

## ADOPT BBMRI-ERIC GRANT AGREEMENT NO. 676550

### DELIVERABLE REPORT

Deliverable no	D5.6_M24
Deliverable Title	Stakeholder Meeting Report
Contractual delivery month	12 (September 2016) 24 (September 2017)
Responsible Partner	BBMRI-ERIC (Common Service ELSI)
Author(s)	Michaela Th. Mayrhofer

### STAKEHOLDER MEETING REPORT

#### Executive Summary

The BBMRI-ERIC Stakeholder Forum is the main interface for European patients' organisations, civil society, industry and academia to **interact with the biobanking universe**.

Via the Stakeholder Forum, we aim at building a sustainable, egalitarian relationship (ensured by the fact that the Stakeholder Forum is part of the BBMRI-ERIC Governance Structure) that would make us more aware of each other's needs in relation to key issues related to biobanking, such as **data protection, informed consent in health research, health research priorities, and other ethical legal and societal issues (ELSI)**.

We aim at a participatory governance model and open dialogue.

The ADOPT funding guarantees funding for workshops and engagement activities of the Stakeholder Forum. This report highlights key activities in relation to the stakeholder engagement.



## Copyright notice



This work by Parties of the ADOPT BBMRI-ERIC Consortium is license under a Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>).

## Document log

Issue	Date (yyyy-mm-dd)	Comment	Author/partner
D5.6	2016-09-30	Report M12	Michaela Th. Mayrhofer
D5.6_Rev1	2017-10-08	Revised: 19 April 2016 instead of 19 April 2019	Michaela Th. Mayrhofer
D5.6_M24	2017-11-08	Updates M24, revision according to mid-term review to provide more information on discussions, outcomes, decisions, lessons-learned (short/medium/long term)	Michaela Th. Mayrhofer, Francesco Florindi



## Table of Contents

1. Background .....	4
2. Approaches (Methods) .....	4
2.1 Integral Part of the BBMRI-ERIC Governance .....	4
2.2 Resources .....	5
2.3 Phases to (re)establish Stakeholder Engagement .....	6
2.4 Meetings .....	7
3. Results .....	7
3.1 Delay .....	8
4. Discussion and Conclusions.....	8
5. Next Steps .....	8
6. References.....	9
Appendix I .....	10



## 1. Background

Close interaction with the pan-European stakeholders as well as the public is essential for the success and proper social embedment of BBMRI-ERIC. As early as 2006, an EPPOSI conference brought together for the first time patient science as well as clinicians to discuss the future of biobanks, which gave rise to well-grounded has launched already during its Preparatory Phase a comprehensive consultation and engagement process with a broad range of stakeholder leading to a Patient Participation Consultation Document under the leadership of the Irish Platform for Patients' Organisations, Science and Industry (IPPOSI, a daughter of EPPOSI) as well as empirical studies (focus groups, interviews and questionnaires) in various countries regarding biobanking knowledge.

Therefore, the Stakeholder Forum shall drive a multi-stakeholder dialogue that is needed to enhance the levels of trust between the different actors, to share information and institutional knowledge, and to generate solutions and relevant good practices on the functioning of biobank partnerships with the ultimate goal focusing on improvement of health. Commercial interests are intrinsic to success in pharmacogenomics but access to publicly funded registries and biobanks not straightforward according to national regulatory frameworks. These issues are related both to patient and public trust and patient participation intrinsic to research biobanking.

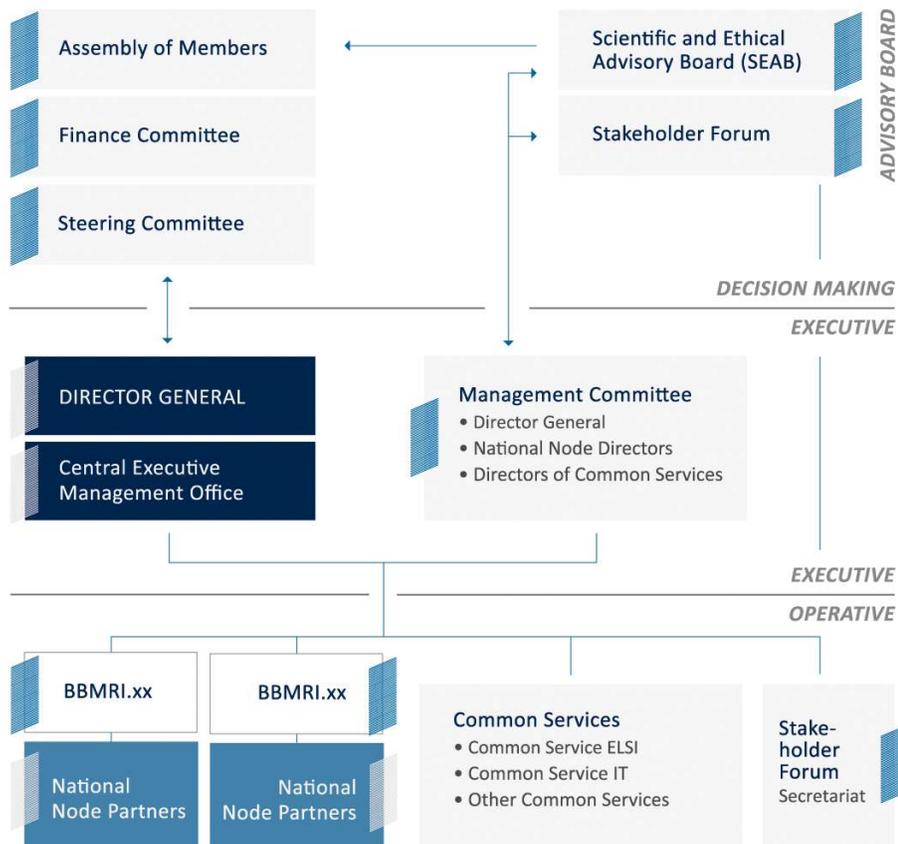
## 2. Approaches (Methods)

### 2.1 Integral Part of the BBMRI-ERIC Governance

Within BBMRI-ERIC, the Stakeholder Forum will continue in the context of the Common Service Stakeholder Forum Secretariat. The Forum and Secretariat are established as integral parts of BBMRI-ERIC's governance structure, which shall ensure long-term sustainability.

Figure 1: Governance Structure





## 2.2 Resources

### IN-KIND BBMRI-ERIC: Engagement Officer

In September 2017, the role of Engagement Officer was created within BBMRI-ERIC. The Engagement Officer is responsible for stakeholder issues related to BBMRI - ERIC in close interaction with the Director General and the Chair of the Stakeholder Forum. The position is entirely funded by the BBMRI-ERIC core budget.

### ADOPT BBMRI-ERIC: Other costs (meetings & travel)

Thanks to ADOPT funding, the Stakeholder Forum has resources for hosting and participating in meetings/workshops/seminars/conferences specific to and relevant for stakeholder engagement in an open dialogue and participatory format.



## 2.3 Phases to (re)establish Stakeholder Engagement

### ***Phase I - 2015: Reviving Stakeholder Engagement after the BBMRI Preparatory Phase (2008-2011)***

During the preparatory phase of BBMRI a Stakeholder Forum was setup under the leadership EPPOSI and its executive manager Derick Mitchell (IPPOSI). It held several meetings and produced profound reports. These findings were incorporated into the BBMRI Business Plan [v21.1 of 03/12/2012]. In the Annual Report 2014 of BBMRI-ERIC it is reported that the Secretariat is expectantly hosted by Belgium and operational in 2015. Preparatory talks lead to a proposal of Belgium, which was discussed between the Director General and representatives of The Belgian National Node on 28 October 2014 in Brussels. At that time it was assumed that Belgium can offer to host the Secretariat but internal discussion between EPPOSI and the National Node led to the decision of the DG to postpone a decision on the Secretariat until these internal discussions were settled. Meantime, the Belgian Node withdrew the original offer to host the Forum and EPPOSI was caught in internal struggles. BBMRI-ERIC decided to reconsider in 2016.

### ***Phase II - 2016: Reconceptualising the Stakeholder Forum***

On 19 April 2016, the patient chapter was established and the stakeholder engagement initiative was officially relaunched (report, see Annex). Having identified patients as the most crucial stakeholder group, BBMRI-ERIC firstly met with representatives of patient advocacy groups representing areas of expertise on genetics, rare diseases, chronic diseases, healthy ageing/prevention, degenerative diseases, cancer, obesity, and infectious diseases to explore the relaunch of BBMRI-ERIC's stakeholder engagement with them. The patient group stakeholders included the European Institute of Women's Health, the European Cancer Patient Coalition, EURORDIS – Rare Diseases Europe, Genetic Alliance UK, Alzheimer Europe, and the Dutch VSOP. The meeting took place in Brussels on April. It marked the beginning of a transparent consultation and participatory stakeholder engagement process, which will be enlarged by additional chapters involving industry and learned societies representatives in (e.g., EFPIA, ESR, etc).

On 26 July 2016, the patient chapter agreed on key aspects of the governance structure and the vacancy note for the Engagement Officer (see Annex).

### ***Phase III– 2017: Mapping Stakeholders of BBMRI-ERIC, National Nodes and Biobanks and Developing a Strategy***

In April 2017, the selection process for the Engagement Officer was completed. The start of the selected candidate was foreseen for September 2017. In order not to lose further time, a BBMRI-ERIC Stakeholder Workshop was planned for September to be held in Stockholm. The workshop was an internal BBMRI-ERIC event, bringing together National Node experts dealing with stakeholder engagement. The workshop was preceded by a survey, submitted to all participants, the result of which were used to stimulate the discussion during the workshop. The survey is therefore integral part of the workshop results (full report, see Annex).



