



**BBMRI**  
STAKEHOLDER'S  
FORUM

# **BBMRI: A Step Closer** Stakeholder's Forum Report



Residence Palace, Brussels  
09 June 2010





# A Step Closer

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## CONTENTS

### 1. The report and its aim

### 2. Introduction

### 3. BBMRI: European and International Context

#### 4. Stakeholder Workshops

- Industry Stakeholders Workshop
- Patient Stakeholders Workshop
- Clinical and Scientific Stakeholders Workshop

#### 5. General Talking points

- Importance of Public Engagement for Biobanking
  - Improving and Funding Interoperability
    - Expert Centres
    - Ethical Review
  - Making Use of Dormant Resources
    - Intellectual Property

### Appendix I - Meeting Agenda

### Appendix II - Meeting Evaluation Form Summary

## THE REPORT AND ITS AIM

This report seeks to summarise the discussions that took place and the talking points that emerged during the BBMRI Stakeholders Forum meeting in Brussels on 9th June 2010, which brought together researchers from academia and industry, patient organisations, research administrators, ethicists and lawyers from all over Europe.

The report should be considered as a follow-up to the report produced from the BBMRI Stakeholders Forum meeting on September 15th, 2009. The report has been produced from a combination of the meeting rapporteurs' summaries and BBMRI Stakeholders Forum staff. Presentations from plenary sessions and workshops, as well as all previous reports are all available on the Stakeholders Forum section of the BBMRI website ([www.bbmri.eu](http://www.bbmri.eu)).



## INTRODUCTION

Allied to the rich history of healthcare in Europe, biobanking is seen internationally as a specific European strength. However, Europe is unable to maximise the potential of its biobanks because the community is heavily fragmented and needs to harmonize. The EU is now looking to create the first pan-European legal entity designed to help biobanks interoperate and collaborate to improve European research capabilities.

BBMRI (The Biobanking and Biomolecular Resources Research Infrastructure), as one of the first European Research Infrastructure projects funded by the European Commission, is coming to the end of its preparatory phase. The initiative is looking to soon afterward provide access for the scientific community to the millions of biosamples in collections and banks around Europe.

In opening the meeting, Chairman of the BBMRI Stakeholders Forum, Michael Griffith stated that the meeting had been specifically designed according to the recommendations from the September 2009 event. Griffith stated the forum objective to put the stakeholders at the centre of the planning and development of BBMRI through a transparent mechanism to ensure that the public interest is maintained. "It is essential that we are open to public scrutiny and to ensure that stakeholders are properly informed and can make informed decisions. Creation of an international community of BBMRI stakeholders, is the first part of that process", he said.





## BBMRI: EUROPEAN AND INTERNATIONAL CONTEXT

“The health-related global challenges (Aging Societies, Public Health, Pandemics and Security) can only be addressed by providing access to biological materials allied to information from healthcare”, said Kurt Zatloukal, coordinator of the BBMRI preparatory phase. BBMRI is designed as an instrument to help the scientific community go beyond the frontier of knowledge and capacity of what they can achieve alone. “BBMRI is seen at the European Commission level as a very visible example of a research infrastructure which can not only support research but can also have very wide impacts for society, health and for the development of an efficient and attractive Europe,” said Hervé Pero, of DG-Research, European Commission.



Hervé Pero

The need to construct not only a European, but a global network for biobanking activities was well recognised at the meeting. BBMRI is attempting to establish parallel contact with initiatives outside of Europe (for example in China, USA, Korea). “The OECD has produced guidelines on human biobanks and genetic research databases which have already achieved a basic operability on a global scale, provide very good principles for setting up infrastructure and also place emphasis on stakeholder involvement” said Zatloukal. “Very similar projects have emerged recently in parallel both in the EU and in the USA, and we can use these OECD principles to implement a global network”, he said.

**“BBMRI can not only support research but can also have very wide impacts for society, health and for the development of an efficient and attractive Europe”**

- Hervé Pero

## BBMRI-ERIC: KEY ROLE OF MEMBER STATES

Of the variety of legal options for the implementation of its preparatory phase, it is quite clear that BBMRI finds the ERIC (European Research Infrastructure Consortium) legal instrument as the most suitable for its distributed “multisided hub and spoke” structural model. The ERIC is an instrument specifically designed by the European Commission for the projects under its ESFRI roadmap, which allows consortia to operate in different Member States under one legislation and also offers VAT-free status. The vision of BBMRI-ERIC is to establish a central headquarters in a nominated member state with BBMRI ‘hubs’ in member states who officially commit to being members.

“It was nice to hear recently that BBMRI is one of the most advanced on the ESFRI roadmap, so we can be proud that we have made significant progress”, said Eero Vuorio, Executive Manager of BBMRI. BBMRI should be submitting its application for ERIC status in autumn 2010, with an expected start date of spring 2011. “The BBMRI-ERIC statutes are essentially ready, but it has not been an easy process, and some items remain unresolved, not least the determination of the sizes of the national contributions”, Vuorio added.

