



**BBMRI**  
STAKEHOLDER'S  
FORUM

# **Building a Biobanking Research Infrastructure For Europe**

## **BBMRI Stakeholder's Forum**



Renaissance Hotel, Brussels  
16 September 2009







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BBMRI Stakeholder's Forum  
Information/Discussion Meeting

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## THE REPORT AND ITS AIM

This report covers the main discussion threads at and conclusions from the BBMRI Stakeholder's Forum in Brussels on 16 September 2009, which brought together researchers from academia and industry, patient organisations, research administrators and ethicists and lawyers from all over Europe. Since many of the points raised in the various sessions covered the same topics, this report is not a chronological, blow-by-blow account. Rather, it seeks to summarise the discussions that took place and the talking points that emerged. This report has been produced by the meeting rapporteur, Pete Wrobel. The report should be read in conjunction with the recommendations produced from a combination of the meeting evaluation forms and the dinner for speakers; these are reproduced in summary form in the Appendices.



## INTRODUCTION

One of the great strengths of Europe's medical research is that it has a large number of biobanks – organised repositories of human biological samples from both healthy and ill people. Without these, Europe's medical research would be severely disadvantaged.

Europe leads the world in biobanking, but there is much more to be done. Europe's biobanks, though numerous and containing a huge amount of samples, lack a network that would make those samples available to researchers across the continent (and beyond) who can make best use of them.

It was the realisation of what could be achieved through biobank networking that led the European Union to designate biobanking as one of its first European Research Infrastructure projects, and to dedicate €5 million to helping it get going. And so BBMRI, the Biobanking and Biomolecular Resources Research Infrastructure, was born.

The first aim of the BBMRI Stakeholders Forum was to build an international community – “a real forum” as Forum Chairman Michael Griffith put it when opening the meeting – out of the diverse stakeholder groups. But Griffith did not stop there: “We also want to increase awareness of the need for network biobanking activities in Europe and right across the world. And finally we want to develop support for key activities in biobanking,” he said.

More immediate Forum objectives were to provide an update of what BBMRI has achieved so far, then to provide a platform for stakeholders to raise concerns and questions, and finally, said Griffith, to encourage stakeholders to become actively involved, not only in the meeting but going forwards.

Apart from the many points and suggestions to emerge, there was one overarching conclusion: **the need to develop sectoral subgroups of the Stakeholder's Forum**. Many of the questions asked about the involvement of patients and industry were getting slightly different answers from different sectors, Griffith noted in his closing remarks, and BBMRI needs to understand what those answers are.

## BBMRI: THE POWER OF MANY

With more than 200 associated groups, BBMRI is the largest research infrastructure project in Europe.

While biobanking is one of Europe's truly recognised research strengths, said Eero Vuorio from the University of Turku, Finland, like everything else in Europe the whole system is fragmented. The repositories are all national and often too small for modern genetic analyses. "To obtain the power of many we have to be able to combine the resources we have," he said. "This is what BBMRI is all about."



Michael Griffith and Eero Vuorio

That work has already started, and Vuorio described the fruits of the preparation phase. With membership constantly increasing, governance issues are becoming increasingly important. Vuorio outlined a possible legal structure for BBMRI as a European Research Infrastructure Consortium (ERIC). If successful, it would make BBMRI the first to infrastructure to achieve the new legal status recently enabled by the European Council, as Jean-Emmanuel Faure from the European Commission explained. That would be "really exciting", said Christian Ohmann, Chair of the Network Committee of ECRIN, the European Clinical Research Infrastructure Network.

***"To obtain the power of many we have to be able to combine the resources we have"***

**- Eero Vuorio**

Vuorio described the proposed structure as a "multisided hub and spoke". This would have a central secretariat, with national members each with their own biobanks and resource centres, and associated partners in hospitals, universities and other service providers.

In all, BBMRI has a variety of Work Packages preparing different aspects including project management, population-based biobanks, disease-based biobanks, biomolecular resources and technologies, databases and biocomputing, ethical, legal and social issues (ELSI) and funding and financing.

A major focus of the preparatory phase, said Kurt Zatloukal from the Medical University of Graz, Austria, has been to assess what resources exist and what technologies are available. "We are not starting from scratch but using previous work as a building block," he said, such as the OECD's Best Practice Guidelines for Biological Resources. As an OECD process it guarantees that what BBMRI does in Europe will be compatible with similar initiatives elsewhere in the world.

In what Zatloukal described as "a very strong signal of commitment", BBMRI has just launched a prototype process in which the most advanced biobanks will try to implement basic aspects of the infrastructure on a voluntary basis.



Kurt Zatloukal

The general policies have already been affirmed. BBMRI will respect the primacy of national and European legislation. No data on individuals will be publicly accessible. There will be fair access for researchers, after ethical committee approval. OECD guidelines on informed consent, infrastructure and management will be implemented. BBMRI still needs to develop standard operating procedures for sample collection and processing – these, said Zatloukal, will be based the WHO IACR guidelines for cancer research.

“One size won’t fit all,” he said. “We are taking the ‘adaptor’ approach, building on national and existing approaches. We can’t combine everything, so we will combine what is suitable.”

Zatloukal introduced a subject that was to take up much of the discussion later on: cooperation with industry. “Particularly important will be collaboration on quality management,” he said, working to prove the concept that the new infrastructure will improve the way research is performed.

BBMRI, he said, is looking at the idea of “expert centres” that might facilitate industry’s access to data without giving the impression of commercialisation. These expert centres would not directly shift samples to industry, but would carry out bespoke analyses for industry (this would also reduce requirements for transporting samples).