## 2.4 Meetings

Representatives of the patient chapter were invited to partake in BBMRI activities, seminars and conferences such as the European Biobank Week 2016 in Vienna, the Global Biobank Week 2017 in Stockholm and seminars (see ISC reports, see references) and encounters with stakeholders (e.g. EMA, London; EFPIA, Brussels). Wherever feasible, travel funds from ADOPT BBMRI-ERIC were used to ensure participation.

## 3. Results

It was agreed that the structure of the Stakeholder Forum shall be organised in organisational chapters (e.g. patient or industry) and topics (e.g. informed consent).

Figure 2: Governance Structure



It was agreed that the chairperson of the Stakeholder Forum shall be a patient advocacy group representative and will be automatically a member of the BBMRI-ERIC SEAB. Currently, Alastair Kent (Genetic Alliance UK) is the chair.

It was agreed to focus on the input in the code of conduct activities (represented by the chair of the Forum) until the Engagement Officer is hired.

It was agreed on a Vacancy Note based on the input from the patient Stakeholder Forum members (see Annex).



It was agreed (and thereafter executed) that the Director General of BBMRI-ERIC and the chair of the Stakeholder Forum shall select the Engagement Officer. Ultimately, this was Francesco Florindi (CV, see Annex).

### 3.1 Delay

The deliverable was delayed as the vacancy of the engagement officer was only filled in September 2017. The engagement officer resumed work immediately and organized a BBMRI-ERIC internal workshop identifying the key stakeholders in BBMRI-ERIC member states was organized on 12 September 2017 in Stockholm. An internal report on the workshop was finalized on 17 October 2017 (see Annex). This deliverable report was delayed due to a longer sick leave by the author.

## 4. Discussion and Conclusions

The BBMRI-ERIC Stakeholder Forum shall be established as the main interface for European patients' organisations, civil society, industry and academia to **interact with the biobanking universe**. Via the Stakeholder Forum, we hope to build a sustainable, egalitarian relationship that would make us more aware of each other's needs in relation to key issues related to biobanking, such as **data protection, informed consent in health research, health research priorities**, and other **ethical legal and societal issues (ELSI)**.

We strongly believe that the Stakeholder Forum shall be a **2-way communication platform**, where we co-create knowledge and understand each stakeholder's needs and position. In practice, we would like to **co-decide with you on key actions to be undertaken jointly**, and plot a **work programme for 2018-2019** in line with your expectations and needs. Your time and energy are precious: the Stakeholder Forum is not meant to increase the already heavy burden of activities that you have. We hope to create added value for all parties involved, by agreeing on a **voluntary basis** on joint initiatives, where appropriate.

## 5. Next Steps

### Short Term:

- Develop BBMRI-ERIC Engagement Strategy draft based on workshop results
- Engage with identified stakeholders

### Mid Term:

- Support National Nodes (e.g. best practices)
- Develop BBMRI-ERIC Engagement Strategy

### Long Term:

- Ensure sustainable stakeholder engagement as an ongoing dialogue and inclusion in BBMRI-ERIC work programme



## 6. References

ISC, Summary report following the BBMRI-ERIC working meeting on health and life sciences GDPR Code of Conduct, Brussels, 1 February 2017, see [http://box5133.temp.domains/~codeofc1/wp-content/uploads/2017/10/Summary-Report\\_BBMRI-ERIC\\_CoC\\_Meeting-01.02.2017.pdf](http://box5133.temp.domains/~codeofc1/wp-content/uploads/2017/10/Summary-Report_BBMRI-ERIC_CoC_Meeting-01.02.2017.pdf)

ISC, Event report **From Biosamples to Personalized Medicine**, Seminar, 31 May 2016, Brussels, request from [tjasa.petrocnik@iscintelligence.com](mailto:tjasa.petrocnik@iscintelligence.com)

1<sup>st</sup> Code of Conduct for Health Research Meeting, Brussels, see <http://box5133.temp.domains/~codeofc1/wp-content/uploads/2017/10/Summary-Report-Meeting-07.06.2017.pdf>



## Appendix I

### 19 April 2016 – Patient Chapter Stakeholder Forum, Meeting Agenda and Syntethis



#### STAKEHOLDER FORUM BBMRI-ERIC KICK-OFF MEETING

**When:** 12-16:00, 19 April 2016

**Where:** Rue de la Science 14b, B-1040 Brussels, Brussels

**Aim:**

According to its Statutes (Article 3.1), *BBMRI-ERIC shall establish, operate and develop a pan-European distributed research infrastructure of Biobanks and Biomolecular Resources in order to facilitate the access to resources as well as facilities and support high quality biomolecular and medical research.*

This goal can only be achieved with the inclusion of key stakeholders in a transparent manner through a context-dependent consultation and participatory engagement process. In a first step, BBMRI-ERIC and representatives of patient advocacy groups representing areas of expertise on genetics, rare diseases, chronic diseases, healthy ageing/prevention, degenerative diseases, cancer, obesity, and infectious diseases will meet to identify the key topics for the years to come and define the detailed parameters of how such a constructive dialogue can be put into place.

The meeting is chaired by Alastair Kent.

12:00: Welcome and Lunch

13:00: Tour the Table (all)

13:30: Introducing BBMRI-ERIC (mission, governance, current achievements) - (Jan-Eric Litton)

14:00: Discussion (Alastair Kent, chair)

15:00: Identify "burning issues" and establish jointly a Workplan of the Stakeholder Forum (all)

16:00: End of the Meeting



## BBMRI-ERIC & PATIENT ORGANISATIONS JOIN FOR ENGAGEMENT PROCESS

In its mission to facilitate the access to resources and support high quality biomolecular and medical research <http://www.bbmri-eric.eu>/BBMRI-ERIC aims to involve key stakeholders in its work to ensure their voice is heard and represented in European biomolecular and health research. As donations of valuable human biological samples and the corresponding data, stored by the biobanks, are essential for understanding human diseases and corresponding prevention programmes, BBMRI-ERIC is dedicated to consulting the biobanking stakeholder community in this process.

Identifying patients as the most crucial stakeholder group, BBMRI-ERIC firstly met with representatives of patient advocacy groups representing areas of expertise on genetics, rare diseases, chronic diseases, healthy ageing/prevention, degenerative diseases, cancer, obesity, and infectious diseases on 19 April 2019, therewith relaunching its stakeholder engagement. The stakeholders of patient groups included BBMRI-ERIC, the European Institute of Women's Health, European Cancer Patient Coalition, EURORDIS - Rare Diseases Europe, Genetic Alliance UK, Alzheimer Europe, and the Dutch VSOP.

Patients and families with life limiting conditions do believe in the crucial role of scientific research to make new and better treatment available. Patients therefore accept to donate their data and samples to be shared amongst legitimate users for the purpose of advancing understanding and contributing to the realisation of the potential for health gain providing there is an appropriate framework in place. For these reasons, the patient stakeholder group believes it would be appropriate to establish a framework to support legitimate uses of data and samples, and reduce the risk of misuse or abuse of patient data to an acceptable level, bearing in mind that the elimination of all risk of misuse will probably only be achievable through the creation of a governance framework that is so tight that desirable applications are likely to be impeded to an unacceptable extent.

The meeting, chaired by Alastair Kent of Genetic Alliance UK, marked the beginning of a transparent consultation and participatory stakeholder engagement process, which will be enlarged by chapters on industry representatives and other organisations and learned societies (e.g., EFPIA, EMA, etc.). **The overall aim is to address key issues for a continuous constructive dialogue to ensure stakeholders' needs are well represented in the activities of BBMRI-ERIC.**



## 26 July 2016 – Patient Chapter Stakeholder Forum, Agenda and Vacancy Note Engagement Officer



### PATIENT STAKEHOLDER FORUM MEETING

#### Draft Agenda

**Date:** 26 July 2016 - 09:30-14:00

**Venue:** ISC Intelligence in Science, Rue de la Science 14b, 1040 - Brussels (Belgium)

- (1) On endorsement (Jan-Eric Litton)
- (2) Rules of Procedures of the Stakeholder Forum (draft) (all)
- (3) Role description of "Engagement Officer" for the Stakeholder Forum (draft) (all)
- (4) Informing on Open Science Cloud (Jan-Eric Litton)
- (5) GDPR FAQs + update on Code of Conduct (Michaela Th. Mayrhofer)
- (6) Other

---

#### Practical information:

- Travel costs are covered by the ADOPT BBMRI-ERIC project and can be directly arranged by our secretariat (preferred by our administration).
- For details please contact Ms Meghan McCarroll: [secretary@bbmri-eric.eu](mailto:secretary@bbmri-eric.eu) (+43 316 34 99 17 0).



## VACANCY NOTE

**Job title:** "Engagement Officer"

**Job Location:** The Central Executive Management Office of BBMRI-ERIC in Graz, Austria

**Job Purpose:** The **Engagement Officer** is responsible for stakeholder issues related to BBMRI-ERIC in close interaction with the Director General and the Chair of the Stakeholder Forum.

### Short description of BBMRI-ERIC:

*The pan-European Biobanking and Biomolecular resources Research Infrastructure is a distributed bio-medical and life science infrastructure for sustainable storage and dissemination of biobanked samples and associated data in Europe. On 22 November 2013, BBMRI was officially awarded the Community legal framework for a European Research Infrastructure Consortium (ERIC). This specific legal form is designed to facilitate the joint establishment and operation of research infrastructures of European interest. BBMRI-ERIC will provide access to the collections of partner biobanks and biomolecular resources, their expertise and services on a non-economic basis.*

*BBMRI-ERIC is an **inclusive, equal-opportunity employer** offering attractive conditions and benefits appropriate to an international research organization. Further information on the aims, mission, governance, and statutes of BBMRI-ERIC can be found at [www.bbMRI-eric.eu](http://www.bbMRI-eric.eu).*

### Key Responsibilities and Accountabilities of the Role

The Engagement Officer will be responsible for engaging with stakeholders related to BBMRI-ERIC and organizing the Stakeholder Forum in close interaction with the Director General and the Chair of the Stakeholder Forum. The Stakeholder Forum includes, among others, representatives from patient advocacy groups, learned societies and industry, which are involved and/or affected by biobanking activities. It is set up to allow for a platform of exchange as well as a participatory governance to include stakeholder concerns into the activities of BBMRI-ERIC through a transparent engagement process. The key responsibilities further include liaising on stakeholder issues with BBMRI-ERIC bodies as appropriate, including required documentation and communication. As required he/she supports networking, the development of requests for proposals for external services, the design of project documentation; public relations and dissemination activities. The Engagement Officer has an advocacy role within and outside of BBMRI-ERIC.