Although the decision-making process is still in progress, official commitments for the construction of BBMRI-ERIC have been received from six European Member States and BBMRI is on the national roadmap in a further eight countries. In addition, Austria has made an offer to be the official host of BBMRI-ERIC. “Further national funding commitments, albeit with strings attached, can also be used towards building the BBMRI-ERIC, and more and more countries are preparing national roadmaps in this regard” said Vuorio.

Hervé Pero welcomed the BBMRI-ERIC proposal and emphasized that in order to ensure sustainability, communication with politicians – both at the European and Member State levels - will be vital. “We need to ensure that our political decision makers

are aware of all the direct and indirect impacts and returns for stakeholders which will be generated if we build the BBMRI-ERIC” Pero said. “The final decisions for membership of BBMRI-ERIC are made politically in finance departments where unfortunately, scientists are relatively small players. These impacts have very strong socio-economic implications and need to be demonstrated to the finance minister in each Member State” he said.

**BBMRI: TOWARDS IMPLEMENTATION**



**Eero Vuorio**

Vuorio described how BBMRI has grown into a 53-member consortium with over 280 associated organisations from over 30 countries, making it the largest research infrastructure project in Europe. Some of the key achievements of the BBMRI preparatory phase are highlighted in table 1.1 below.

Vuorio highlighted the discussion on interoperability versus standardisation. “BBMRI is based on interoperability of existing biobanks” he said. “You

cannot standardise what is already existing, only what is to come” – touching on some of the issues which remain under discussion including ethical and legal issues, data and sample management processes, and pilot/demonstration projects.

BBMRI needs to operate not only within the ERIC legal framework but also at the local level as biobanking activities will always remain in the local environment. It is very clear that BBMRI will not produce data online which is related to individual donors – only data that has been aggregated and that summarizes ‘healthy’ populations or patient disease groups will be made available. Consent issues will look to implement the OECD guidelines. Best practices on handling biological materials, and standard operating procedures will consult the consensus documents produced by the WHO/IARC, ISBER and the NCI.

**“BBMRI is based on interoperability of existing biobanks”**  
 - Eero Vuorio

Access policy is currently under discussion in BBMRI. The European Commission has very specific requirements in the ERIC guidelines that access should be open and fair to all scientific communities. This is a particular challenge for biobank samples due to their own national jurisdictional ethical review and the informed consent requirements that cannot be overruled by any European Directive. “In addition, in order to provide fair access to researchers, BBMRI must agree on registration procedures, standard agreements, quality



**Hervé Pero, Eero Vuorio, Derick Mitchell, Michael Griffith, Anne Cambon-Thomsen**

assurances, integrated data sets and the provision for enrichment of annotations” said Martin Yuille of the University of Manchester. “We need to work out the specifics of how these can be done, based on our experience and based on the practices that evolve”, he said.



Kurt Zatloukal



**TABLE 1.1**

### **Key Achievements of BBMRI Preparatory Phase (2008-2010)**

In addition to the stated deliverables of the BBMRI preparatory phase, some additional achievements have been highlighted.

1. Inventory of the European Biobanking Environment – a comprehensive overview of over 260 biobanks, from both population and disease-based.
2. Demonstration of increased interoperability in prototypes, pilot projects and large EC-funded projects.
3. Strong emphasis on interaction with publics with active participation of patient organisations.
4. Socio-Economic Impact Studies.
5. Close interaction with other science fields and research infrastructures.
6. Increased coordination of national biobanking activities in several Member States.
7. Driving innovation on new IT solutions on how to provide anonymity, particularly by avoiding re-identification when complex data becomes integrated.
8. Creation of next generation analytical approaches for Metabolomics, Cryobiology, Infectious diseases – (e.g. linking of high security labs to healthcare for new pandemics, creating patient-specific stem cells, etc.)
9. Providing a way to structure National Biobanking Infrastructure and Networks (e.g. BBMRI.nl, BBMRI.se etc.)
10. Assisting in building research infrastructures in a single member states (e.g. Biocentre Finland)



## STAKEHOLDER WORKSHOPS

Parallel workshops were organised to identify the main areas of discussion within a particular stakeholder group. The following summary describes the cross-stakeholder discussions which took place in each workshop in order to identify common ground and consensus to move the proposed infrastructure forward.

### INDUSTRY STAKEHOLDERS WORKSHOP

This workshop involved senior leaders and experts from the industries with specific biobanking interests (e.g. biopharmaceutical, biotechnology, diagnostic, biostorage etc.). Presentations focused on the potential for public-private-partnership in biobanking within the pre-competitive research area.