**“From the industry perspective, BBMRI is not just laudable, it is essential, not only in the European context but globally as well.”**

- Detlef Niese

In order to further convince stakeholders and funders, BBMRI has asked economic experts to develop reports on its likely impact on healthcare and the wider economy. This will take into account the impact of coordination on national and regional biobanks, not just at the European level.

The discussion that followed showed that all stakeholders are united in their belief that the BBMRI initiative is sorely needed. “We have to share data,” said Hildrun Sundseth of the European Cancer Patient Coalition. “From the industry perspective,” said Detlef Niese from Novartis Pharma, “BBMRI is not just laudable, it is essential, not only in the European context but globally as well.”

There are, though, a number of critical issues to be solved before these expert centres can be created – not least funding, and the principles around informed consent from sample donors.

Funding in general remains a priority for BBMRI. As Georges Dagher from INSERM, France, explained, most funding for biobanks is short term. BBMRI wants to link fragmented funding sources into “a few sustainable dedicated streams”, he said. One idea is to ask national and regional biobanks to apply for European structural funds.



Detlef Niese



## ADVANCING BIOBANKING THROUGH COLLABORATION

The whole point of BBMRI is to leverage the power of many, and so it was no surprise that a session on collaboration formed a central part of the Stakeholder's Forum.

The session began with a presentation by Ulf Landegren from Uppsala University, Sweden, who described BBMRI's work in gathering the tools for analysing biobank samples and reported on two main achievements. First, it has created a Web portal for molecular tools, [www.molmeth.org](http://www.molmeth.org), designed as a dynamic database with modules that can be updated. Second, it is preparing a catalogue of protein binding agents, trying to raise binders against all human proteins. The catalogue is not yet available, he said.

In addition, as reported later in the meeting, BBMRI has taken several initiatives over harmonisation of data, including a minimum data set.

Another BBMRI Work Package is looking at database harmonisation and IT infrastructure. The challenge here, said Jan-Eric Litton of the Karolinska Institute, Sweden, is that data definitions change over time.

The underlying principles of the model have been set: confidentiality of donors, a user-centred approach, up-to-date technologies, flexibility, extensibility, efficient query processing – and last but not least “a very, very low effort to join”.



Ulf Landegren, Jan-Eric Litton

Litton's colleagues in BBMRI are also coping with the challenge of how to connect to existing medical ontologies, as well as how to integrate data on phenotype and genotype – all the while dealing with different national and regional languages, and the variety of ethical, legal and social issues.

The Work Package is looking at standardisation but, admitted Litton, “the situation is very complicated in Europe”. It will take a final look in the spring, though Litton doubted whether there would be a recommendation on standardisation. What is industry thinking? That is, perhaps, the wrong starting point. David Cox from Pfizer, San Francisco, put it very directly: “Industry doesn't speak with one voice, not even within a single company.” Instead, speaking as a scientist, he said there are “really interesting opportunities for public-private collaborations, and challenges too – but not insurmountable ones”.



David Cox

Although the public does not normally associate industry with open access and altruism, things are changing. Above all, said Cox, “the pharmaceutical industry needs to engage the broader scientific and healthcare community in a more collaborative fashion in order to achieve its goals.” Why? Historically, he said, there has been poor alignment of molecular understanding to clinical need. Industry starts with clinical outcome, he said. “But you can't start with the clinical outcome unless you have the samples and patients you need, and there isn't enough of this in companies.”

For Cox, there are several challenges. They include how to link biobank materials to multiple sources of healthcare information while protecting all stakeholders. "It's the biggest missing part right now," he said. "You can have the biggest collection but if it's not linked with epidemiological information it's not that useful scientifically."

And then there is the issue of reconciling altruism and open collaboration with intellectual property and profit. The solution, he said, is collaboration at the precompetitive stage: "Focus on that and work as a true scientific and intellectual partner."

Andrew Lyall, project manager of ELIXIR, Cambridge, UK, warned that Cox and his industrial colleagues "have work to do to persuade companies that this is the right way".

The way forward said Cox, is for scientists – in industry and academia – to lead by example: "Set up pre-competitive collaborations and show how it works," he said, rather than waiting for companies to set policies.

Finally, Cox warned academia against looking at industry merely as a source of cash: "Private sector contributions of knowledge and data are more important than money," he said.

One knowledge contribution that private industry could make might be in how to coordinate biobanks internationally, to judge from the

contribution of Julie Corfield from AstraZeneca R&D, UK. The company decided in 2000 that there was "significant value in globalising our biobanking activities", she said. The challenges AstraZeneca faced in international collaboration, and in seeking to adopt standard categorisations, are not unlike those faced by BBMRI.

Later, in the final panel session, Georges Dagher explained what concrete steps are being taken towards collaboration between academia and industry, including a closed workshop in Paris in October bringing together people from industry and BBMRI to discuss the outline of the new expert centres, as well as what services and facilities the consortium can provide. This will be followed by an open meeting on biobanks on 16 December, also in Paris, a big part of which will focus

on expert centres. Dagher also invited industry to contribute to the White Paper that BBMRI is contributing to the European Parliament.

***“Industry doesn't speak with one voice, not even within a single company.”***

-David Cox





## PROVIDING AN ETHICAL AND LEGAL PLATFORM

### PATIENTS

The point of departure for any discussion about ethics has to be the patient, and Fabrizia Bignami from Eurordis, the European Organisation for Rare Diseases, who spelled out what patients expect: “That BBMRI will be the place where international harmonisation of biobanking practices is achieved. And we would like it to actively involve patients in the governance of any future biobank infrastructure.”