### Requirements of the Role

The Engagement Officer is expected to have a high level experience in liaising with various stakeholders from multiple fields and has to be comfortable to engage in the scientific context in which BBMRI-ERIC operates and, in particular, understands and empathizes with the cause of patient advocacy. Previous experience in stakeholder engagement and science communication is considered an advantage, as well as in-depth knowledge in one of the scientific fields that BBMRI-ERIC represents. Excellent interpersonal skills, the ability to effectively liaise with colleagues and stakeholders on all levels in a distributed, international, interdisciplinary environment and the ability to undertake/deliver the required tasks without losing a sense of humor as well as clarity in oral and written communication are essential requirements. As English is the common working language of



BBMRI-ERIC applicants must be fluent in English. A fluency in other languages is considered an advantage.

In order to provide effective support, the jobholder will need to stay abreast of the development of BBMRI-ERIC, as well as related organizations and initiatives and may from time to time have to attend meetings outside normal working hours and undertake international travel. The role-holder is also required to stay abreast of key scientific developments within the scope of BBMRI-ERIC, therefore we seek for applicants knowledgeable in a field relevant for BBMRI-ERIC (scientific degree or other qualifications).

### **Employment Terms and Conditions**

The Engagement Officer will be directly employed by BBMRI-ERIC at its Central Executive Management Office in Graz, Austria. The employment follows the Austrian employment law. BBMRI-ERIC offers fringe benefits like complementary health insurance, and a private pension scheme, relocation and travel grant as well as local support for housing.

It is a full-time position. The appointee will be offered a possibility for gradual transition to relocate to Graz, Austria.

### **Salary**

According to European/international standards for similar role and responsibilities and requirements of this function (57,000-60,000€ as minimum annual gross salary; final salary dependent on terms of qualification and negotiation).

### **Application Procedure**

For applications to be valid, candidates must submit:

- A Curriculum Vitae [CV] with photo
- A letter of motivation
- Supporting documents (for example, certified copies of degrees, references etc.)

In case of any questions, please contact:

Michaela Th. Mayrhofer PhD, Senior Project Manager/Chief Policy Officer Common Service  
ELSI, [michaela.th.mayrhofer@bbmri-eric.eu](mailto:michaela.th.mayrhofer@bbmri-eric.eu), +43 664 88 72 18 74

Please send the required documents via e-mail to the following address: [admin.dir@bbmri-eric.eu](mailto:admin.dir@bbmri-eric.eu)

Deadline for application is 24 March 2017; anticipated start of work is July 2017.



## 12 September 2017 – Meeting Report, Stakeholder Workshop

Annexes of this report can be provided upon request.



# Report

## BBMRI-ERIC Stakeholder Workshop

Stockholm, Sweden, 12<sup>th</sup> September 2017

List of participants .....	2
Agenda .....	3
Executive summary – Action Points – Next Steps .....	4
Introduction.....	8
Objectives & genesis of the meeting.....	8
Results of the prep survey .....	9
Key outcomes.....	9
Stakeholders mapping.....	13
Biobanks universe.....	13
Academia – Researchers .....	13
Citizens and Patients – Participants in biobanking.....	14
Healthcare professionals.....	14
Policy makers .....	16
Regulatory bodies.....	17
Industry.....	17
Fundors .....	18
Media.....	18
Multistakeholder initiatives .....	18
Updated list of stakeholders’ clusters.....	19
Power-Interest grid .....	20
National Node’s power-interest grid .....	20
BBMRI-ERIC’s power-interest grid .....	22
Best practices.....	23
France .....	23
Italy.....	23
Malta .....	24
The Netherlands .....	24
United Kingdom.....	24
General comments on best practices sharing .....	25
Next steps.....	25
Support to National Nodes.....	25
BBMRI-ERIC stakeholder engagement strategy .....	25
Conclusions and feedback .....	25
List of annexes .....	26



<b>Annex 1: Survey</b> .....	26
<b>Annex 2: Replies to the survey</b> .....	26
<b>Annex 3: Results of the survey</b> .....	26
<b>Annex 4: Stakeholders list discussed during the workshop</b> .....	26
<b>Annex 5: PowerPoint presentation</b> .....	26
<b>Annex 6: Photos from the event</b> .....	26
<b>Annex 7: Provisional list of stakeholders</b> .....	26

These meeting and report have received funding from *the European Union’s Horizon research and innovation programme* under grant agreement No 676550.



### List of participants

- BE Annelies Debucquoy
- BE Sofie Bekaert
- BE Isabelle Huys
- DE Antje Schütt
- FI Anu Jalanko
- FR Michael Hisbergues
- IARC Maimuna Mendy
- IT Sara Casati
- IT Marialuisa Lavitrano
- LV Vents Silis
- MT Gillian Martin
- NL Martin Boeckhout
- NO Berge Solberg
- PL Jakub Pawlikowski
- PL Lukasz Kozera
- PL Dominik Strapagiel
- SE Mats Hansson
- SE Heidi Howard
- SE Deborah Mascalzoni
- UK Jessica Sims
- UK Victoria Chico
- BBMRI-ERIC Michaela Th. Mayrhofer
- BBMRI-ERIC Carmen Cristea
- BBMRI-ERIC Francesco Florindi

### Apologies

- DE Cornelia Rufenach
- DE Wiebke Lesch
- LV Vita Rovite
- NO Isabelle Sylvie Budin Ljøse
- MT Joanna Vella
- UK Phil Quinlan
- GR Dimitris Thanos

**Total: 30 registered participants**



## Agenda

WHEN	WHAT	BY WHOM
14:00	Welcome, tour de table	Michaela
14:05	Objectives & genesis of the meeting	Michaela & Cornelia
14:10	Results of the prep survey	Francesco
14:20	<p>Discussion on the results of the survey – part 1</p> <ul style="list-style-type: none"> <li>□ 14:20: Definition of NN stakeholders <i>Related survey questions:</i> <ul style="list-style-type: none"> <li>○ Q1 Who are the stakeholders you engaged with so far?</li> <li>○ Q3 Are there other stakeholders you think you should/could engage with?</li> </ul> </li> <li>□ 14:30: Best ways to engage with stakeholders. <i>Related survey questions:</i> <ul style="list-style-type: none"> <li>○ Q2 How do you engage with stakeholders?</li> </ul> </li> </ul> <p>Brief presentations of best practices from:</p> <ul style="list-style-type: none"> <li>○ France - Michael Hisbergues</li> <li>○ Italy – Sara Casati</li> <li>○ Malta - Gillian Martin</li> <li>○ the Netherlands - Martin Boeckhout</li> <li>○ United Kingdom - Jessica Sims</li> </ul>	All
15:10	Coffee break	
15:25	<p>Discussion on the results of the survey – part 2</p> <ul style="list-style-type: none"> <li>□ 15:25: Strengths and weaknesses in ongoing engagement activities <i>Related survey question: SWOT analysis</i></li> <li>□ 15:40: Opportunities and threats in future engagement work <i>Related survey question: SWOT analysis</i></li> <li>□ 16:10: What BBMRI-ERIC can do for you/with you? <i>Related survey questions</i> <ul style="list-style-type: none"> <li>○ Q4 Who are the stakeholders BBMRI-ERIC should engage with?</li> <li>○ Q5 What should BBMRI-ERIC stakeholder forum achieve?</li> </ul> </li> </ul>	All
16:40	Wrap up & next steps	Michaela & Francesco
	AOB	
17:00	End of meeting	

### Executive summary – Action Points – Next Steps

The report summarises the outcome the BBMRI-ERIC Stakeholder Workshop, held in Stockholm during the Global Biobank Week 2017. The workshop was an internal BBMRI-ERIC event, bringing together National Node experts dealing with stakeholder engagement. The workshop was preceded by a survey, submitted to all participants, the result of which were used to stimulate the discussion during the workshop.

The workshop aimed at:

- Exchanging experiences on how the National Nodes are engaging with stakeholders;
- Laying the foundations for a BBMRI-ERIC exchange forum to learn from each other;
- Mapping the main stakeholders on three levels:
  - BBMR-ERIC level;
  - National Node level;
  - biobank level.
- Generate concepts how an infrastructure can support the National Nodes and biobanks in their stakeholder activities.

### Results of the prep survey

13 Nodes replied to the prep survey. The analysis of the replies showed that the National Nodes are engaging with stakeholders at different levels. Important differences exist in the way the Nodes define and perceive each cluster of stakeholders. This is due to the specificities of each country. Likewise, the Nodes' opinion on who are BBMRI-ERIC stakeholders at EU/international level varies. Therefore, there is the need to agree on a shared list of key stakeholders, to map them and to define their roles at local, national and EU level.

The vast majority of the Nodes agree that BBMRI-ERIC should play a role in facilitating knowledge exchange on stakeholders' engagement among the Nodes, and to provide guidance and training to the Nodes.