In his summary of the workshop, rapporteur Alfredo Cesario from San Raffaele Hospital, Rome, highlighted the 'apparent' clash in the interests and motivations of industry and the public sector in biobanking. "This in fact, is not a clash at all, he said, as both sectors can actually obtain what they are really interested in, without having to compromise on their respective ideals and principles".

"There is now a great opportunity to create win-win situations in the area of public-private-partnerships with regard to biobanking", said Klaus Lindpaintner of Biobanks LLC (see also talking point e.). "The biopharmaceutical industry is currently establishing where it can push the sharing limit and there is general agreement that items can be shared such as 'drug target validation' and in cases where large international studies are required", he said.

***“The key is to identify what you are happy to share”***

- David Myles

There was general agreement among stakeholders that the Expert Centers that BBMRI wishes to establish (see talking point c.) would have the requisite expertise to share with industry and industry would have complimentary tools to share with these expert centers.

The current economic difficulties and pressures from within the biopharmaceutical industry have been well-documented. "Industry needs to consider different approaches to collecting annotated samples to enable the identification and validation of drug targets in a rigorous manner", said Julie Corfield of Astrazeneca. "There is also an ethical dilemma - you could say industry is duty bound to optimise and share those samples (if consent permits) with the people who may have the necessary skills to develop a platform of evidence that is appropriate for a target", she added.



Pre-competitive research is an area which is under much discussion within industry at the moment with many biopharmaceutical companies operating in small consortia at this level. "Astrazeneca are looking at fundamentally redefining our boundaries of what we mean by pre-competitive at the policy level to provide the framework for an operating model", Corfield said. Astrazeneca recently identified three areas which they "must do" in this pre-competitive area in order to transform projects by sharing without affecting their competitiveness; (a) target validation tools and approaches; (b) information sharing in regard to "failed" targets, and (c) working together in areas where the company lacks sufficient 'data power' to generate knowledge (e.g. patient registries). "Biobanks can make a huge contribution towards patient stratification and development of biomarkers, which is very much aligned with the momentum behind the personalized healthcare philosophy", Corfield said.

What is happening in the Innovative Medicines Initiative (IMI) is a good example of how industry has been prepared to come together and share. Ann Martin of IMI described how many of the currently-funded IMI projects have biobanking elements to them and David Myles of GlaxoSmithKline spoke about the UBOPRED IMI project, which is investigating the underlying causes of severe asthma. "The key is to identify what you are happy to share",



said Myles. For him, where the industry could really come together is in finding a better understanding of the different types of diseases they are attempting to fight. “Industry is facing a cliff-face with costs going up and successes going down”, he said. “We recognise that we cannot do things in the old way, and with multiple different phenotypes in many diseases, you cannot hope to achieve or to afford it” he said. “Ultimately industry needs to spread the risk across the public sector/industry/academia. Not one sector has all the necessary skills, resources, expertise but if the industry are to find new therapies, we have a great opportunity here to come together to do this”, he added. Already some discussions are taking place on the Intellectual Property (IP) arising from the results of the first IMI projects and many feel that this will be the benchtest of these large-scale public-private partnerships.



In the discussions that followed, the speakers were asked how the “sharing” process would work in practice? “In the case of a company-sponsored clinical trial, ask the company to take not one biosample, but two – one for analysis within the company and one for storage within a public database”, said Lindpaintner. As a company is a sponsor, the dialogue on sharing would have to be between the company and the public health/academia/government as to how this should be carried out.



Neil Formstone, a patient representative of the Wales Cancer Bank, stated that samples were only truly useful when they were accompanied by a comprehensive package of medical data. “The costs of collecting and maintaining this anonymised data, as well as obtaining the sample, will have to be borne, in whole or part, by the end user or else there will be no funds to undertake this vital part of the process. This may entail the Expert Centres in part funding some of the costs in collecting and holding this data”, he said.

“A compromise could be that industry pays for collecting the sample and for collecting part of the data, as long as the public sector is made aware that this is happening. There may be a way to leverage the amount of money that is already being spent on these large studies, by adding an additional amount of funding to create the kind of more broadly-annotated database that goes along with the sample”, suggested Lindpaintner.

Is this consistent with other positions in pharma/biotech? “It is very clear that challenges remain in terms of the willingness to share, and how it fits with other business decisions in industry,” said Corfield. “Defining the appropriate clinical data which can be shared or combined with a sample, and once defined, adopting consistent information standards for the annotation of both clinical data and samples are significant challenges for us all”, she said. Ann Martin highlighted one of the IMI projects currently under evaluation for setting up a business model for re-use of Electronic Health Record (EHR) data through an independent broker. The goal is to provide a platform that functions across many EHRs that provides anonymized access to patient data for the purpose of clinical research.



## PATIENT STAKEHOLDERS WORKSHOP

This workshop involved prominent members of European patient organisations, especially those already involved in biobanking for both common and rare diseases. A series of presentations focused on the role of patient organisations in biobanking, communication with patients about biobanking research as well as the integration of biobanks with patient registries.