Alastair Kent, Erik Tambuyzer, Fabrizia Bignami, Neil Formstone

That infrastructure, she said, should be “the reference point for biobanking in Europe and beyond”, so that professionals and patients are easily attracted. Patients, she said, can help in awareness campaigns, but they are “ready for more direct involvement”. This should be systematic, “not just two or three people in a Stakeholder Forum”, she said.

Her view was echoed by Neil Formstone, a patient representative from the Wales Cancer Bank, where patients were involved in the biobank’s governance right from the start. “You have to accept that we have to be in at the very beginning of the process. No *faits accomplis*.” he said, “Patients don’t expect you to do everything they ask, but they do want their opinions to be listened to and taken into account when taking a decision” he added.

“What I would say to the researchers is that we are willing to help,” said Rod Mitchell from the European Federation of Crohn’s & Ulcerative Colitis Associations. “We don’t have a lot of money but we are passionate about what we are involved in.”

### ACCESS

Once a biobank is established, how does it decide who should get the samples? That was the question addressed by Martin Yuille from the University of Manchester, UK, and an associate coordinator of BBMRI (though speaking in a personal capacity). Yuille put forward the concept of a “fair access policy” to ensure that annotated human samples are treated not as commodities but as what he called a “shared national resource”.

Access, said Yuille, needs to be driven by science. “You can’t treat all stakeholders as having equal rights. You are doing all this for the benefit of science; if two parties argue [over access to samples], you have to work out which is the best research.”



Martin Yuille

Fortunately, no one needs to re-invent the wheel over fair access. UNESCO has already done it. “Fair” means “fair to everyone”: to the donor, the collector, the researcher, the biobank, and to various legal entities. For the donor, said Yuille, it means “first of all privacy and confidentiality”. And all deposits and withdrawals must be backed with evidence of research ethics committee approval.

**“Fair” means “fair to everyone”: to the donor, the collector, the researcher, the biobank, and to various legal entities.**

- Martin Yuille

**HARMONISATION**

The complexities – and the importance – of the ethical, legal and social issues (ELSI) are such that BBMRI has a Work Package dedicated to them. BBMRI has as an explicit remit to develop an infrastructure properly embedded into European ELSI frameworks. And that, as pointed out by Jasper Bovenberg from the Legal Pathways Institute for Health and Bio-Law in the Netherlands, raises the question of what “European” is in the ethical context.



**Lea Harty, Silvia Matile-Steiner**

However, if harmonisation is easier than standardisation when it comes to databases, it still seems to be a step too far in ethics. “How can we talk about ethical harmonisation in Europe when we have just faced the stem cell dispute?” asked Erik Tambuyzer from Genzyme, Belgium. “It would probably be more adequate to speak about an equivalent high level of standards overall,” added Silvia Matile-Steiner from F. Hoffman-La Roche, Switzerland.



**ETHICS**

Given such a wide possible field, where does BBMRI focus? On consent, access and feedback, privacy and harmonisation, said Bovenberg. It amounts, he said, to an ongoing process “driven by the interplay of many different voices”.

One way of easing ethical issues could be to develop best practices on access to biobanks so that researchers might have a smoother passage when seeking ethical committee approval, suggested Karl Freese from DG Sanco, European Commission. The problem, of course is that ethics committees have not agreed on common standards and practices, and do not look likely to any time soon. That, said Zatloukal, is why BBMRI is considering setting up one ethics committee within ERIC to deal with all projects going through it.

But ethics is not all about hurdles. Alastair Kent from the Genetic Interest Group, UK, took a positive view. “When you look at public participation in research, it is important to give people the information to enable them to make a decision to be involved... Too often ethics are seen as a way of stopping scientists doing things.” His plea: “Start using ethics as a tool to make progress.”

A key issue is public opinion. In order to assess it, BBMRI has held focus groups in Austria and the Netherlands, as well as working with the Eurobarometer survey. The key findings are that there appears to be a broad lack of knowledge and understanding of biobanks, and that people become more positive once they know more.



## THE LAW

When it comes to law, the current situation in the European Union is a patchwork, said Bovenberg. “But top-down EU harmonisation is problematic and time consuming. The alternative is to build on existing expertise.” BBMRI is doing this by developing a legal platform using Wiki technology to unearth what evidence is out there. “Wiki provides BBMRI with a practical tool to upload documents,” he said – directing people to the Wiki platform at [www.legalpathways.eu](http://www.legalpathways.eu).



Neil Formstone, Jasper Bovenberg

One issue that should not present legal hurdles is the movement of data and samples. “BBMRI is a European Community resource,” said Bovenberg. “That opens the way to a certain approach to tackling the legal patchwork problem. We can try to harmonise and it will take years, but if you have established home state compliance you can shift your data across Europe. As long as there are common minimum standards met there is a free flow of data and samples.”

**“BBMRI is a European Community resource.”**

- Jasper Bovenberg



## TALKING POINTS

### 1: STANDARDISATION VERSUS HARMONISATION

At the heart of any database is the definition of the data being held – and with biobanks having grown up over a period of up to 50 years, dealing with different diseases and different populations, definitions vary. What, then, is the potential for BBMRI to standardise definitions across Europe?

Take care, was the response from stakeholders from industry and academia. Detlef Niese warned against clear categorisations: “They all assume that our disease taxonomy is accurate,” he said. “Pathology is descriptive at the moment, we need to move to the molecular basis.” Martin Yuille warned that standardisation is a very long process.