### Stakeholders mapping

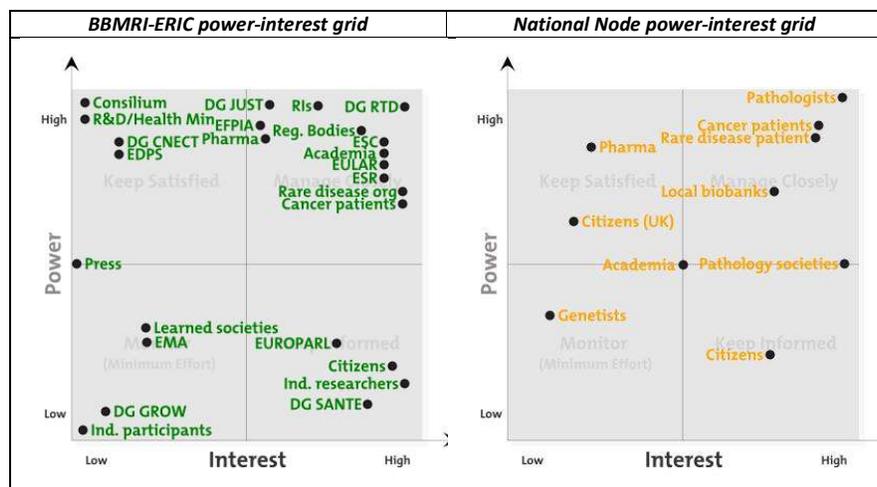
From the survey, BBMRI-ERIC HQ draw a list of group of stakeholders to be discussed with the participants to the workshop, with the objective of defining the key stakeholders at local (biobank), national (Node) and EU (BBMRI-ERIC) levels. Furthermore, the participants refined the definitions of each of the stakeholders' clusters.

Local biobanks' stakeholders	National Node's stakeholders	BBMRI-ERIC's stakeholders
<b>Biobank universe</b>		
<input type="checkbox"/> Local biobanks <input type="checkbox"/> Biobanks professionals	<input type="checkbox"/> Other National Nodes <input type="checkbox"/> Biobanks professionals <input type="checkbox"/> BBMRI-ERIC shall map and compare those bodies <input type="checkbox"/> BBMRI-ERIC	<input type="checkbox"/> ESBB <input type="checkbox"/> ISBER
<b>Academia / no-profit research</b>		
<input type="checkbox"/> Individual researchers <input type="checkbox"/> Universities / research centres	<input type="checkbox"/> Universities / research centres <input type="checkbox"/> National scientific societies	<input type="checkbox"/> European/international scientific societies <input type="checkbox"/> Other research infrastructures
<b>Industry</b>		
<input type="checkbox"/> Spin offs from academia <input type="checkbox"/> Multinational pharmaceutical companies <input type="checkbox"/> MedTech-IVD companies <input type="checkbox"/> IT Service providers		European / international trade associations
<b>Funders</b>		
<input type="checkbox"/> National-regional public funders <input type="checkbox"/> Insurance companies (country specific)	<input type="checkbox"/> National-regional public funders <input type="checkbox"/> EU-international public funders <input type="checkbox"/> Insurance companies (country specific)	<input type="checkbox"/> EU-international public funders
<b>Policy makers</b>		
<input type="checkbox"/> Regional-local policy makers <input type="checkbox"/> Ethic committees	<input type="checkbox"/> National policy makers (e.g.: ministry) <input type="checkbox"/> Ethic committees (where there are national ones) <input type="checkbox"/> Biobanks governing bodies	<input type="checkbox"/> Regulatory bodies (ISO, CEN...) <input type="checkbox"/> European policy makers (MEPs, Commissioners...) <input type="checkbox"/> EU institutions-agencies (European Commission, EMA...) <input type="checkbox"/> Biobanks governing bodies (BBMRI-ERIC shall map and compare those bodies)
<b>Citizens - Patients</b>		
<input type="checkbox"/> Local patients' associations <input type="checkbox"/> Individuals, families	<input type="checkbox"/> National patients' associations <input type="checkbox"/> National consumers' and civil rights associations	<input type="checkbox"/> European patients' associations <input type="checkbox"/> European consumers' and civil rights associations
<b>Healthcare professionals (non-researchers)</b>		
<input type="checkbox"/> Hospital (incl. managers) <input type="checkbox"/> Individual HCPs (including GPs)	<input type="checkbox"/> National learned societies	<input type="checkbox"/> European learned societies, including <ul style="list-style-type: none"> <li><input type="checkbox"/> General Practitioners</li> <li><input type="checkbox"/> Genetic counsellors</li> <li><input type="checkbox"/> Pathologists</li> </ul> <input type="checkbox"/> Disease specific societies
<b>Media</b>		
<input type="checkbox"/> Local press, TV <input type="checkbox"/> Academic journals	<input type="checkbox"/> National press, TV <input type="checkbox"/> Academic journals	<input type="checkbox"/> National/European press/media outlets <input type="checkbox"/> Academic journals
<b>Multistakeholders initiatives</b>		
	<input type="checkbox"/> National (formal & informal) coalitions/consortia	<input type="checkbox"/> European coalitions/consortia <input type="checkbox"/> Umbrella associations



### Power-interest grids

Each stakeholder was evaluated for their power and interest in the work of the National Nodes and BBMRI-ERIC. As a result, the participants to the workshop produced 2 power-interest grids, one for the National Nodes, one for BBMRI-ERIC.



From the power-interest grid it emerged that BBMRI-ERIC should focus its stakeholder engagement on:

- European Commission (in particular DG RTD, DG JUST, DG CNECT);
- Industry (EFPIA);
- Patients' organisations (in particular in the field of cancer and rare diseases);
- Regulatory bodies (CEN, ISO) and EU agencies related to the implementation of the GDPR (EDPS);
- Other research infrastructures;
- Health and research ministries, together with EU governments' Permanent Representatives;
- Selected learned societies with high interest in biobanking.

### Best practices

Best practices from 5 Nodes were showcased during the workshop. The participants agreed that the group convened during the workshop shall meet again and shall establish a platform within BBMRI-ERIC to keep sharing experiences.

### Conclusions & next steps

- **Support to National Nodes**
  - National Nodes demonstrated high expertise and understanding of the needs of stakeholders;
  - The vast majority of Nodes reported lack of resources (including: budget, dedicated staff etc.) as the primary obstacle to the development of engagement strategies (see Annex 2 SWOT analysis). Furthermore, all the Nodes reported that more guidance and training is needed to carefully plan stakeholder engagement strategies (Annex 2);
  - BBMRI-ERIC should provide the workshop participants with a **permanent platform** to:
    - Share best practices;
    - Identify synergies and collaboration among National Nodes and BBMRI-ERIC;
    - Keep working together on stakeholder engagement issues.
  
- **BBMRI-ERIC stakeholder engagement strategy**

The report shall be used by BBMRI-ERIC as a baseline for the production of its own engagement strategy, in particular:

  - Produce a transnational stakeholder engagement strategy, fulfilling the following criteria:
    - The strategy shall build on the successes and experience of the Nodes, and work in synergy with the Nodes engagement activities;
      - National initiatives remain competence of each National Node. If the Node believes that BBMRI-ERIC involvement in national engagement activities would be fruitful, BBMRI-ERIC's role shall first be agreed and negotiated with the National Node;
    - The BBMRI-ERIC engagement strategy shall focus on transnational issues and European/international stakeholders identified in the mapping exercise;
    - BBMRI-ERIC stakeholder engagement strategy shall be supported by appropriate communication at EU level;
  - Update the BBMRI-ERIC stakeholders' list.



## Introduction

This report summarises the outcome the BBMRI-ERIC Stakeholder Workshop, held in Stockholm during the Global Biobank Week 2017. The workshop was an internal BBMRI-ERIC event, bringing together National Node experts dealing with stakeholder engagement. The workshop was preceded by a survey, submitted to all participants, the result of which were used to stimulate the discussion during the workshop. The survey is therefore integral part of the workshop results. Furthermore, the report includes issues discussed in bilateral talks between BBMRI-ERIC HQ and National Node representatives who could not join the meeting, as well as email exchanges with National Nodes representatives before and immediately after the workshop.

For practical reasons, the report does not include quotes or contributions from specific participants, unless strictly necessary to the understanding and usefulness of the report itself.

Notes from the workshop were taken by Carmen Cristea and Francesco Florindi.

## Objectives & genesis of the meeting

The Stakeholder Workshop was organised by BBMRI-ERIC to:

- Exchange experiences on how the Nodes are engaging with stakeholders;
- Lay the foundations for a BBMRI-ERIC exchange forum to learn from each other;
- Identify the main stakeholders on three levels:
  - BBMR-ERIC level;
  - National Node level;
  - biobank level.
- Generate concepts how an infrastructure can support the National Nodes and biobanks in their stakeholder activities.

The workshop agenda was divided in three parts:

- Presentation of the results of the prep survey (**Annexes 1, 2, 3, 5**), to kick off the debate on common ground;
- Validation of the stakeholders' clusters that emerged from the prep questionnaires (**Annex 4**);
- Identify best practices and produce a SWOT analysis for BBMRI-ERIC stakeholder engagement.

The last part of the workshop was not fully performed due to time constrains.

Antje Schnett was invited to elaborate on the genesis of the workshop. The workshop's original idea came from a proposal elaborated by the German biobank Node, which recently kicked off its new engagement strategy. They surveyed 180 patients to assert their level of awareness on biobanking, and followed up with qualitative semi-structured interviews with researchers and biobank managers from university hospitals to know what the National Node can provide to support local level engagement. The German Node suggested BBMRI-ERIC HQ to perform a similar exercise with all the Nodes to define how BBMRI-ERIC can support National Nodes in their stakeholders' engagement.

## Results of the prep survey

In preparation of the workshop, a prep survey was disseminated to all National Nodes directors (Annex 1). BBMRI-ERIC HQ received 13 replies to the survey, which were analysed and presented during the workshop (Annexes 2, 3 and 5).

