effective monitoring system, integrating the International Organisations Policy Task Force - Provide National Nodes with quarterly update on market landscape/policies 	Q1 Q1-Q4
National Nodes	<ul style="list-style-type: none"> - Provide HQ team with relevant updates via MC/International Organisations Policy Task Force and GDPR Task Force 	Q1-Q4

2.3 Management Tools

BBMRI-ERIC has a variety of stakeholders with different requirements and needs. In order to build intelligence around these and to have the option to share important information internally at the HQ, a customer relationship management (CRM) tool will be used. CRM will be instrumental in delivering on the objectives lined out in the chapters on Stakeholders and Marcom activities and goals.

Owner	Deliverable	Timing
HQ team Graz	<ul style="list-style-type: none"> - Select the best CRM software for BBMRI-ERIC's needs and set it up - Map various stakeholders, report trends 	Q1 Q3
Projects	<ul style="list-style-type: none"> - ADOPT contribution to CRM 	Q1-Q4

3 SERVICES AND TOOLS

The main services and tools that BBMRI-ERIC can provide to its Member States are currently related to Quality, IT and ELSI. This section lays out the activities related to the development, improvement and deployment of these services and tools.

3.1 Quality

An efficient quality management system (QMS) includes quality assurance (QA) and quality control (QC) processes. Embedded in a comprehensive QMS, it is one of the main tasks of biobanks to describe and control the quality of samples and data used for research & development. An applied performance evaluation will lead to continuous improvement of the QMS and is crucial in further optimising the quality of samples and data in the European biobanks.

3.1.1 Data Quality and Quality Grade of Biobanks and Collections

A focus on the quality of the collections and samples forms the necessary basis for the validity of the resulting data. Those biobanks that meet the high-quality demands according to European and International Standards can qualify for a Quality-Grade that will be developed and launched in 2018. Additional awareness and education around the Quality of Data will start.

Owner	Deliverable	Timing
HQ - Quality	<ul style="list-style-type: none"> - Q-Grade according to self-assessment - Quarterly update on access request/output to self-assessments to all National Nodes (deliver performance indicator) - Cooperation with CS-IT and ISO/TC 276 WG5 - Definition of Data Quality in White Paper 	Q1-Q4 Q1-Q4 Q1-Q4 Q1-Q4
Projects	<ul style="list-style-type: none"> - SPIDIA4P - EDIREX - ADOPT 	
National Nodes	<ul style="list-style-type: none"> - Support and promote Quality-Grade of biobanks and collections and those aiming for it - Contribute to the Data Quality White Paper 	Q1-Q4 Q1-Q4

3.1.2 Introduction of the Performance Evaluation

BBMRI-ERIC will develop a concept paper for an Auditing Program in 2018. 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 Audit Program should support biobanks with a hands-on management tool for achieving continual improvement in their organization.

Owner	Deliverable	Timing
HQ - Quality	<ul style="list-style-type: none"> - Development / Introduction of Audit Program Concept Paper - Quality-Grade according to Audit Program - Quarterly update on output of Audits to all NN; deliver performance indicator 	Q1-Q4 Q1-Q4
Projects	<ul style="list-style-type: none"> - EDIReX 	
National Nodes	<ul style="list-style-type: none"> - Contribute to the development of a BBMRI-ERIC Audit Program Concept paper - Introduce BBMRI-ERIC Audit Program within the NN biobanks - Perform BBMRI-ERIC Audit in NN biobanks (deliver reports and performance indicators) - Perform BBMRI-ERIC Audit in EDIReX Project 	

3.2 CS IT

BBMRI-ERIC offers IT support to improve the visibility and findability of biobanks in order to increase the use of the stored material and its data. Several tools are developed to support researchers in finding material also enabling effective communication between the parties involved.