In his review of the workshop content, rapporteur Alastair Kent from Genetic Alliance UK summarised the presentations and discussions through a number of recommendations for action by BBMRI.



### a. Public & Patient Appreciation and Understanding

**BBMRI should consider how the ground can be prepared for public understanding of biobanking, in particular with regard to engaging with local and national patient organisations, for them to be in a position to act as advocates for the adventure of biobanking.**

All citizens of Europe have the potential to be approached to become involved in biobanking at some stage. Even if not, it is important to feel part of a community which endorses the legitimacy of the adventure in order to enable it to be sustainable. In addition, the network of biobanks within BBMRI should develop good practices in patient engagement and learn from examples beyond the EU. BBMRI has the potential to offer a regulatory role in enforcing these good practices in patient engagement. In this regard, the development of a web portal for public communication would be very useful.

### b. Communication and Language

**A contingency should be in place within the “national hubs” of BBMRI for the demonstration of a commitment towards the development and implementation of a local language dissemination strategy for patient participation in that member state.**

BBMRI should look at robust models for the creation and dissemination of information, appropriate translation (both linguistically and culturally), and must pay particular attention on the right of ethnic minority populations to be considered for participation in biobank research.

### c. Donor Communication

**BBMRI should collect examples of successful strategies from different types of biobanks who have addressed the issue of donor communication at different points of the donor participation process.**

This includes communication prior to recruitment; before, up to and including the point at which consent is obtained; during the research process; and afterwards in relation to the significance of results.

### d. Publication of Results

**It is recommended that BBMRI develop a strategy by which the results from studies, in particular negative results, can be publicly communicated.**

Negative results can accrue from either doing “good science” that produces an outcome with no difference, or by producing “bad science”. Both possibilities have implications for researchers due to possible consequences for investors, other academics, etc. How you bring the information into the public domain is difficult and will require realistic processes of dissemination.

### e. Capacity Building

**BBMRI must invest in capacity building for Patient Organisations.**



Not all patient organisations are equally developed in relation to available resources, knowledge and/or state of evolution. Training courses for patient engagement in biobanking would be most welcome in this regard. The ERIC Statutes should incorporate patient organisation representatives as members to address patient involvement beyond tokenism.

#### f. Opportunity to Participate

**There should be systematic development of the awareness of the opportunity to participate in biobanking.**

There is no such thing as the “right to participate” in biobanking. However, BBMRI should look at ways in which it can create a “virtuous circle” so that professionals and the public together can be aware of what is going on in relation to biobank research, and that due respect is offered in relation to where different stakeholders are coming from. Examples of this in practice include posters in clinics, ‘opt out’ clauses, information leaflets attached to consent letters, etc.



Patient Stakeholder Workshop - Nathalie Kayadjanian, Jan Geissler, Filippo Franchini, Michael Griffith



## CLINICAL AND SCIENTIFIC STAKEHOLDERS WORKSHOP

This workshop was designed to stimulate discussion among clinical and scientific investigators involved in biobanking whose research activities will be significantly improved through access to BBMRI resources. Participants included researchers from clinical trials units, physicians and scientists providing and storing tissue for biobanking, pathologists responsible for maintaining biobanks and members of ethics committees). Presentations focused on quality management & good practices, networking and clinical trial, ethical and governance issues, and using biobanks for genetic studies on common diseases.



**Manuel Morente**

A network is the natural environment of biobanking". So said Manuel Morente, of the National Centre for Cancer Research (CNIO), Madrid. "Networking within and between countries is essential as no centre or country has the potential to solve complex health questions on its own", he said. "Of course, there are different types of networks but the diversity can be accommodated within a common set of standardized procedures, quality control programs and good coordination". There are also limitations to networking, he added, and not all 'peculiarities' should be erased when defining the common aspects. Morente went on to emphasize that 'Public' biobanks are essential for clinical trials as they ensure transparency and accountability.

**“A network is the natural environment of biobanking.”**

- Manuel Morente

There are many variables and bottlenecks in the healthcare environment which impact on the biological quality of a sample. For example, 75% of causes of errors in biomarker development happen at the stage of handling samples. How this relates to the quality of research data produced from these samples is something we really need scientific evidence on. So said Bharat Jasani, from the School of Medicine in Cardiff University, Wales who emphasized the importance of using sample tracking systems for tissue biobanks.

Emmanuelle Rial-Sebbag from INSERM concentrated on the ethical and social challenges that are required when building and implementing biobank networks to ensure people have 'control' over their samples and data. BBMRI has performed a review of ethical and legal approaches across 25 different countries, which it is hoped, will lead to the identification of 'core' ethical items for consideration in BBMRI-ERIC.