The survey was structured to answer three main questions:

- Stakeholder mapping:**
  - Which are the stakeholders you engaged/want to engage at National Node level?
  - Which are the stakeholders BBMRI-ERIC level should engage at the EU/international level?
- How did you engage with stakeholders?**
- What is BBMRI-ERIC role in stakeholder engagement?**

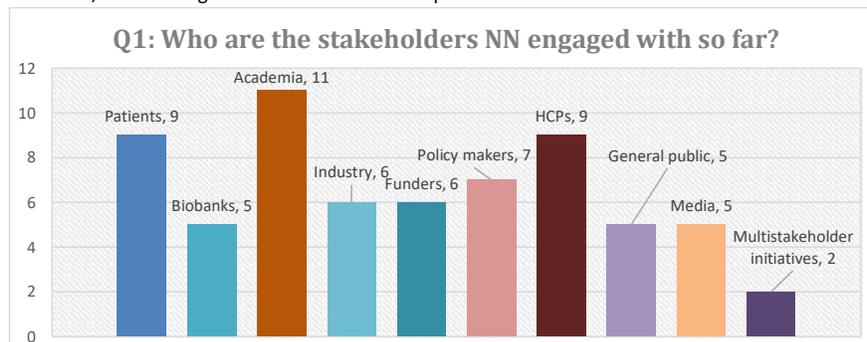
The survey included also a SWOT Analysis regarding the stakeholder engagement at National Node level.

## Key outcomes

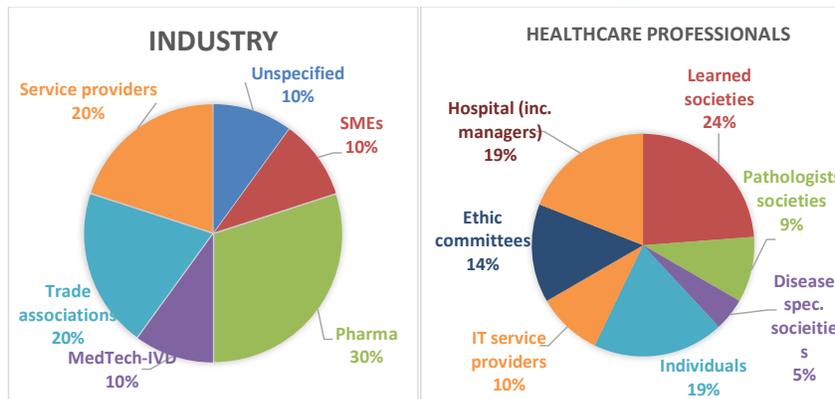
The analysis of the replies showed that the National Nodes are engaging with stakeholders at different levels. Important differences exist in the way the Nodes define and perceive stakeholders. This is due to the specificities of each country. Likewise, the Nodes' opinion on who are BBMRI-ERIC stakeholders at EU/international level varies. The survey identified the stakeholders' clusters that need to be better analysed in partnership with the Node to agree upon a baseline stakeholder mapping. For this reason, BBMRI-ERIC HQ listed all the stakeholder mentioned and presented them to the participants of the workshop to trigger the debate (Annex 4).

### Which are the National Node's stakeholders?

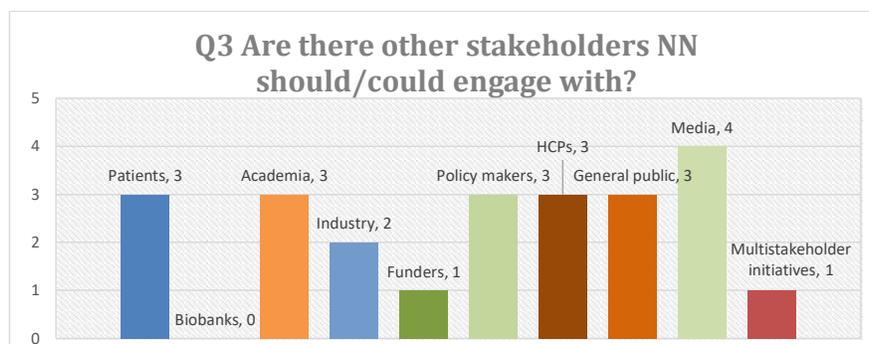
The majority of National Nodes interact closely with citizens/patients (participants to the biobank), academia/research organisations and healthcare professionals.



However, some stakeholders' clusters are complex and varied in their composition, and need to be better analysed to guarantee the right actions are implemented.

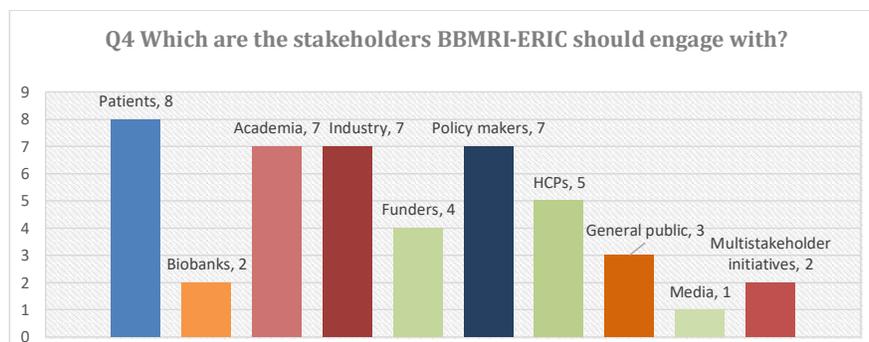


National Nodes generally find difficult to efficiently interact with media and the general public. Relationships with citizens/patients, policy makers and researchers could also be improved

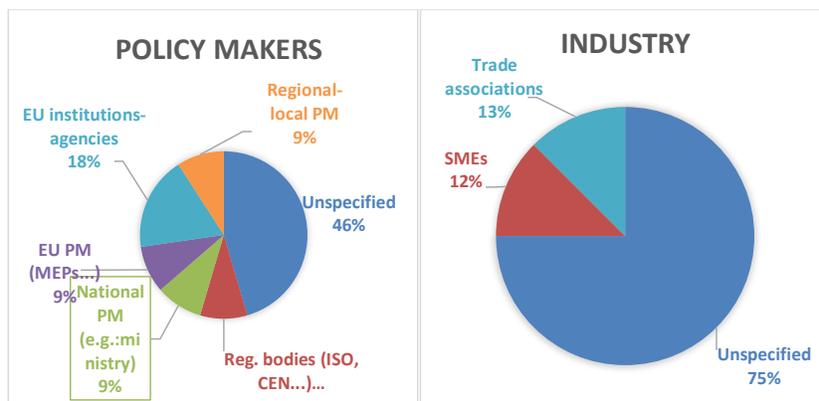


Which are BBMRI-ERIC's stakeholders?

The National Nodes believe BBMRI-ERIC should focus its engagement strategy on patients/citizens associations at EU level, academia and other research infrastructures, as well as industry and policy makers at the EU level.

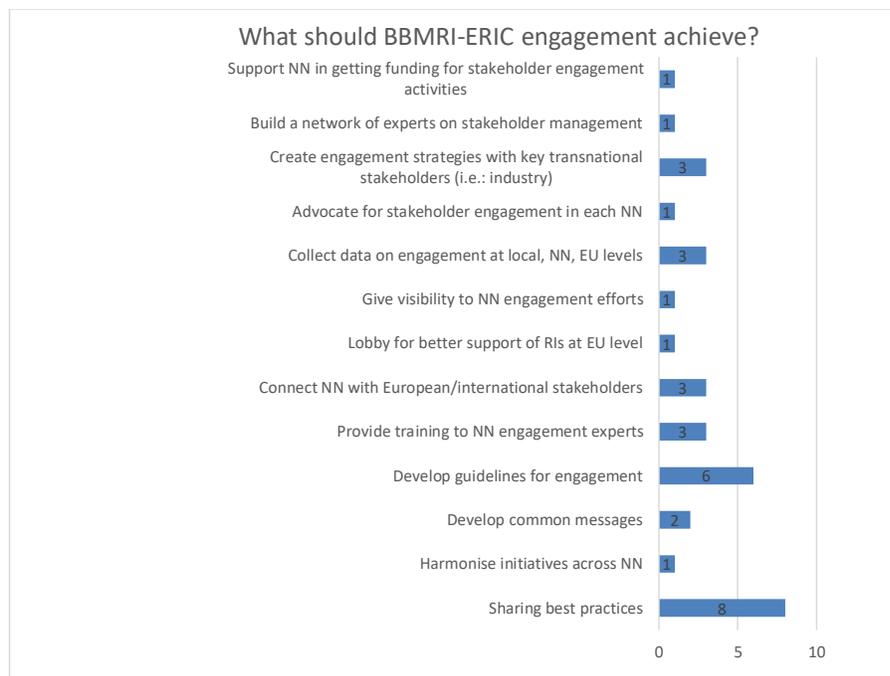


However, a higher level of detail is necessary to carefully map certain stakeholders' clusters, like industry and policy makers.



What should BBMRI-ERIC do to support the Nodes?

The vast majority of the Nodes agree that BBMRI-ERIC should provide guidance and training to the Nodes on stakeholder engagement, by pooling and sharing best practices, and by providing training and guidelines for engagement.