3.2.1 Core IT Services

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

Owner	Deliverable	Timing
Common Services – IT	Directory 5.0 and 4.x maintenance <ul style="list-style-type: none"> - improved user interface based on user focus group studies (4.x) - adding “linked data” (RDF/JSON-LD) interface to improve FAIR compliance - integration with the Connector –automated data updates from the biobank into the Directory 	Q1-Q3
	Negotiator 2.0 <ul style="list-style-type: none"> - support for multiple source systems for requests (BBMRI.uk directory, RD-Connect) - implementation of request completion notification (notification by the biobank whether samples/data have been delivered) - implementation of notification of research results (data, papers, etc.) offered by the researcher back to the biobank after finishing the project 	Q2
	Connector <ul style="list-style-type: none"> - Integration of RD-Connect Sample Catalogue (is this agreed with RD-Connect; what is about the other RD groups?) 	Q2
	BIBBOX 3.0 <ul style="list-style-type: none"> - integration of the Connector - “Dockerisation” and integration of the Connector into the reference tool for simple installation inside biobanks. This will include data export/mapping functionality for LIMS / BIMS applications, e.g. OpenSpecimen and Baobab and EDC solutions, e.g. Phenotips, RedCap, Limesurvey, OpenClinica (optional). 	Q3
	BBMRI-ERIC AAI <ul style="list-style-type: none"> - simplified registration workflow of “homeless users” - support for identity linking - support for multi-factor authentication 	Q4

	CCDC – data collection tool for CRC-Cohort - maintenance and user support - Integration of the CCDC into the Connector/Sample Locator	Q1-Q4
Projects	ADOPT - Supporting development of Connector, Locator, MDR CORBEL - Development of Life Sciences AAI RD-Connect - Supporting development of Negotiator 2.0 - Migration of ID-Card and Sample Catalogue to BBMRI-ERIC AARC2 - Piloting Life Sciences AAI using eInfrastructure services (to become sustainable home to BBMRI-ERIC AAI) EOSCpilot - development of policies related to privacy-sensitive data processing and storage in cloud - analysis of ELSI requirements and compliance for authentication profiles	Q1-Q3 Q1-Q4 Q1-Q4 Q1-Q3 Q1-Q4
National Nodes	Directory - curated data about the biobanks, focusing on most sought for parameters: (a) refining available diagnosis, (b) providing quality-assessed collections, (c) refining available material types Connector - piloting in at least 20 biobanks or National Nodes across a minimum of 5 member states BIBBOX - Provide training at supporting for at least 5 new installations. The functionality will cover (at least) a sample management App and an electronic data capturing App BBMRI-ERIC AAI - national verification of identity of “homeless users”	Q1-Q3 Q2 Q3 Q4

3.2.2 Upcoming IT Services

Common Services IT will continue to expand their portfolio and services. First releases of the Locator and data harmonisation services are planned and supported with required resources. BBMRI-ERIC also leads the development of provenance information standard in ISO in order to allow computer-based assessment of the quality of samples and data.

Owner	Deliverable	Timing
Common Services – IT	Locator 1.0 <ul style="list-style-type: none"> - first release of federated search tool allowing to query sample availability information (privacy-preserving) - piloting in at least 20 biobanks or National Nodes across a minimum of 5 member states 	Q1-Q4
	MDR with Data Harmonization Support <ul style="list-style-type: none"> - first release of metadata repository with support for metadata harmonization recipes - including data harmonization recipes collected during building CRC-Cohort 	Q1-Q4
	ISO TC276 WG5: Provenance information standardisation <ul style="list-style-type: none"> - development of the standard describing complete history of samples and data - piloting preliminary versions of the standard 	Q1-Q4
Projects	EOSChub <ul style="list-style-type: none"> - development of policies related to privacy-sensitive data processing and storage in cloud analysis of ELSI requirements and compliance for authentication profiles 	Q1-Q4

3.2.3 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 	Q1-Q4
	Operational IT infrastructure <ul style="list-style-type: none"> - support for failover transfers between CNR (Italy) and BBMRI-ERIC backup facility hosted in Austria 	Q2-Q4
	CS IT User Forum development to help with alignment of users' needs to the design and development of CS IT products <ul style="list-style-type: none"> - recruiting additional representatives of users – especially academic and industrial researchers - focus studies on the usability of the Directory, Negotiator, Connector, BIBBOX, Helpdesk 	Q1-Q4

3.3 CS ELSI

The BBMRI-ERIC Common Service ELSI provides support on ethical, legal and societal issues related to biobanking activities. It relies on a network of experts, who are in various degrees linked to the National Nodes and organised in several task forces. The results of the task forces' work are included in the self-serving ELSI Knowledge Base, informing the custom-based, federated ELSI Helpdesk. The vision and aim are to provide available, feasible, practical, usable, reliable, verifiable and sustainable ELSI guidance to our customers.