"The main challenge in this context is that the current ethical methodology of biomedical research and clinical trials does not systematically work when applied to biobanks, particularly in relation to informed consent. Also there is a need for changes in the operational governance of biobanks with an enhancement of interactions between science and society (balancing different 'logics')", she added. Rial-Sebbag also proposed a new concept for Informed Consent, which she called 'Enlightened Consent'. "Rather than being a legal requirement, consent should be a mechanism to involve participation within a flow of information linking participants, scientists and the community", she said.

"The next frontiers for biobanking are data information storage and access", said Samuli Ripatti,

of the Institute of Molecular Medicine (FIMM), Helsinki who highlighted the progress being made in research into the genetics of common diseases through Genome Wide Association Studies (GWAS). “As we turn biological information into digital information, we turn biobanks into databases. This information needs to be made amenable to meta-analysis, modeling, development of prediction models, etc.”, he said. Ripatti described the work of the Global Lipid Genetic Consortium, which is looking at the underlying causes of high levels of cholesterol. “The main lesson we have learned in our project is the importance of Information Technology Management to provide the linkage between baseline information and complex sets of phenotypic and genotypic data”, he said.

In his summary of the discussions, rapporteur Pierre Hainaut of the International Agency for Research on Cancer (IARC) identified that the data produced from genetic studies involving biospecimens can have a significant impact on the participant as a person (e.g. low risk vs. high risk genetic traits). “Researchers need to be aware of these impacts and the scope of their consent procedures needs to take this into account”, he said.



**Anne Cambon - Thomsen**

A discussion on how to motivate and raise the participation rates of the medical community in biobanking identified personal attitudes, a feeling of ‘ownership’ over sample collections and lack of time and resources as the major obstacles to their participation. In order to increase the scientific recognition of medical practitioners participating in biobanking, Anne Cambon-Thomsen of INSERM proposed the idea of a ‘Bioresource Impact Factor’ as a means of measuring how a biobank is used. “The idea behind it is to change the feeling of ‘loss’

when a biobank gives access to its samples, to a feeling of ‘benefit’ because if your biobank is used a lot, you can have a measure of that”, she said. In addition, a recommendation was made that doctors should be trained in biobanking practices as part of their medical studies.

**“The next frontiers for biobanking are data information storage and access”**

- Samuli Ripatti

The role of BBMRI in enhancing quality standards was also highlighted and research into evidence-based procedures and protocols that are adapted to each particular context was called for. “BBMRI may set ‘baseline’ standards and requirements for joining the network (technical, ethical, access rules, etc.) but not everything needs to meet the highest standards”, Hainaut commented.

Based on the experience of Wales and Spain, discussions on the optimal strategy for management of national biobanking networks within BBMRI suggested that Quality Control (QC) can be used as a way to bring operators and technical staff of biobanks together in face-to-face meetings with the national coordinator acting as an ‘honest broker’. “Also, there is a whole new field of research opening up where biomarkers become more important for assessing the quality of specimens and BBMRI may help to develop this field at the European level” said Hainaut.



**Clinical Stakeholders Workshop - Bharat Jasani, Samuli Ripatti, Frank Wells, Emmanuelle Rial**

## GENERAL TALKING POINTS

### A. IMPORTANCE OF PUBLIC ENGAGEMENT FOR BIOBANKING

As biobank networks become more prominent and numerous, there is an essential need to educate not only the public, but also researchers in academia and industry on what the role and value of biobanks is. This was the opinion of the majority of stakeholders at the meeting.

A realistic, rational and effective strategy for public communication was called for. "This strategy should be devised to reach people and messages should be prepared according to people's needs and what they want to know, rather than what scientists are able and not able to say in lay words", said Alastair Kent. Support was expressed for the funding of a Web Portal which incorporates targeted information (depending on the relevant stakeholder needs), using e-learning and social networking to educate large numbers of professionals and publics on biobanking principles and practices.

"We have to approach this challenge from both sides", said Kurt Zatloukal - those involved in biobanking need to make themselves available to deliver the right message but also the public need to be willing and open to receive an interaction and interface.

A strong emphasis on interaction with publics has already begun in the BBMRI preparatory phase through focus groups in a number of European countries. Allied with the soon-to-be published Eurobarometer information, containing ten specific

questions on biobanking, the results of these studies will form the foundation of a public communication and awareness strategy to be developed during the BBMRI implementation phase.

The need to take biobanking out into the curriculum of public schools and medical training was also emphasized. "In a very proactive manner, start to educate the population of Europe", said Klaus Lindpaintner. "We are all patients, and eventually we are all going to be part of it, and the sooner we try to engage the public, the better off we are", he added.

The issue of resources within the biobanking community was raised by several stakeholders. "We should count on the stakeholders who are involved in biobanking in order to translate the information into lay language. If you agree to be in partnership with all stakeholders, then the resources can be found from this community", said Fabrizia Bignami from the European Organisation for Rare Diseases (EURORDIS).