Definitely harmonisation not standardisation, said David Cox. “You can’t put everything together but you can get a lot out,” he said, adding, “If you want an international group you won’t get everyone to agree to one standard.”

“You have to harmonise rather than standardise, with the goal of interoperability,” said Barend Mons, a biologist-turned-bioinformatician involved in the Concept Web Alliance, a global network building bottom-up standards across languages, across jargon.

Silvia Matile-Steiner agreed. Her company, F. Hoffman La Roche, has biobanks around the world, in both pharmaceuticals and diagnostics. “We have been working on harmonising them, and have come across all the issues that have been mentioned during the day. We found that it is impossible to make a policy that is absolutely identical all over the world, because users have to comply with local regulations.” Her solution: the standards should be equal everywhere as far as possible, and there, a policy can give the basics, but we must be aware that local legislation can add additional or different requirements. Above all, more consistency is needed in the processes of informed consent and ethics committee approval.

## 2: EXPERT CENTRES

One of the biggest challenges facing BBMRI is how to give industry access to samples and data. Without this, there is little likelihood of the network leading to new treatments for patients. Yet if surveys are to be believed, the public is wary of giving samples that will be used by industry. “People are relatively willing to give samples to biobanks,” said Eero Vuorio. “But when you talk about giving samples to industry the percentage drops dramatically.”

But as Vuorio pointed out, academia doesn't develop drugs: industry does. So how to deal with this Catch 22? One solution proposed by BBMRI is expert centres under BBMRI control to which samples would be shipped and then analysed on behalf of companies. Industrial stakeholders were clearly intrigued with the idea, and could see benefits.

The idea also looks somewhat like the rare disease centres of reference, said Karl Freese from the European Commission, adding that these are also important as they are a legal environment linked to patient rights in cross-border healthcare. “You might find it useful to link up with the rare disease community,” he said.

Lea Harty of Pfizer, Connecticut, saw expert centres as a mechanism for making the most use of a precious resource. What, though, would be the business model? And were there any more details of the operating model? Also from Pfizer, David Cox

**“We should look at these expert centres not as ways of hiding the relationship, but do it in the bright sunlight and develop absolutely transparent relationships.”**

-Detlef Niese

was unsure of the concept as described. “With expert centres, I wouldn't see people doing it for industry but industry being a partner.”

In fact, BBMRI is still at the early stages of developing the concept, and now wants to sit down with industry and discuss how it might work while guaranteeing value for industry. “What we can foresee is that we have to ensure confidentiality for industry and that industry can exploit the intellectual property for product development,” said Kurt Zatloukal. What matters, he said, is that the results of the analysis are returned to the public.

Emmanuel Chantelot from European Biopharmaceutical Enterprises, Belgium, was looking for some clarification. BBMRI, he said, was trying to do two things here: on the one hand pulling together biobanks

across Europe to share benefits; and on the other hand to provide a service offering to SMEs and large pharma. “At this stage it is not yet crystal clear how BBMRI as an entity can deliver on both, different, goals,” he said.

## 3: PUBLIC ATTITUDES TO INDUSTRY

There is a general view, backed up by some opinion research, that the public is wary about biobanks working with industry. “As a Brussels dinosaur I have sat through long debates about human material. If the general public gets a notion that it is for profit, you have lost everything,” said Hildrun Sundseth from the European Cancer Patient Coalition.

“I don't think it is wise to stop here and just accept that we have difficulties in communicating and understanding,” said Detlef Niese. “It's a two-way street. There are examples where companies have placed some of their material in the public domain, such as breast cancer. We should look at these expert centres [see Talking Point 2] not as ways of hiding the relationship, but do it in the bright sunlight and develop absolutely transparent relationships.” The way around the problem, said Martin Yuille, is



collaboration. What matters then is the terms of collaboration between scientists, whether they are in a company or not.

Among patients the word “biobank” often raises more worries than concerns, said patient representative Valentina Bottarelli from Eurordis. She too made a plea for clarity and transparency about the aims and objectives of biobanks. Patients want results from what happens with their research, she said.

It is not clear, however, to what extent industry's use of samples actually deters potential donors. Neil Formstone, a patient representative from the Wales Cancer Bank, UK, declared that pharmaceutical company involvement is simply not a problem. “It has never been an issue with any person [donating],” he said. But, he added, “When you see pharma companies making billions of pounds of profits, you've got to communicate the whole process to the public.” His approach was one of frankness: “We are honest. We say that if your sample goes to a pharma company and they manage to create a therapy that it will not be in time to help you.” Use patients to get these arguments across, he said.

#### 4: GETTING BACK TO THE PATIENT

To what extent can or should biobanks get back to donors if it appears that the samples they have given indicate that they are at risk of a particular disease?

It's a difficult subject, with no clear ethical or legal guidance. Nor is it even clear what should be fed back to patients. Most of the time we don't know what the information we get from sequencing people's genes means, said David Cox: “You need trials to know whether this variant results in this outcome, and more importantly whether you can do anything about it.”

As Jasper Bovenberg explained, the law differs in every jurisdiction. But he said that at international level there is a growing tendency to stipulate that researchers have an obligation in general to feed back results to patients. That obligation can be

quite specific. “In the Netherlands, you could make a case that if the information relates to a treatable condition that there is an obligation on the researcher to contact the patient,” he said.

There is a big grey area where there is information that could be of interest to the participant. And, said Bovenberg, it could be very costly to go back to thousands of patients every time you have a finding. But, he said, there should be an obligation to at least have a policy on when to feed back and how. Indeed, a survey in Italy indicated that all the people who could understand the information they were given said yes to being contactable in the future regarding use of their samples.