Owner	Deliverable	Timing
Common Services - ELSI	<ul style="list-style-type: none"> - Developing ELSI Helpdesk (custom-based) and Knowledge Base (self-serving tool) - Adapting Ethics Check based on test cases 2017 - Develop education & training activities for biobankers, researchers, National Nodes on prioritised ELSI topics (e.g. GDPR, societal engagement) together with national nodes and the CS ELSI experts - Analysis and preparation of publication of survey on ELSI challenges on IC (TF Societal) - Lessons learned from pilot activity with cancer patients (TF Societal) - Modelling engagement strategies in collaboration with other projects, organizations and Stakeholder Forum includes striving for joint terminology and conceptualizations on e.g. patient/donor/citizen (TF Societal) - Mapping exercise on practices of returning research results (TF Societal) - Inform and comment on the draft Code of Conduct (TF GDPR) - Legal and ethical support on issues such as access policy, MTA/DTAs, templates and collateral - National experts to liaise with National Nodes - Establishment of an effective monitoring system for task forces - Lessons learned from US risk-based ethics review - Identify good examples, biobanks providing benefits for patients and innovation – Good examples - Identify emerging ELSI issues to address and support sustainable biobanking 	<ul style="list-style-type: none"> Q1-Q4 Q1 Q2-3 Q1-Q4 Q1-Q4 Q1-Q4 Q1-Q4 Q1-Q4 Q1-Q4 Q1-Q4 Q1-Q4 Q1-Q4 Q1-Q4 Q1-Q4 Q1-Q4 Q1-Q4

Projects	<ul style="list-style-type: none"> - ADOPT (WP7: lead: task forces & meetings to run a service & ethics check, WP2/3: participant, ELSI support implementation colon cancer study) - CORBEL (WP5: lead, conceptualizing CS ELSI for all BMS RIs, WP3: participant, access policy) - Identify new & dedicated ELSI projects - EDIReX (WP3 - ethics support) - RD-Connect (WP3: Code of Conduct) - B3Africa (WP2: share info with CS ELSI and on BBMRI-ERIC) 	<p>Q1-Q4</p> <p>Q1-Q4</p> <p>Q1-Q4</p> <p>Q1-Q4</p> <p>Q1-Q3</p> <p>Q1-Q3</p>
National Nodes	<ul style="list-style-type: none"> - Nominate/update representative to ELSI Task Forces - Provide info on national ethical, legal and societal aspects whenever relevant (e.g. status of GDPR implementation, benefit sharing) - Provide input to task forces wherever relevant 	<p>Q1</p> <p>Q1-Q4</p> <p>Q1-Q4</p>

4 INNOVATION AND DEVELOPMENT

BBMRI-ERIC needs to be on top of new trends and developments in order 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. An overview of the various fields of interest for 2018 is described in this work stream.

4.1 Technology Watch

The task of the Technology Watch is to observe, track, filter out and assess potential technologies from a very wide field extending beyond the normal confines of the sector. A Technology Watch process can be broken down into four main phases: a needs audit, data collection, processing of the data collected and integration and dissemination of the results. The Technology Watch process must be capable of identifying any scientific or technical innovation with the potential to create opportunities or avoid threats and will work closely together with the Market Landscape team.

Owner	Deliverable	Timing
HQ	<ul style="list-style-type: none"> - Set up Technology Watch working group, within the Stakeholder Forum - Connect with Industry Pillar as additional information source - Create connect to include in overall communication towards National Nodes and biobanks 	<p>Q2</p> <p>Q2</p>
Projects	<ul style="list-style-type: none"> - ADOPT 	Q1-Q3

4.2 Microbiome

The human microbiome is still having increased attention due to its potential role in health and disease, resulting in the potential demand for specific biobanks to support microbiome research. The potential needs further exploring to advise the National Nodes and the opportunities and challenges around Microbiome and biobanking.

Owner	Deliverable	Timing
HQ	<ul style="list-style-type: none"> - Connect and intensify microbiome community with BBMRI-ERIC - Explore and map potential for National Nodes 	Q2-Q3
Projects	<ul style="list-style-type: none"> - SPIDIA4P 	Q1-Q4

4.3 Rare Diseases

In March 2017, a workshop around Integrating Research and Healthcare for Rare Diseases took place, where the objective was to discuss opportunities for structured cooperation in rare diseases research, tools and healthcare and creating a sustainable environment for this specific area. In combination with the previous idea of setting up a Common Service around Rare Diseases, 2018 will be used to explore the real potential and needed supporting structure for next steps around services within BBMRI-ERIC related to Rare Diseases.