### B. IMPROVING AND FUNDING INTEROPERABILITY

"Finding ways to interoperate and collaborate has major implications for funding mechanisms as you cannot fund harmonization in a competitive funding environment - the groups that apply for funding are forced to come up with new and different solutions to the same problem" said Zatloukal. "At a certain stage, for some specific fields, you have to encourage collaboration and we have to look at how to create values by collaboration through new funding schemes". he said. Peter Riegman of



Klaus Lindpaintner, Manuel Morente, Fabrizia Bignami, Kurt Zatloukal, Derick Mitchell, Michael Griffith



ERASMUS, Rotterdam asked if BBMRI can 'adapt the rules' for competition to reward sharing. "This will lead to people trying to find each other, rather than walking away", he said.

"Compliance with minimal standards are necessary to achieve interoperability. However, most international guidelines on biobanking are based, not on scientific evidence, but on individual experience. How to achieve this interoperability will require different solutions for different levels; for example the ethical and legal levels", said Zatloukal.

### C. EXPERT CENTRES

How BBMRI-ERIC interacts with industry is a source of much debate. "The relationship between Pharma/Biotech needs to be established in a transparent manner. BBMRI needs to be aware of the sensitivities and should create honesty about the need for interaction, which requires clear rules for engagement", was the consensus from the stakeholders in the patient workshop.

The Expert Centres solution supported by BBMRI will build the interface between the public and private sectors as a non-profit joint-venture set up in the pre-competitive environment.

"Human biological material cannot be sold as it is against international legal conventions" said Kurt Zatloukal. Furthermore there is valuable information and knowledge related to the samples that cannot be shared by shipment but requires personal interaction. Therefore expert centres should create a framework that not only provides access to samples and data but also facilitates sharing of knowledge between academia and industry.

The principle of the BBMRI expert centres is that the research performed is a "transformation" of the finite starting material into data and knowledge that can be easily shared. The BBMRI plan is to establish expert centres in different parts of the world. Even though some countries have restrictions on export of samples over borders, the data arising from the analysis of a sample can be shared. If the analysis is done in the environment where the samples have been generated, this removes these restrictions and reduces costs for transfer and shipping. "All centres

must use the same reference guidelines and material, ensuring that the data generated in any centre would be of identical quality to that produced by any other", said Zatloukal.

### D. ETHICAL REVIEW

How can we trust that the research will be performed according to sound ethical principles? – so asked Anne Cambon-Thomsen, workpackage leader of the Ethical, Legal and Social Aspects of the BBMRI Preparatory Phase. Just like a scientific review of a project, BBMRI needs an ethical review process as well. The existing situation is that local Research Ethics Committees (RECs) have to give their approval for a project where the samples are contained within that country.

At the moment BBMRI are planning to issue a call for expression of interest for membership of a BBMRI ethical review panel. "This would consist of a small group of experts who have specific expertise on assessing ethical aspects of European projects and on whose expertise we can rely on", said Cambon-Thomsen. "BBMRI is currently favouring a 'hybrid model' where a standing committee meets regularly with a certain mandate which can be renewed, while at the same time having external experts giving input on these projects", she said. "This is a very welcome development", said Frank Wells of the European Forum for Good Clinical Practice (EFGCP). The idea of BBMRI is not to go over the heads of any existing ethics committee but rather to send the BBMRI opinion in the form of advice, to the local ethics committee, so they can take this into account in their own assessment. Jochen Taupitz, a member of the German National Ethics Council questioned the relevance of any decision from such a panel in the case where there is no need for a researcher to consult an ethics committee or if a local ethics committee does not exist. "Then the opinion of the BBMRI committee will be the only one considered in this case", was Cambon-Thomsen's response.



Frank Wells, Samuli Ripatti



Alastair Kent

## E. MAKING USE OF DORMANT RESOURCES

There are banks of biosamples lying in freezers all around Europe (e.g. hospital archives, samples left over from clinical trials etc.) - a huge resource that has immense value waiting to be liberated. However, there can be large ethical and quality issues associated with these retrospective collections and the samples may not always be well characterised.

The general understanding among stakeholders at the meeting was that once a sample is in a repository, it should be exploited for the benefit of everybody. "Make sure we don't miss the opportunity that is out there on specimen collections that are being carried out in clinical development studies in large pharmaceutical companies", was the message from Klaus Lindpaintner. "I think there is a clear synergy to be leveraged to create a win-win opportunity where nobody is giving up anything as yet and where added value can be created", he said.

A recommendation from the Patient Stakeholder Workshop was that pressure should come from BBMRI to industry to make better use of their dormant resources. "In this context, the relationship with Industry is a two-way one. BBMRI is not just giving basic research to industry, but recognising industry's contribution toward the generation of scientific knowledge. "If you can capitalise on this, you can create a win-win-win situation where patients, industry and the clinical and academic community can all benefit", said rapporteur Alastair Kent.