### SWOT analysis

The SWOT Analysis shows that National Nodes have very clear ideas on what are their key strengths and weaknesses. Lack of resources represent the main internal obstacle to a successful engagement strategy at the National Node level. The list of opportunities offers a great source of ideas for future projects and initiatives at national and BBMRI-ERIC for the future, and shall be the basis for the next phase of engagement with the participants of the workshop (due to time constraints, the SWOT analysis was not discussed during the workshop).

n Strengths: helpful, internal origin		n Weaknesses: harmful, internal origin	
6	Solid collaborations/network with other biobanks	9	Stakeholders are not aware of what biobanks do/difficult to engage with them
4	Being part of BBMRI-ERIC (catalyser of engagement initiatives/new projects)	8	Lack of resources (EUR, time...)
3	Presence at national/international congresses	4	Insufficient engagement with academia
2	Solid collaboration with regulatory bodies/standardisation	2	Insufficient engagement with patients
2	Database of stakeholder contacts	2	Don't know how to engage effectively/in a sustainable manner
2	Donors (patients) have positive attitude vs R&D	2	Lack of political support
2	Solid collaboration with most/all stakeholders	2	No incentives to engage/Leadership not aware of role of stakeholders' engagement
2	Support from national regulators/connections with politicians	1	Insufficient engagement with HCPs
1	Motivated volunteers (on both NN/stakeholders sides)	1	Being a small biobank
1	Experience in organising events	1	Difficult to portrait the panorama of different projects existing in biobanking
1	Communication/press officer	1	Biobank/NN leadership no aware of importance of stakeholder engagement
1	Established relationship with media outlets	1	Insufficient engagement with industry
1	Solid collaboration with charities		
1	Support from main medical centres		
1	Experience in engaging with stakeholders		
n Opportunities: helpful, external origin		n Threats: harmful, external origin	
2	Joint educational events (for biobanks, users)	5	Donors lack confidence in biobank (data protection)
1	New regulations (IVD-GDPR)	3	Issues with ethical committees
1	Upcoming ISO Standards	3	Governance issues/fragmented organisational responsibilities
1	Best practices sharing: opportunity to reproduce successful initiatives	2	Competition between different stakeholders
2	Production of joint initiatives (white papers, guidelines on engagement...)	1	Implementation of GDPR
1	Local environment: NN is based in thriving city/research hub	1	Abuse of stakeholder engagement for individual/particular benefit
1	Personalised Medicine will help biobanks importance grow	1	Data leaks
1	National training programmes in partnership with health ministry	1	Structure/funding of research programmes hamper sustained engagement effort
1	Agreements among POs, biobanks and institutions to promote biobanking	1	Ability to engage stakeholders: what if stakeholders do not feel the need to engage?
1	Bridge between policy-makers and research institutions	1	Competition from other research fields
1	In collaboration with RECs, harmonization of evaluation practices.	1	BBMRI-ERIC could overlap national engagement efforts
1	Quality and ESI Help Desk.		
1	Supporting accreditation Programmes.		
1	Healthcare system's issues that biobanking might improve		
1	Building a united front in regulatory affairs & research policy		
1	Raising level of trust in population		
1	Public interest in science		
1	Political willingness to develop biobanking/public-private partnerships		



## Stakeholders mapping

The participants were asked to comment on Annex 4 and on the results of the prep survey. The participants proceeded to discuss each stakeholder cluster, with the objective of defining the key stakeholders at local (biobank), national (Node) and EU (BBMRI-ERIC) levels. Furthermore, the participants refined the definitions of each of the stakeholders' clusters.

## Biobanks universe

**Definition:** all actors (individuals and organisations) of which the biobanking community is composed. It includes professionals working within the biobanks, population biobanks, disease-specific biobanks, National Nodes, BBMRI-ERIC and other international networks of biobanks/biobankers (ISBER, ESBB).

### Local biobanks

The interest of local biobanks towards the Node varies across countries. The Swiss biobanks Node was mentioned as an interesting case: Swiss local biobanks have considerable power over the work of the Node, but they were not aware/interested in the Node activities, therefore did not engage (this changed in recent times). In the UK, biobanks are very autonomous, therefore they decide their level of engagement with the Node, hence the Node works on keeping the biobanks' interest high. In Finland, there are only 9 biobanks established by the law, which mandatorily collaborate with the National Node.

The participants agree that regardless of the individual biobank's interest, they play a crucial role in the life of the Node.

## Academia – Researchers

**Definition:** non-for-profit users of biobanks samples (both individual researchers and research organisations). Other research consortia/infrastructures.

It was noted that many researchers are not aware of BBMRI-ERIC's work and solutions. The National Node can share info effectively only within the biobanks linked to the Node, while several other biobanks might remain uncovered. The participants agreed that those biobanks are potentially extremely interested in BBMRI-ERIC's work, and could benefit from a targeted communication campaign, possibly supported by BBMRI-ERIC.

### Other research infrastructures

The relationship between several BBMRI-ERIC stakeholders and other research infrastructures (RIs) was discussed. Depending on the national interests, stakeholders might be involved in both BBMRI-ERIC and other RIs, with the possibility to create confusion: for example, it was reported that in few countries the same researchers are involved in both BBMRI-ERIC and ELIXIR, splitting their time between the two.

The participants agreed that BBMRI-ERIC must collaborate with other RIs in common policy/research issues, for example in the development of the Code of Conduct. Therefore, teaming up with other research infrastructure will be necessary to achieve certain specific policy/research goals (i.e.: EU funded projects). This role makes other RIs very influential towards the work of BBMRI-ERIC and National Nodes.

## Citizens and Patients – Participants in biobanking

### Definition:

- Individual level: patients or healthy individuals contributing with their samples to the life of the biobanks.
- Societal level: the public (not involved in biobanking), consumer organisations, civil rights movements and patients' associations.

### Examples

- Rare Diseases Europe (EURORDIS)
- European Cancer Patient Coalition (ECPC)
- Bureau of European Consumers (BEUC)

It was underlined that it is useful to differentiate between healthy participants to the biobanks and patients. Both stakeholders should be included in the mapping. The Nodes stressed the need to better involve healthy participants in the life of the biobank.

Regarding patients, two groups of patients have shown a high degree of interest in the role of biobanks: **cancer patients** and **rare diseases patients**. Their interest is proportional to their vulnerability: with few therapeutic options available, cancer and rare diseases patients turned to research (including biobankers) for support. Rare diseases and cancer patients showed a high level of influence both on drug development and in the life of clinical biobanks, often setting up their own biobanks. Via their advocacy work, patients' organisations demonstrated to be able to stir funding and policy leverage towards specific research areas. Cancer patients' organisations possibly hold higher power levels than rare disease patients' organisations, due to the higher funding allocated to cancer research. At the European level, rare disease and cancer patients' associations attract and influence important funding streams for National Nodes and BBMRI-ERIC, and have influence over research priorities of industry.

For less vulnerable individuals (healthy participants) **trust** is the key for their engagement: the lower the trust, the higher the likelihood that their support towards biobanking will drop, and therefore the higher the likelihood of funding withdrawal or lack of political support. Care.data was mentioned as an example of deteriorated trust of the civil society towards biobanking.

There have been important advancements in the way patients and consumer groups understand biobanking. However, at the EU level, it is important to keep patients and citizens well informed, via a high level of engagement with patients and consumer groups to ensure a steady flow of information. The participants agreed that to reach large levels of participation in biobanking (and related research) it is necessary to build an alliance with those that are primarily informing patients and citizens regarding their rights. This is a long-term engagement, that will slowly empower patients/consumers to take informed choices. The participants underlined that patients/consumers have considerable power in supporting BBMRI-ERIC policy message.

### Healthcare professionals

**Definition:** all individuals/organisations working within a clinical setting, who are not primarily performing research and are mostly focused on treatment. "Healthcare professionals" includes all learned societies at national/international level.

### Examples

- Hospital managers
- Pathologists
- Genetists
- Nurses
- European League Against Rheumatism (EULAR)
- European Cardiology Society (ECS)
- European Society for Medical Oncology (ESMO)
- European Pathologist Society (ESP)
- European Society of Radiology (ESR)
- European Society of Human Genetics (ESHG)
- Standing Committee of European Doctors (CPME)
- European Federation of Nurses Association (EFN)
- International Federation for Clinical Chemistry (IFCC)

Healthcare professional are involved directly in the collection of samples, and can therefore substantially impact the life of biobanks. At the same time, they have little interest in the work of biobanks, unless related to own research projects. Particular attention should be payed to pathologist, working within the hospital: their interest in samples can sometimes conflict with those of the biobanks.

National learned societies can be very interested in biobanks, and have a high impact in promoting biobanks at the local level.

At the EU level, learned societies are important partners of BBMRI-ERIC and can contribute to influence the EU research and funding agendas. This is particularly true for disease specific learned societies. BBMRI-ERIC can collaborate with learned societies on scientific publications (several learned societies control high impact journals) and shared research interests (for example, it was reported that BBMRI-ERIC was approached by the European Society for Radiology and the European Society for Cardiology regarding IT and imaging research). Furthermore, learned societies can help to expand BBMRI-ERIC's pool of influential contacts, as high-level doctors/healthcare professionals often lead medical societies. Finally, learned societies might have shared interest towards international/EU policies and legislations, which makes them important lobbying partners.

### General practitioners

A discussion arose regarding the need to include general practitioners (GPs) in the stakeholders list. Getting GPs to engage with biobanks might be complicated, depending on the bureaucratic organisation of healthcare services at national level. GPs might also have an important education deficit in relation to biobanks. For these reasons, any meaningful engagement initiative with GPs must have a top-down approach, with BBMRI-ERIC and European GPs associations involved.

The same line of reasoning applies to all other healthcare professionals' societies: connection/alliances shall be built at the BBMRI-ERIC/EU level, and afterwards expanded at national/individual level.

In this context, it was underlined that any BBMRI-ERIC engagement activity at the national level shall first be agreed and negotiated with the National Node. National initiatives remain therefore individual competence of each National Node.



### Policy makers

**Definition:** those involved in the production and enforcement of regulations and policies affecting biobanking, from the local to the European/international level.

#### Examples

- Council of the European Union
- European Parliament
- European Commission
- Regional governments
- National ministries of research
- National ministries of health

#### European Commission

The participants recognised that BBMRI-ERIC's relationship with the European Commission is very healthy. However, there are important differences in the way BBMRI-ERIC should interact with the different European Commission's Directorate Generals (DGs), due to the different balance of power and interest across DGs.

#### *RTD*

RTD holds considerable power in relation to BBMRI-ERIC due to the funding they provide (via H2020), and for their stimulus to the ESFRI process. BBMRI-ERIC role within RTD is recognised: BBMRI-ERIC is hold up by the highest political level of RTD as the perfect examples of an ERIC.