Owner	Deliverable	Timing
HQ	<ul style="list-style-type: none"> - Further awareness creation of Helpdesk service Rare Diseases - Include Rare Diseases in quality communications and harmonizing standards discussion - Establish governance model for sustainability of rare disease biobanks 	Q2-Q4 Q2-Q4 Q1-Q2
Projects	<ul style="list-style-type: none"> - ADOPT - RD-Connect - European Reference Networks 	Q1-Q2 Q1-Q3 Q1-Q4

4.4 Continued Activities

Several work streams are initiated in previous years where concrete deliverables need to be developed. An overview of the ongoing projects that still could potentially benefit the various stakeholders is listed.

Owner	Deliverable	Timing
HQ	<p>Immortalized Cell Lines</p> <ul style="list-style-type: none"> - Sharing the SOPs with the National or Organisational Nodes for comments, the inclusion of a chapter on cell line quality in the online self-assessment tool. <p>Infectious diseases</p> <ul style="list-style-type: none"> - Explore and potentially intensify cooperation with ERINHA and EVAg 	Q2 Q2-Q4

5 FUNDING

5.1 Core Budget

The budget tables for 2018 are included in the separate document “Budget 2018” and provide full transparency for both estimated expenses as well as membership fees for 2018, 2019 and 2020. As it is difficult to predict which countries might join during 2020, the budget outlook 2020 is broadly based on the outlook 2019. Also, the current gross domestic product (GDP) data have to be used for the calculation of future annual contributions and requires an update in the following years’ budgets. For the Work Programme 2019, it will be possible to provide a better estimation for 2020.

Core Budget	2017 approved [€]	2017 Q1–3 actual [€]	2018 applied [€]	2019 expected [€]	2020 expected [€]
Earnings	2,213,220	1,450,383	2,546,125	2,608,319	2,599,569
Expenditures	-2,213,220	-1,450,383	-2,546,125	-2,608,319	-2,599,569

The figures in column “2017 Q1–3 actual” (January to September 2017) are the actual numbers of this year (as of 16 October 2017). Two countries, namely Germany and Malta, have paid their contribution only during October 2017 and are therefore not included in this table.

For the purpose of this version of the budget submitted, it is important to mention that one country, namely Greece, has not yet paid (as of 23rd of October 2017) their annual contributions for the years 2014–2015, nor 2017. The invoices to France was issued only recently due to the time needed to clarify succession of people in BBMRI.fr. 5 other countries have not paid their mandatory contribution and were reminded, namely Belgium, Czech Republic, Finland, Latvia and Turkey. Despite promising signs from three countries to join during 2017, Slovenia, Lithuania and Ireland have not yet submitted their requests for admission. For Ireland and Lithuania, 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 2018 are as follows:

- The FC has asked to show two versions of the mandatory contribution table. Budget 2018a includes those countries expected to join during 2017/2018 and a separate Budget 2018b which excludes such countries.
- For Budget 2018a, one more country had declared their will to join during 2018, namely Bulgaria (Member). We have positive signals also from other countries (Luxembourg and Portugal) but have excluded these from our calculations as, very likely, they will join only at a later stage. As a 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, modified by the need to recalculate personnel costs. The Common Service IT budget estimates are based on the figures from the approved application 2015, updated with additional costs for two countries (NL and CZ) and redistribution of expenses of CS IT Directorate. As a result, individual member host country contributions are decreased.
- As shown in previous budget requests for 2017 and 2016, a large number of grant applications with BBMRI-ERIC participation have been granted. BBMRI-ERIC is the primary recipient of funding within these applications (€1,054,174 is foreseen as interim finance payment or actual payments during 2018). There are reasonable amounts foreseen for Linked Third Parties (National or Organisational Nodes) and other partners, namely €674,040 during 2018. No further posts are requested for 2018. Therein you also see that it is not intended to open a lawyer position nor the Biological Resources Manager position within the next years (at least not from core budget). One can also easily identify the split of expenses for those employees who are currently on 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. The expected negative net earnings for 2018 (-€676,396) represent the situation that EU grants do not follow calendar years but are grants with pre-finance payments and then reimbursement mode. This means that the organisation always needs to have expenses in advance and is reimbursed only after reporting or the end of the project duration.
- On page 4 of the budget tables, one will also identify the decrease of overall contracting from 2017 budget of €169,866 to this years’ amount of €130,000 and an internal shift from consulting to marketing. This is a logical step of reprioritisation of the Work Programme 2018. A slight increase in expenses for AoM (incl FC and SC) is justified by better coordination mechanisms set up by the chairs of AoM and FC.
- The biggest difference to the previous budgets is the cost-neutral introduction of earnings and spending for the Annual Biobanking Conference (estimated €410,000 for 2018) and a separate yet smaller dedicated budget for Quality activities.