## F. INTELLECTUAL PROPERTY

Publicly-funded biobanks (e.g. as part of a university) are under increasing pressure from governments to

generate funds and valorise their research. This pressure finds expression in the form of Intellectual Property (IP) which can be a severe impediment to sharing.

In the Expert Centre model proposed by BBMRI, the data generated from analysis of samples is published early to ensure that the IP is not generated at this stage of the process. "This shift of the role of IP towards the product was actually proposed by a major biopharmaceutical company - a very welcome development", said Zatloukal.

A discussion was called for on the different motivations and altruism that exist between industry vs. public initiatives in relation to sharing and IP. David Myles responded that the primary motivation for companies within the IMI projects is to increase their success rate. The UBIOPRED consortium discussions on IP reached a mutual understanding where all participants within the project (both public and private) would have free access to all the information and could make use of it. "Academic centres, through their technology transfer offices could get their own IP, through maybe design of a kit, which industry would be more than happy to pay for the use of", he said. Carine Malcus of Biomerieux confirmed that there is a better recognition also in the diagnostic industry that innovation can come from a partnership and not just from a company alone.

Patient Organisations do not have a problem with IP arising from their donations, was the message from Neil Formstone. "As long as you are open and honest about where that sample will go, then there is no problem. However, there remains a need for industry to ensure understanding among donors that their sample is going to be utilized for what they want to see - future health benefits - and that you are not simply squabbling over financial considerations", he said.

**“ you can create a win-win-win situation where patients, industry and the clinical and academic community can all benefit ”**

- Alastair Kent

## PATIENT PARTICIPATION DOCUMENT

As part of the final session of the meeting, Fabrizia Bignami of EURORDIS, representing patient stakeholders, presented Kurt Zatloukal with the *"Patient Participation in BBMRI"* consultation document. This document is intended to be used as a guideline of basic principles reflecting patient participation in both new and existing biobanks within the implemented research infrastructure. After an extensive consultation process, the document - endorsed by many prominent European patient organisations - was presented for consideration in the drafting of policies and procedures for the implementation of the research infrastructure.



Presentation of patient paper - Michael Griffith, Fabrizia Bignami, Kurt Zatloukal



## CONCLUSION

The long term aim of the Stakeholders Forum, as described by Derick Mitchell in his closing summary, is to ensure that there is an established role for stakeholders within the implemented BBMRI infrastructure. "Our vision is to be the catalyst for biomedical and biobanking research in Europe and our strategy will be to combine educational and engagement processes to ensure that this dialogue is not only continued but increased", he said. There has been clear support from the coordinators of the BBMRI preparatory phase and from stakeholders alike and there is a plan for the forum within the BBMRI-ERIC proposal. "We are greatly encouraged by the emphasis being placed on this, and we need to work to ensure that the Governing Authority of the BBMRI-ERIC (i.e. member state representatives) are similarly motivated", he said.





## APPENDIX I: MEETING AGENDA

## WELCOME AND INTRODUCTION

**Welcome and Introduction**

*Michael Griffith, Chair of BBMRI Stakeholder's Forum*

**Support to Existing and Future Research Infrastructures**

*Hervé Pero, Head of Unit, Research Infrastructures,  
DG-Research, European Commission*

## SESSION 1: BBMRI – A STEP CLOSER

This session focused on BBMRI preparatory phase goals and achievements and elaborated on the proposed implementation status of the BBMRI-ERIC. Future interactions with clinical, industry, academic, patient and user stakeholders were highlighted.

Session Chair: **Michael Griffith**  
*BBMRI Stakeholders' Forum*

Panel Chair: **Derick Mitchell**  
*BBMRI Stakeholders' Forum*

PRESENTER	TITLE OF TALK
<b>Eero Vuorio</b> <i>University of Turku, Finland</i>	"BBMRI (2008-2010) Successes and Challenges"
<b>Kurt Zatloukal</b> <i>Medical University of Graz, Austria</i>	"BBMRI-ERIC: Towards Implementation"
<b>Martin Yuille</b> <i>University of Manchester, UK</i>	"User access to resources and services provided by BBMRI"
<b>Anne Cambon-Thomsen</b> <i>INSERM, France</i>	"Ethical Review Processes in BBMRI"

**10:40am** PANEL AND OPEN FORUM DISCUSSION

## SESSION 2: PARALLEL STAKEHOLDER GROUP WORKSHOPS

As part of a comprehensive consultation and engagement process, individual stakeholder workshop sessions aimed to focus attention on the unmet needs of each stakeholder group. Summary session in the main meeting room followed.