Patients, it appears, do want to know. Stephen MacMahon from the Irish Patients Association, said that he was still not convinced as a patient advocate that patients cannot be informed if something should be identified. Neil Formstone said that if possible, yes, new information should be fed back to patients – but it cannot be promised. “You've got to be real with people,” he said.



Barend Mons, George Dagher

**5: CONSENT - TO WHAT?**

Informed consent continues to attract much discussion, especially from the patient perspective. Biobanks draw a distinction between blanket consent (covering anything) and broad consent (covering most uses), and the OECD guidelines go for broad consent. The Eurobarometer survey found that although the issue of anonymity is considered more important than consent, there is opposition to broad consent forms.

But as Alastair Kent pointed out, public attitudes are inconsistent: "They think it commonsense that biobanks should share and network, but they don't like giving broad consent." And in practice, said Neil Formstone, there is no problem: the experience at the Wales Cancer Bank is that 98.7% of patients agree to consent when approached before surgery, and 99.5% after surgery.

The answer, perhaps, is to involve patients and healthy people much more in the process of research. Martin Yuille outlined a project in Manchester, UK, that aims to change the way in which consent is obtained from citizens in relation to research. Citizens will be asked to opt in to participating in medical research in a general way. This separates consent to research from consent to treatment. The result, he said, will be that citizens become advocates of and participants in research. "New types of research would be enabled because

you would be in touch with people you could contact for further information."

Certainly, there was no support at the Forum for the idea of "automatic sampling", that is, a legal framework where the presumption is that patients consent to their samples being used for biobanking unless they explicitly say otherwise. Avril Daly, speaking for Retina Europe, also pointed to the responsibilities of professionals to protect patients with serious problems who may give samples without thinking.

Hildrun Sundseth called for a "very comprehensive policy", adding that since information can affect the whole family, consent "is not only the patient's decision".

Clarifying consent procedures may make things easier going forwards, but that still leaves the question of how to deal with all the samples collected under earlier consent regimes. As Lea Harty explained, "We have been doing biobanking for just ten years, but even in that time we have seen large changes in the ethical landscape and the kinds of research being done - so many of the older consents may be limited."

A final issue was raised by Martin Yuille: the ability to withdraw consent once given. "We haven't been able to implement this yet," he said, "but we feel it is very important."

*“More or less no one in Europe knows what a biobank is.”*

-Herbert Gottweis



Herbert Gottweis



Eibhlin Mulroe, Avril Daly

## 6: THE NEED FOR INTERACTION WITH THE PUBLIC

“More or less no one in Europe knows what a biobank is.” That, said Herbert Gottweis, University of Vienna, is one result of the research BBMRI has carried out into public attitudes to biobanking. “There is a huge communications job to be done,” said Eibhlin Mulroe from IPPOSI, Ireland.



**Derick Mitchell**

As Gottweis pointed out, most people in Europe are not patients and don't see themselves as patients. “But they are there, and they are voters, and they can very easily get upset about things,” he said. Part of the challenge, as noted elsewhere in the Forum, is that Europe is so diverse.

“There are substantial inconsistencies when it comes to public opinion,” Gottweis said. But one point is crucial: given that all the groups surveyed said that they did not know about biobanks, they develop their ideas on the individual questions as they might do in a discussion. “So public opinion is never consistent. Typically its very contradictory,” he said.

One strategy being pursued by BBMRI is to create a Web 2.0 structure that will enable not just communication but also interaction with European publics.

Closing the meeting, Forum Executive Manager Derick Mitchell pledged BBMRI's commitment to firmly establish the role of stakeholders as part of an implemented BBMRI network. “In order to build a trusted relationship with stakeholders, we need to put them at the heart of the decision making process, and this meeting has signaled the beginning of that relationship”.

## MAIN RECOMMENDATIONS

The following recommendations were produced from a combination of Appendix II and III.

### 1. BBMRI Stakeholder's Forum should develop the following working subgroups

- a. Patient Group Stakeholders – “The Patient Role”
- b. Industry Stakeholders – “Pre-Competitive Research”
- c. Biobanking Community – “Data Harmonization”

### 2. BBMRI Stakeholder's Forum should be incorporated into a transparent communication strategy towards the lay public and patients for addressing public perception and societal benefits.

### 3. Any Public-Private cooperation between BBMRI and industry needs to be fully defined to protect public interest and needs.

### 4. BBMRI should establish an ethical review committee

### 5. The definition and advisory role of “stakeholders”, within BBMRI governance, needs to be clarified.

### 6. BBMRI should develop closer links with the following groups

- a. EU e-health
- b. The publishing community
- c. The Innovative Medicines Initiative (IMI)

## APPENDIX I: MEETING AGENDA

## SESSION 1: BBMRI – THE POWER OF MANY

**9:00am** This session focused on BBMRI preparatory phase goals and achievements and elaborated on the sustained funding and financing solutions for this key resource. Future interactions with clinical, industry, academic, patient and user stakeholders were also highlighted.