- In terms of earnings, the submitted draft budget 2018 of €2,546,125 is split into hosting country contributions of €158,831 (this is for Headquarters in Graz, and the Common Services respectively) and membership contributions of €1,917,131 and other earnings of €470,163 (incl the cost neutral Annual Biobanking Conference). As in previous years, this results in an overall decrease of membership fees for most countries if version a) is chosen. 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 in relation to each other is mirrored and adapted in relative terms to the annual contribution. In case of version 2, a slight increase for most countries is foreseen.
- BBMRI-ERIC has a series of internal regulations in place, which are part of our Operations Handbook, the basis for the travel policy.

Owner	Deliverable	Timing
HQ	- Budget and forecasting plan on annual basis with quarterly reports	Q1-Q4
	- Increase automation in managing and reporting finance	Q1-Q2

5.2 Fundraising Activities

BBMRI-ERIC continues its activities to allocate additional funding for its core activities (e.g., H2020). By actively monitoring the developments in the market, early signals of upcoming calls can be addressed and actions taken. Additionally, BBMRI-ERIC will start to explore fundraising activities outside of the regular H2020 projects, relying also on the input from the Stakeholder Forum.

Owner	Deliverable	Timing
HQ	- Develop forecasting tool in CRM	Q1
	- Setup of Monthly Monitor for specific Calls	Q1-Q4
	- Target potential new member states and existing Member States for renewal	Q1-Q4
	- Explore Industry Pillar in Stakeholder Forum as potential new funding source	Q1-Q4
	- Intensify connection to other EU bodies (Structural Funds, Commission of Regions)	Q1-Q4

6 NEW PROJECTS

6.1 EDIReX

EurOPDX Distributed Infrastructure for Research on patient-derived cancer Xenografts

Topic: H2020-INFRAIA-2016-2017 **Type of Action:** RIA **Duration:** 48 months

Start date: 1st February 2018 **Grant agreement:** 731105

Web: (not yet available)

Total request Grant by Consortium: € 5,156,198.75

Total request Grant by BBMRI-ERIC: € 70,558.75

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 13.5 (threshold 10)

Abstract:

Counteracting high attrition rates in oncology drug development and providing optimal therapeutic management of cancer patients require preclinical models that properly recapitulate the complexity and diversity of human tumours. Patient-derived tumour xenografts (PDXs), established by transplanting tumour fragments into immunodeficient mice, are being widely embraced by the scientific community as preclinical tools for target and biomarker discovery. The overall goal of EDIReX is to establish a cutting-edge European infrastructure offering Trans-national Access (TA) of PDX resources to academic and industrial cancer researchers, including the distribution of cryopreserved samples to third parties, the structured biobanking of user-developed models, and the performance of efficacy studies. To ensure interoperability in services, TA initiatives will be backed by Networking Activities (NAs); these will be mainly centred around the establishment of standard procedures for PDX quality control, long-term storage, and therapeutic mouse trials. NAs will also entail the adoption of shared ethics parameters for animal experimentation, the wide dissemination of services and project results, and the design of plans to ensure sustainability of the infrastructure. User outreach will be maximised by Joint Research Activities through a three-pronged approach: i) the implementation of a public Data Portal for efficient and user-friendly query and visualisation

of clinical, molecular and pharmacological annotation of the models; ii) a cross-validation mouse trial to harmonise interlaboratory procedures, thus improving the quality and reliability of service provision; and iii) the development of exploratory, more advanced PDXbased preclinical platforms, such as orthotopic and humanised models and in vitro PDX-derived cells. Capitalising on all these assets, EDIREX will contribute to structuring the European Research Area and global cooperation of research infrastructures.