#### *CONNECT*

DG CONNECT is eroding part of the political power of RTD, as it focuses heavily on issues related to data policies, industry and economic growth (big data, cloud computing, European Open Science Cloud, etc.).

#### *SANTE*

DG SANTE is interested in the work of BBMRI-ERIC, but there has been no funding opportunity for BBMRI-ERIC yet. The DG holds modest political power within the Commission.

#### *JUST*

Very relevant to the implementation of the GDPR.

#### *European Data Protection Supervisor (EDPS)*

The power of this body will increase with the implementation of the GDPR.

#### Biobanks governing bodies

The participants defined the bodies that rule the functioning of biobanks as all the national actors that, according to the national laws and regulations, manage the functioning of biobanks. They shall be included in the mapping as policy makers. Biobanks governing bodies vary from country to country, and the participants agreed BBMRI-ERIC should map and compare all the governing bodies across Europe, to provide a benchmark to National Node regarding their policy engagement at local level.

### Insurance companies

The group discussed the role of insurance companies. In several countries (NL, BE) insurance companies have an important role in the financing and set up of biobanks, and could be considered as policy makers. However, the participants agreed they should be primarily seen as funders.

### Regulatory bodies

**Definition:** governmental, European and/or international agencies responsible for the design and implementation of technical norms affecting the running of biobanks (ISO, CEN, EMA...).

#### **Examples**

- International Standards Organisation (ISO)
- European Committee for Standardisation (CEN)
- European Medicines Agency (EMA)

The participants agreed that ISO/CEN play a crucial role in the running of the biobanks and should be close partners in the engagement strategy of BBMRI-ERIC.

EMA has shown a small interest in biobanks and its role in the life of biobanks and BBMRI-ERIC is in general limited to the drug lifecycle.

### Industry

**Definition:** for profit companies involved in the life of the biobanks.

While discussing a definition for industry, the participants agreed that a more granular work on the industry stakeholders' mapping is necessary. A single company can in fact hold different roles at the same time. Therefore, the participants agreed that it would be useful to map industry stakeholders also in consideration of their function/role, and to further extend the industry mapping with a market analysis.

The following roles of industry stakeholders were identified:

- Industry as service provider to the biobanks;
- Industry as client of the biobanks (user of the samples);
- Industry as funder, via its financing of clinical trials (for example Members of the European Federation of Pharmaceutical Industries and Associations (EFPIA));
- Industry as spin off from academia, and/or connected to research projects (for example researchers holding shares of a company);
- Private-public partnerships, for example the Innovative Medicines Initiative (IMI)

BBMRI-ERIC engagement with individual companies was discussed. The idea is that large companies have multinational interests, hence requiring a European approach.

### Collections managed by pharmaceutical companies

The participants discussed the role of pharma companies' collections of samples, i.e.: those created by a company within a multinational clinical trial. It was underlined that those collections can be very vast and, due to the process by which they were created, they fall within a legal grey area. These collections are disrupting the relationship between biobanks and pharma industry:

- Companies can rely on their own samples for research, therefore undermining biobanks sustainability;
- Companies collections are often not hold up to the same standards of quality and data protection biobanks abide to, therefore creating uncertainty to patients/citizens who contributed to the collections.

#### Trade associations

European trade associations of pharmaceutical companies are important partners for BBMRI-ERIC. In particular EFPIA holds considerable power in the management of large PPPs like the IMI/IMI2 programmes.

#### Funders

**Definition:** public or private organisations providing financial resources to biobanks, National Nodes and BBMRI-ERIC.

Industry and other private source of funding (as opposed to public funds) shall be included.

#### Media

Definition: press, tv and radio, academic journals.

All participants agreed that the relationship with media should better nurtured, at both national/EU level. Several positive examples of successful media engagement exist across the Nodes and can be leveraged.

The participants agreed that the press is not generally interested in biobanking, until a breakthrough (positive or negative) happens. For this reason, the participants suggested to work on contingency plans/crisis management at the National Node level. BBMRI-ERIC can play a role in managing contacts with the press at the EU level and/or in managing media crisis.

#### Multistakeholder initiatives

**Definition:** national/international coalitions or consortia (more or less formal) working together for a specific policy or research objective.

#### Examples:

- EU level: European Alliance for Personalised Medicine (EAPM)
- National level: Health-RI (The Netherlands)



### Updated list of stakeholders' clusters

Local biobanks' stakeholders	National Node's stakeholders	BBMRI-ERIC's stakeholders
<b>Biobank universe</b>		
<input type="checkbox"/> Local biobanks <input type="checkbox"/> Biobanks professionals	<input type="checkbox"/> Other National Nodes <input type="checkbox"/> Biobanks professionals <input type="checkbox"/> BBMRI-ERIC shall map and compare those bodies <input type="checkbox"/> BBMRI-ERIC	<input type="checkbox"/> ESBB <input type="checkbox"/> ISBER
<b>Academia / no-profit research</b>		
<input type="checkbox"/> Individual researchers <input type="checkbox"/> Universities / research centres	<input type="checkbox"/> Universities / research centres <input type="checkbox"/> National scientific societies	<input type="checkbox"/> European/international scientific societies <input type="checkbox"/> Other research infrastructures
<b>Industry</b>		
<input type="checkbox"/> Spin offs from academia <input type="checkbox"/> Multinational pharmaceutical companies <input type="checkbox"/> MedTech-IVD companies <input type="checkbox"/> IT Service providers		European / international trade associations
<b>Funders</b>		
<input type="checkbox"/> National-regional public funders <input type="checkbox"/> Insurance companies (country specific)	<input type="checkbox"/> National-regional public funders <input type="checkbox"/> EU-international public funders <input type="checkbox"/> Insurance companies (country specific)	<input type="checkbox"/> EU-international public funders
<b>Policy makers</b>		
<input type="checkbox"/> Regional-local policy makers <input type="checkbox"/> Ethic committees	<input type="checkbox"/> National policy makers (e.g.: ministry) <input type="checkbox"/> Ethic committees (where there are national ones) <input type="checkbox"/> Biobanks governing bodies	<input type="checkbox"/> Regulatory bodies (ISO, CEN...) <input type="checkbox"/> European policy makers (MEPs, Commissioners...) <input type="checkbox"/> EU institutions-agencies (European Commission, EMA...) <input type="checkbox"/> Biobanks governing bodies (BBMRI-ERIC shall map and compare those bodies)
<b>Citizens - Patients</b>		
<input type="checkbox"/> Local patients' associations <input type="checkbox"/> Individuals, families	<input type="checkbox"/> National patients' associations <input type="checkbox"/> National consumers' and civil rights associations	<input type="checkbox"/> European patients' associations <input type="checkbox"/> European consumers' and civil rights associations
<b>Healthcare professionals (non-researchers)</b>		
<input type="checkbox"/> Hospital (incl. managers) <input type="checkbox"/> Individual HCPs (including GPs)	<input type="checkbox"/> National learned societies	<input type="checkbox"/> European learned societies, including <ul style="list-style-type: none"> <li>○ General Practitioners</li> <li>○ Genetic counsellors</li> <li>○ Pathologists</li> </ul> <input type="checkbox"/> Disease specific societies
<b>Media</b>		
<input type="checkbox"/> Local press, TV <input type="checkbox"/> Academic journals	<input type="checkbox"/> National press, TV <input type="checkbox"/> Academic journals	<input type="checkbox"/> National/European press/media outlets <input type="checkbox"/> Academic journals
<b>Multistakeholders initiatives</b>		
	<input type="checkbox"/> National (formal & informal) coalitions/consortia	<input type="checkbox"/> European coalitions/consortia <input type="checkbox"/> Umbrella associations



### Power-Interest grid

The power-interest grid is designed to guide the National Nodes/BBMRI-ERIC in prioritising engagement initiatives, and to identify the right engagement initiative for each stakeholder group.

Each stakeholder was evaluated for their power and interest in the work of the National Nodes and BBMRI-ERIC. As a result, the participants of the workshop produced 2 power-interest grids, one for the National Nodes, one for BBMRI-ERIC.

**Definition of “power”:** a powerful stakeholder is the one that:

- is necessary to [National Node/BBMRI-ERIC] needs and objectives, and/or;
- can disrupt the [National Node/BBMRI-ERIC] plans.

**Definition of “interest”:** an interested stakeholder is the one that:

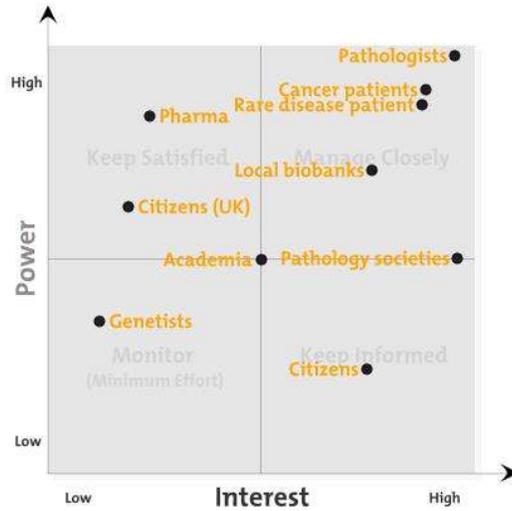
- Follows with attention the work of [National Node/BBMRI-ERIC] and/or;
- Is aware of how the work of [National Node/BBMRI-ERIC] can benefit/damage him/her.

Each stakeholder can fall within one of the 4 possible scenarios:

- High power, high interest = Manage closely:** these are the stakeholders [National Nodes/BBMRI-ERIC] must fully engage with and make the greatest efforts to satisfy.
- High power, less interest = Keep satisfied:** [National Nodes/BBMRI-ERIC] should put enough work with these stakeholders to keep them satisfied, but not so much that they become bored with our message.
- Low power, high interest = Keep informed:** [National Nodes/BBMRI-ERIC] should keep these stakeholders adequately informed, and talk to them to ensure that no major issues are arising.
- Low power, low interest = Monitor:** [National Nodes/BBMRI-ERIC] should monitor these stakeholders, but do not bore them with excessive communication.