Session Chair: **Christian Ohmann**  
*European Clinical Research Infrastructure Network (ECRIN)*

Panel Chair: **Emmanuel Chantelot**  
*European Biopharmaceutical Enterprises (EBE)*

PRESENTER	TITLE OF TALK
<b>Jean-Emmanuel Faure</b> <i>DG-Research, European Commission</i>	“The European Union actions for Research Infrastructures”
<b>Eero Vuorio</b> <i>University of Turku, Finland</i>	“BBMRI: Preparation Phase and European Context”
<b>Kurt Zatloukal</b> <i>Medical University of Graz, Austria</i>	“BBMRI: Towards Implementation”
<b>Georges Dagher</b> <i>INSERM, France</i>	“Funding and Financing”
<b>Markus Perola</b> <i>National Public Health Inst., Helsinki, Finland</i>	“Population-Based Biobanks in a Global Context”
<b>Thomas Meitinger</b> <i>HelmholtzZentrum, München, Germany</i>	“Overview on Participation of Disease-Related Biobanks”

**10:35am** **PANEL AND OPEN FORUM DISCUSSION**  
**Panelists:** Chairs and Speakers from Session 1 and  
**Detlef Niese, Novartis**  
**Hildrun Sundseth, European Cancer Patient Coalition**

## SESSION 2: ADVANCING BIOBANKING THROUGH COLLABORATION

**11:30am** The construction of the BBMRI network will facilitate technological platforms in areas such as biological resources, high-throughput techniques, bioinformatics and other advanced analytical tools for data analysis. Such platforms will also foster collaboration between academic, clinical, patient and industry stakeholders leading to the development of new diagnostic, prognostic, and therapeutic tools for human diseases and their variants

Session Chair: **Jean-Jacques Cassiman**  
*European Society of Human Genetics (ESHG)*

Panel Chair: **Frank Wells**  
*European Forum for Good Clinical Practice (EFGCP)*



PRESENTER	TITLE OF TALK
<b>Ulf Landegren</b> <i>Uppsala University, Sweden</i>	"Gathering the tools for analysing biobank samples"
<b>Jan-Eric Litton</b> <i>Karolinska Institute, Stockholm, Sweden</i>	"Database harmonisation and IT infrastructure"
<b>David Cox</b> <i>Pfizer, Biotherapeutics and Bioinnovation Center, San Francisco, CA</i>	"International Biobanking: Opportunities and challenges for private-public collaboration"
<b>Julie Corfield</b> <i>Astrazeneca R&amp;D, Charnwood, UK</i>	"Collaboration in Biobanking: sustaining R&D activities of the Pharmaceutical Industry"

**12:30pm****PANEL AND OPEN FORUM DISCUSSION****Panelists:** Chairs and Speakers from Session 2 and**Barend Mons**, *The Netherlands Bioinformatics Centre (NBIC)***Valentina Bottarelli**, *EURORDIS***Stephane Berghmans**, *European Science Forum***SESSION 3: PROVIDING AN ETHICAL AND LEGAL PLATFORM****2:00pm**

BBMRI aims to provide a platform for ethical, legal and societal guidance on biobanking in general. This session included an evaluation of the European ethical and legal frameworks and will endeavour to identify solutions on how to implement a pan-European infrastructure. Representatives from all stakeholder groups discussed the possible impacts of the BBMRI initiative on each group.

Session Chair: **Alastair Kent***Genetic Interest Group, European Genetic Alliances Network (EGAN)*Panel Chair: **Erik Tambuyzer***Genzyme Corp.*

PRESENTER	TITLE OF TALK
<b>Fabrizia Bignami</b> <i>EURORDIS and The EuroBioBank Network</i>	"Biobanks: Patients' Role and Expectations"
<b>Martin Yuille</b> <i>University of Manchester United Kingdom</i>	"Fair access: a practical approach to policy on access for European biobanking"
<b>Neil Formstone</b> <i>Patient Representative, Wales Cancer Bank</i>	"Biobanks: Patients' Inputs and Outcomes"

<p><b>Jasper Bovenberg</b>  <i>Legal Pathways Institute  for Health and Bio-Law,  The Netherlands</i></p>	<p>“BBMRI:  Ethical, Legal and Societal Issues”</p>
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**3:20pm**      **PANEL AND OPEN FORUM DISCUSSION**  
**Panelists:** Chairs and Speakers from Session 3 and  
**Lea Harty**, *Pfizer Global R&D, CT, USA*  
**Silvia Matile-Steiner**, *Hoffman La Roche*

**SESSION 4: STAKEHOLDER'S OPEN FORUM PANEL**

**4:00pm**      The BBMRI Stakeholder's Open Forum Panel has been assembled from a combination of meeting speakers and stakeholder representatives. As part of a comprehensive process of dialogue and exchange of ideas, this panel engaged in a 60-minute open forum to allow for interactive communication and engagement with relevant stakeholders.

Session Chair: **Michael Griffith**  
*Chair of BBMRI Stakeholder's Forum*

Panel Chair: **Eero Vuorio**  
*University of Turku, Finland*

**4-5pm**      **PANEL AND OPEN FORUM DISCUSSION**  
**Forum Panelists:**  
**Tobias Schulte in den Baumen**  
*Public Health Genomics European Network (PHGEN)*  
**Jean-Emmanuel Faure**  
*DG-Research, European Commission*  
**Kurt Zatloukal**  
*Medical University of Graz, Austria*  
**Jeanette Ridder-Numan**  
*Ministry of Education, Culture and Science, The Netherlands*  
**Rod Mitchell**  
*European Federation of Crohn's & Ulcerative Colitis Associations (EFCCA)*  
**Herbert Gottweis**  
*University of Vienna*  
**Lea Harty**  
*Pfizer Global R&D, CT, USA*  
**Neil Formstone**  
*Patient Representative*  
**Erik Tambuyzer**  
*Genzyme Corp.*

**5:00pm**      **CLOSING REMARKS**  
**Derick Mitchell**  
*Executive Manager, BBMRI Stakeholder's Forum*

## APPENDIX II: MEETING EVALUATION FORM SUMMARY

The following answers are in order of abundance of responses received.