6.2 EOSC-hub

Integrating and managing services for the European Open Science Cloud

Topic: H2020-EINFRA-12-2017

Type of Action: RIA

Duration: 36 months

Start date: 1st January 2018

Grant agreement: 777536

Web: (not yet available)

Total request Grant by Consortium:

€ 33,376,631.75

Total request Grant by BBMRI-ERIC:

€ 25,625.-

Linked Third Parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: Development of policies for sensitive human data to be hosted or processed in the European Open Science Cloud.

Status: score 11.5

Abstract:

EOSC-hub builds on existing technology already at TRL 8 and addresses the need for interoperability by promoting the adoption of open standards and protocols. By mobilizing e-Infrastructures comprising more than 300 data centres worldwide and 18 pan-European infrastructures, this project is a ground-breaking milestone for the implementation of the European Open Science Cloud. The result will be an integrated catalogue of services, software and data from the EGI Federation, EUDAT CDI, INDIGO-DataCloud and major research e-Infrastructures.

6.3 CETOCOEN Excellence

Topic: H2020-WIDESPREAD-2016-2017 **Type of Action:** CSA **Duration:** 12 months

Start date: 1st September 2017 **Grant agreement:** 763677

Web: (not yet available)

Total request Grant by Consortium: € 384,867.50

Total request Grant by BBMRI-ERIC: € 43,005.-

Linked Third Parties/BBMRI-ERIC Framework Agreement: none

Benefit/tasks for BBMRI-ERIC: Developing methods for integrating biobanks with exposome data.

Status: 14,5

Abstract:

The aim of this project is to exploit research capacities built in Central Europe with support of the European Structural and Investment Funds and develop a cutting-edge research platform capable of addressing major scientific and societal challenges of contemporary Europe in the area of Environment and Health. It will enhance a scientific value of existing regional population studies and turn them into the accessible source of valuable information by developing sustainable biobanking platform and harmonizing their protocols, questionnaires, and standard operating procedures to allow for their joint assessment and interpretation of results. Existing research programmes will be expanded to address questions related to a wider range of factors (generically called exposome) impacting human health and wellbeing. To identify new biomarkers of exposures, effects, and susceptibility to pathologies, innovative approaches to the assessment of multiple exposures have to be developed including omics technologies, novel methods for integrative analysis, software tools and computational models, chemical sensors and triggers allowing for tracing such processes in biological systems. This innovative research is well aligned with the European and national strategic priorities and documents (including the National Innovation Strategy), and will generate substantial new knowledge needed for prioritization of future research and policy actions in the area of chemical management as well as practical tools applicable in health protection, prevention, diagnostics, and intervention with the aim of minimising the burden of disease, improve the health and well-being of citizens and lower health costs.

6.4 ID-EPTRI

European Paediatric Translational Research Infrastructure

Topic: H2020-INFRADEV-01-2017

Type of Action: RIA

Duration: 24 months

Start date: 1st January 2018

Grant agreement: 777554

Web: (not yet available)

Total request Grant by Consortium: € 3,000,000.-

Total request Grant by BBMRI-ERIC: € 192,500.-

Linked Third Parties/BBMRI-ERIC Framework Agreement: UNIMIB, University of Milano-Bicocca

Benefit/tasks for BBMRI-ERIC: Managing a thematic platform that aims to create ideal conditions for the development and use of paediatric biomarkers, with particular emphasis on enhancing the potential of -omics science in paediatrics.

Status: 13,5

Abstract:

EPTRI is aimed to harnessing the research and services for the development of medicines for children, as well as identify gaps in paediatric medicines research which prevent efficient use of research technologies across pertinent medicine research fields, from discovery and preclinical phase, all the way to ameliorate the therapeutic use of medicines in clinical practice. Sharing understanding of patients' needs and concerted efforts in critical areas of research will end in further enhancing the health of children and will also have a positive impact on European competitiveness in the pharmaceutical sector.

The new RI (EPTRI) will integrate the critical mass of competencies and structures in the paediatric research sector and the consolidated efforts of scientific groups, Networks of Excellence, Research Consortia, specialty Networks to provide 'facilities, resources and related services' to be used by the large scientific community to conduct top-level research in their respective fields of activity. Our final aim is to realise an integrated system which has never been developed in a so structured and comprehensive way in order to bring together all these paediatric activities and the technologies with a big impact on preparing clinical research in so producing a huge acceleration/qualification of procedures for development of new medicines.

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