### National Node’s power-interest grid

The participants agreed that, while useful, the power-interest grid exercise had serious limitations in depicting the situation in all National Nodes at the same time. Individual National Node’s grids should be compiled, following a common methodology and definition. The graph below shows the role of several key stakeholders on which the participants could reach a consensus. The participants recognised nonetheless the usefulness of the exercise to streamline the definitions of the different stakeholders.



Manage closely

- Individual pathologists
- Cancer patients' associations and rare disease patients' associations
- Pathology societies
- Academia / Researchers

Keep satisfied

- Pharmaceutical companies
- Citizens from the UK (see example of Care.data)
- 

Keep informed:

- Citizens, consumer groups, civil rights associations at national level

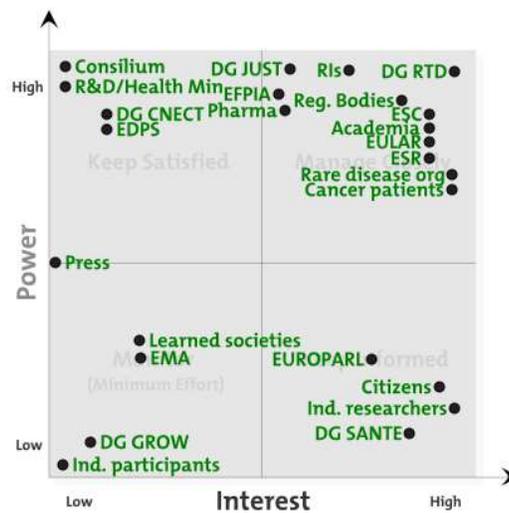
Monitor

- Genetists (both individuals and learned societies)



### BBMRI-ERIC's power-interest grid

The BBMRI-ERIC power-interest grid underlined the groups of stakeholders on which focus the engagement strategy. The majority of stakeholders operate at European/international level. The participants underlined in several occasions that they expect the BBMRI-ERIC engagement strategy to be focused on those stakeholders working at the EU level (EU institutions, European patients/consumers associations etc.) which cannot be otherwise monitored/engaged at the national level.



#### Manage closely

- DG Justice (DG JUST)
- European Federation of Pharmaceutical Industries and Associations (EFPIA)
- Multinational pharmaceutical companies
- Other Research Infrastructures (RIs)
- Regulatory bodies
- Academia
- Selected learned societies like:
  - European Society for Cardiology
  - European League Against Rheumatism (EULAR)
  - European Radiology Society (ERS)
- Cancer patients' associations and rare disease patients' associations

#### Keep satisfied

- Council of the European Union (Consilium)
- Research and health ministries (R&D/Health Min)
- DG Connect (DG CNECT)
- European Data Protection Supervisor (EDPS)
- Press



Keep informed:

- European Parliament (EUROPARL)
- Citizens, consumer groups, civil rights associations at national level
- Researchers
- DG SANTE

Monitor

- Most learned societies
- European Medicines Agency (EMA)
- DG Grow
- Individual participants to biobanks (patients/healthy participants)

## Best practices

Five National Nodes showcased their experience and best practices in stakeholders' engagement. The Nodes were selected on the basis of their replies to the prep survey.

### France

Michael Hisbergues reported that the French Node tried to reach the biobankers through an annual meeting. To attract researchers and clinicians, the French Node took part to business conventions and congresses, with booths and posters presentations. This proved particularly successful and increased researchers interests in using the Node's samples. Concerning engagement with citizens/patients, the French Node hired a communication officer, in charge of organising public events, lectures and other events to explain biobanking in laymen terms.

Other initiatives include:

- Open lectures on scientific trendy topics for citizen;
- Surveys;
- A dedicated internet site comprising targeted at the public, professional and press;
- Videos presentations on YouTube channel;
- Social media (Twitter, Facebook) and professional networks (LinkedIn).

### Italy

Sara Casati described the Italian Node's strategy for engagement: it is based on the assumption that engagement is a setting, not only a process. Such setting is founded on the principles of inclusion, reciprocity, transparency and traceability. The Node implements systematic actions to ensure inclusion and transparency: public calls for participation in national working groups, events etc. which allow stakeholders to participate and influence the work of the Node. The Node provides information to its stakeholders via periodic newsletters and social media, which are curated by a dedicated staff member.

The Node is also using a collaborative online platform, to better include stakeholders in the activities of the Node. For example, the national work plan is co-produced with stakeholders: a survey is submitted to the Node contacts, and is followed by workshops with ELSI experts, patients'

organisations, research ethical committees, who can actively contribute to the writing of the work plan.

Finally, the Node organises a national biobank day, an occasion for the Node's biobanks to organise public events, visits to the biobanks and other outreach activities targeting students and the general public. This is also an opportunity for the biobanks to connect with other research and cultural institutions (example: archaeological museums).

### Malta

Gillian Martin focused her presentation on the close collaboration that the Maltese Node has with the government and with patients' organisations, thanks to personal connections between the Node and key decision makers. The small size of Malta's research community facilitates interactions, which allowed for the creation of close collaboration with likeminded partners. A key example of this collaboration was the Node's key role in the organisation of two high-level events on research and rare diseases within the official calendar of the Maltese Presidency of the European Union.

The Maltese Node took also full advantage of the European Researchers' Night, organising high-impact activities in the capital.

### The Netherlands

Martin Boeckhout explained the Dutch Node strategy for engagement. It has three main components:

- Traditional lobbying;
- Creation of BBMRI.nl own public-based advisory council, comparable with a focus group;
- Stakeholder engagement centering on large multistakeholder initiative Health-RI, in which BBMRI-NL is one of the main partners.

Health-RI builds on the first generations of connected resources that were created by BBMRI-NL, ELIXIR-NL & EATRIS-NL, and is welcoming existing and novel initiatives in the personalized health & medicine domain to join our mission. Building on existing programs and infrastructure initiatives Health-RI already offers many services in the context of the founding initiatives. Health-RI will bring a much higher level of synergy in the fragmented landscape of research programs and infrastructure initiatives by offering the next-generation linked-data & workflow infrastructure tuned for high-end data and information sharing, as well as analytics across distributed data resources, all within one single platform. See [www.health-ri.org](http://www.health-ri.org) for more information.

### United Kingdom

Jessica Sims was asked to report about Biobanking UK's customer relationship management software (CRM) and how it has been used in the context of stakeholder engagement. CRM is an approach to managing an organisation's interaction with current and potential customers/stakeholders. It allows to analyse the relationship of customers/stakeholders and their history of interactions with the organisation. It is mostly used in sales departments. Biobank UK uses it to track the interactions the staff has with all Biobank UK's stakeholders. The software is very useful in managing the contacts of Biobank UK, and in providing insight on all the key stakeholders. The tool Biobank UK chose (Contactually) is quite expensive, and the process to select it and set it up took approximately 3 months. The Finnish and French Node reported their efforts to build similar CRMs: time to set up



such systems is a particular concern. Several Nodes showed their interest in acquiring a similar platform.

### General comments on best practices sharing

The participants agreed that BBMRI-ERIC can play an important role in facilitating the sharing of information on stakeholder engagement across all Nodes. The results of the survey, paired with the discussion at the workshop, show an extreme interest by the participants to create a permanent forum for discussion on stakeholder engagement, to:

- Provide the Node with guidance and information useful for their national stakeholder engagement initiatives;
- Support BBMRI-ERIC stakeholder strategy.

### Next steps

#### Support to National Nodes

- National Nodes demonstrated high expertise and understanding of the needs of stakeholders;
- The vast majority of Nodes reported lack of resources (including: budget, dedicated staff etc.) as the primary obstacle to the development of engagement strategies (see Annex 2 SWOT analysis). Furthermore, all the Nodes reported that more guidance and training is needed to carefully plan stakeholder engagement strategies (Annex 2);
- BBMRI-ERIC should provide the workshop participants with a **permanent platform** to:
  - o Share best practices;
  - o Identify synergies and collaboration among National Nodes and BBMRI-ERIC;
  - o Keep working together on stakeholder engagement issues.

#### BBMRI-ERIC stakeholder engagement strategy

The report shall be used by BBMRI-ERIC as a baseline for the production of its own engagement strategy, in particular:

- Produce a transnational stakeholder engagement strategy**, fulfilling the following criteria:
  - o The strategy shall build on the successes and experience of the Nodes, and work in synergy with the Nodes engagement activities;
    - National initiatives remain competence of each National Node. If the Node believes that BBMRI-ERIC involvement in national engagement activities would be fruitful, BBMRI-ERIC's role shall first be agreed and negotiated with the National Node;
  - o The BBMRI-ERIC engagement strategy shall focus on transnational issues and European/international stakeholders identified in the mapping exercise;
  - o BBMRI-ERIC stakeholder engagement strategy shall be supported by appropriate communication at EU level.
- Update the BBMRI-ERIC stakeholders' list.

### Conclusions and feedback

The participants shared the following comments on the workshop:

- Future meetings shall be advertised more in advance. The fact that the meeting was initially advertised in summer might not have helped to ensure participation from all Nodes;

- No similar workshops have been organised in the past. The participants appreciated the interactive nature of the workshop and the bottom-down approach to define the stakeholder strategy for BBMRI-ERIC. The participants suggested to use this model in other settings.

### List of annexes

**Annex 1: Survey**

**Annex 2: Replies to the survey**

**Annex 3: Results of the survey**

**Annex 4: Stakeholders list discussed during the workshop**

**Annex 5: PowerPoint presentation**

**Annex 6: Photos from the event**

**Annex 7: Provisional list of stakeholders**