### Q1: What was the best thing about this Stakeholder's meeting?

1. Networking with wide variety of stakeholder groups and experts together in an open environment – very rarely available otherwise.
2. Excellent Stakeholder Representation.
3. Update on BBMRI progress and current status.
4. Hearing different perspectives and learning about how BBMRI is addressing its key challenges.
5. The quality of information, exchange of knowledge, debate and discussions from panels.

### Q2: What do you think are the main benefits of BBMRI?

1. Harmonization and coordination of European Biorepositories and Biobanks with emphasis on data harmonization.
2. To overcome fragmentation and become a one-stop-shop for Biobanks.
3. To turn sample collections into effective biobanks who share resources
4. A common European approach to making samples + data available all over Europe in order to foster innovative medical research.
5. Collaboration across member states, particularly in area of Rare Diseases.

### Q3: What are your main concerns about BBMRI?

1. Public-Private Cooperation.
2. Academic research is over-represented. Industry has had no involvement thus far, and there is not enough patient involvement.
3. A real risk of lack of focus when bringing multiple threads of discussion together – in need of an ethical issues overview watching brief.
4. Lack of transparency, no clear communication strategy for lay public and patients in particular for addressing public perception, societal benefits. Need to partner with the general public, not just patients.

5. Preparing and implementing standard procedures aimed at harmonization.

### Q4: Have you any advice for how we can improve our forum?

1. Make more subgroups with industry, patients, etc. - like in P3G.
2. PP cooperation needs to be fully defined to protect public interest/needs/welfare.
3. Need a communication strategy built into the BBMRI to communicate progress to public more clearly.
4. Need more dissemination of BBMRI activities taken through local and national medical doctor associations, university medical schools, research institutes.
5. Cooperation with industry will only be improved project by project – should start joint projects in PPP.

### Q5: Are there any issues which you require further clarification on?

1. Academic-Industry cooperation
2. How will the prototype be developed?
3. How can donors directly benefit?
4. Patient Involvement.
5. How will BBMRI handle the sample release processes which are part of each biobank when BBMRI approves a project application for samples from these biobanks



## APPENDIX III – SPEAKER'S DINNER MEETING SUMMARY

September 15th, 2009

### AGENDA

- Welcome**      **Michael Griffith**  
*Chair, BBMRI Stakeholder's Forum*
- Introduction**   **Robert-Jan Smits**  
*DG-Research, European Commission*
- BBMRI**          **Kurt Zatloukal**  
*Chair, BBMRI Coordination Unit*

### Dinner discussions

#### Summary of Dinner Discussions

1. The rapid implementation of BBMRI is seen as an important signal for the success of the ESFRI road map. To some extent BBMRI is seen as an icebreaker facilitating the implementation of other biological and medical sciences research infrastructures.
2. The model of expert centres was extensively discussed and was highly appreciated by all participants. Several research collaborations with the industry are positioned in a pre-competitive environment and would allow wonderful opportunities to share the research data generated with the public domain. This would create an important added value. Upcoming meetings of BBMRI and industry representatives should help specify the best models for public-private partnerships in the context of BBMRI. Also, the internal and external difficulties of data harmonisation were discussed in the context of pharmaceutical companies.
3. The importance of BBMRI developing closer links with EU e-health was discussed. This area of activity has to deal with standardization / harmonisation and confidentiality / security of health records across Member States.
4. The need for a coherent BBMRI funding and legal policy in which should be communicated to the general public and to policy makers was emphasized during discussions. The lack of proper communication between policy makers and scientists was seen as a major obstacle in this regard.
5. BBMRI's efforts in adopting the ERIC legal status are highly appreciated by the European Commission particularly because BBMRI could be one of the first infrastructures to demonstrate the benefits of this new legal entity. In order to achieve agreement on the statutory seat of ERIC it was recommended that the Research Minister of the hosting country officially expresses his interest.



Kurt Zatloukal, Robert-Jan Smits, Michael Griffith

## APPENDIX IV - HIGHLIGHTED PRESS COVERAGE

## EDITORIALS

NATURE|Vol 461|24 September 2009



<http://www.nature.com/nature/journal/v461/n7263/full/461448a.html>

## Biobanks need pharma

**Which is why Europe's citizens need reassurance that their donations will be in the public interest.**

Medical geneticist Thomas Meitinger remembers when biobanking was a simple craft. As a postdoc thirty years ago, he travelled from Oxford to Yugoslavia to track down a family afflicted with a rare disease causing blindness. The family listened enthusiastically as he explained his research over a fish dinner. He returned with blood samples and over the next decade used them to identify the single gene defect that caused the condition.

Biobanking — collecting tissue or body fluids alongside medical information — is now a large-scale affair. Genomics allows geneticists to track down not just the single genes that convey a strong risk of disease, but also the many low-risk genes associated with the diseases that kill most of us, such as cancer, diabetes and cardiovascular disease. But these very weak gene signals can be picked up only in studies of large populations of up to hundreds of thousands of people.

Europe leads the world in biobanking. It has more than 400 biobanks, some involving hundreds of thousands of diseased and healthy individuals. It is now seeking to make the most of that resource: the European Commission is funding a preparatory study aimed at linking the biobanks into one distributed infrastructure. Now Meitinger, who currently works at the Institute of Human Genetics in Neuherberg, Germany, and the rest of the scientific consortium driving the effort, called the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI), must find stable funding for the project and arrange access for the scientific community.

That's a lot of tough challenges at a time when the general public is sensitive to any issue involving genes and biological material. Key concerns in biobanking are those of anonymity and whether true informed consent can be given by individual donors now too numerous to be educated over dinner.

Another, potentially incendiary, issue is whether the pharmaceutical industry should have the same access rights to biobanks as academic researchers. Europe's citizens could easily turn against biobanking if they start to feel exploited for financial gain. The BBMRI must accommodate industry while avoiding such a backlash.

Biobank resources may be fundamental to understanding the molecular bases of common complex diseases, but it is the pharmaceutical industry that will develop the treatments for such ailments. Companies generate their own biobanks, but these cannot reach the scale necessary to move forward. Industry wants access to large public biobanks, and the BBMRI recognizes its obligation to facilitate new medicines. The consortium hopes that relentless outreach and appropriate control of banked materials will achieve this without antagonizing the public.

At the consortium's first stakeholder meeting last week, patient groups declared that they don't care who gets hold of their diseased tissue "so long as it is out of our bodies and being used to do clinical good". But the large majority of healthy donors will need more persuading that profit-making industry should get access to their voluntary tissue donations.

The concept of expert centres, unveiled by the BBMRI at the meeting, should help. These would do all the molecular analyses on material requested for an approved study and provide data only to clients. Donors' material would not move out of the biobanking infrastructure, and data would be stored for re-use in other studies, so industry could not gain exclusive rights.

Industry must also be prepared to give something back, in the form of access to its own biobanks and their richly financed expertise. Research departments across all companies believe that biobanks and the molecular information generated from them are outside the competitive realm, but their managers tend to be wedded to secrecy. So managers must be persuaded to follow their researchers' instincts, before the public gets the idea that industry is there only to exploit, gets deterred from donating, and the whole enterprise becomes tainted with distrust.



<http://www.euractiv.com/en/science/eu-biobank-benefit-vat-exemption/article-185516>

## EU 'biobank' first to benefit from VAT exemption

Published: Thursday 17 September 2009

A pan-European biobanking initiative looks set to become the first research consortium to benefit from VAT-free status under a new regulation agreed by EU leaders in May.

### Background

Collections of biological materials such as DNA, tissues, cells or blood can be stored in biobanks to help scientists conduct research into cures for diseases. Samples are usually anonymised or coded so that researchers cannot identify the individual whose tissue or blood they are working with. There are at least over 100 biobanks dotted across Europe, but the system for collecting and using the material varies significantly from country to country. In 2008, the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) was set up, with an initial budget of €5 million to improve coordination between biobanks.

The BBMRI is one of 44 initiatives funded by the European Strategic Forum on Research Infrastructures (ESFRI), supported by the EU's Seventh Framework Programme (FP7). Its preparatory phase was initially envisaged as lasting two years, although this may be extended. In May, the European Council adopted a regulation to treat this type of research infrastructure in the same manner as international organisations for taxation purposes. So-called European Research Infrastructure Consortia (ERIC) will benefit from a VAT exemption as well as reduced administrative costs. The group of biobanks would also be exempt from excise duty if it is established as an international agency under the European Research Infrastructure Consortium (ERIC) scheme, and could employ staff in several member states under a common contract. This would allow greater mobility for employees who could move between offices while retaining health and social security benefits. Biobanking experts, gathered in Brussels yesterday (16 September), said Europe is a world leader in the field but needs a more cohesive network of biobanks in order to attract pharmaceutical firms, some of which have moved to Asia in recent years. Kurt Zatloukal from the Medical University of Graz, Austria, who coordinates the Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) said the group aims to harmonise standards in the collection and usage of biomaterials. "Access to biological materials is essential to exploiting technology for the benefit of academia and the pharmaceutical industry. However, we need new resources and a more structured infrastructure to overcome current fragmentation and inefficiencies," he said.

### Need for common standards

Zatloukal noted there are currently no common standards for using DNA, tissue and blood samples, and that quality varies significantly across Europe. Applying a "one-size-fits-all" model will not work, he said, adding that Nordic countries have a tradition of collecting biomaterial, while others are suspicious of sharing personal data with the authorities. The European group is likely to implement new OECD guidelines on the collection of biomaterials, marking its intentions to lead on a global scale. To qualify for ERIC status, a pan-European agency must anchor itself in a single member state. Austria and the Netherlands have both expressed an interest in hosting the BBMRI, but the final decision will have to be worked out at ministerial level. Eero Vuorio, from the University of Turku in Finland, said elevating the biobank initiative to ERIC status will mean starting with a small group of the most advanced member states, with others joining later. The consortium already has registered over 50 participating biobanks as well as more than 200 associate members from the EU, Norway, Iceland, Switzerland, Turkey and Israel, but not all of these will be part of the ERIC. The move comes as the EU executive is beginning the groundwork for its next major research funding plan, the Eighth Framework Programme for Research (FP8), which will replace the current plan in 2013. A major boost in support for Europe's biobanks is expected as policymakers are keen to build up capacity in an area seen as a future growth area.

### Positions

**Michael Griffith**, chairman of the **BBMRI Stakeholders' Forum**, said the network is moving from the preparatory phase towards implementation and must now involve patients, industry, clinicians, funding agencies and end-users in the process. He said it is important to listen to their concerns and provide more information to the public.

**Eero Vuorio** from the **University of Turku** in Finland said the more that people understand about biobanking, the more they accept it.



**For more information on activities of the  
BBMRI Stakeholder's Forum:**

Contact [dmitchell@ipposi.ie](mailto:dmitchell@ipposi.ie) or visit [www.bbmri.eu](http://www.bbmri.eu)

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