## 2A: CLINICAL AND SCIENTIFIC STAKEHOLDERS WORKSHOP

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

Rapporteur: **Pierre Hainaut**  
*International Agency for Research on Cancer (IARC)*

PRESENTER	TITLE OF TALK
<b>Emmanuelle Rial</b> <i>INSERM, Toulouse, France</i>	“Ethical and Governance Issues in Biobanking”
<b>Bharat Jasani</b> <i>School of Medicine, Cardiff University, Wales</i>	“Quality Management and Good Biobanking Practice”
<b>Manuel Morente</b> <i>Spanish National Biobank Network Coordinator, Head of the CNIO's Tumor Bank Unit</i>	“Sample Handling and Identified Bottlenecks”
<b>Samuli Ripatti</b> <i>Institute of Molecular Medicine, Finland</i>	“Using harmonized biobanks to identify genes - modifying risks for common diseases”

## 2B: PATIENT STAKEHOLDERS WORKSHOP

Session Chair: **Michael Griffith**  
*BBMRI Stakeholders Forum*

Rapporteur: **Alastair Kent**  
*Genetic Interest Group, European Genetic Alliances Network (EGAN)*

PRESENTER	TITLE OF TALK
<b>Jan Geissler</b> <i>European Cancer Patients Coalition</i>	“Communication to Patients”
<b>Nathalie Kayadjanian</b> <i>French Association for Neuromuscular Diseases (AFM)</i>	“Why patient organisations should be involved in biobanking”
<b>Filippo Franchini</b> <i>European Network for Research on Alternating Hemiplegia (ENRAH)</i>	“Case Study of Integration of Biobank with Patient Registries”

## 2C: INDUSTRY STAKEHOLDERS WORKSHOP

Session Chair: **Colin MacKay**

*European Federation of Pharmaceutical Industries and Associations (EFPIA)*

Rapporteur: **Alfredo Cesario**

*IRCCS San Raffaele, Università Cattolica del Sacro Cuore, Rome, Italy*

PRESENTER	TITLE OF TALK
<b>Klaus Lindpaintner</b> <i>Biobanks LLC</i>	"Public Private Partnership in the context of biobanking"
<b>Julie Corfield</b> <i>AstraZeneca UK</i>	"Precompetitive Research - Industry Perspective"
<b>David Myles and Ann Marie Martin</b> <i>GlaxoSmithKline and IMI</i>	"Joint Undertakings to promote Public-Private Partnership"

## SESSION 3: STAKEHOLDERS OPEN FORUM

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. Individual and consensus questions will be addressed to the panel and feedback and comments will be greatly welcomed from the broad spectrum of participants.

Session Chair: **Michael Griffith**

*BBMRI Stakeholders' Forum*

Panel Chair: **Derick Mitchell**

*BBMRI Stakeholders' Forum*

### SUMMARY OF WORKSHOPS

#### PANEL AND OPEN FORUM DISCUSSION

##### Forum Panelists:

<b>Kurt Zatloukal</b> <i>Medical University of Graz, Austria</i>	<b>Manuel Morente</b> <i>CNIO</i>
<b>Fabrizia Bignami</b> <i>EURORDIS</i>	<b>Klaus Lindpaintner</b> <i>Biobanks LLC</i>

### CLOSING REMARKS

**Derick Mitchell**

*BBMRI Stakeholders' Forum*



## APPENDIX II: MEETING EVALUATION FORM SUMMARY

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

### Q1: What was the most enjoyable aspect of this meeting?

1. Networking opportunities and exchange of ideas across different disciplines and backgrounds.
2. Practical insights and discussions with pathologists.
3. Feedback on BBMRI current status.
4. Patient Stakeholder Workshop.
5. Great forum to understand the trends within BBMRI from an “outside-in” viewpoint.

### Q2: From today's discussions, what do you think are the main benefits of BBMRI?

1. Establishing the European Biobanking Community.
2. Fostering collaboration and presentation of new ideas.
3. Uniform approach towards quality and innovation of research.
4. Respecting citizens while enabling better science through collaboration.
5. Raising awareness of the need to provide access to large numbers of samples and data.

### Q3: From what you learned today, what are your main concerns about BBMRI?

1. Funding.
2. Transparency on resources dedicated to BBMRI-ERIC and National Members.
3. Harmonization of previously standardized work.
4. Quality of samples vs. quality of data.
5. The breaks in the chain of data from point of care to analysis – can render data useless.
6. Lack of accreditation of expert centers – essential so users know the quality of material and associated data.

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

1. Have the Stakeholders Forum more frequently and in other parts of Europe.
2. Focus more on sample ID and traceability.
3. More information on how BBMRI aim to build the centralized system.
4. More information about the range of quality systems/standards and how they can be applied to different biobanks.
5. Create awareness among public organizations and educational systems in member states.

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

1. How to avoid too much legal framework in order to prevent rigidity when sharing data.
2. Localisation of expert centres and process of selection/individualisation in Member States.
3. What is foreseen for biobanks who do not join BBMRI?
4. Some more detail on the ethical issues.



# CONFERENCE PROGRAMME

## Thursday, September 23

- 14.00-14.15 **Opening Words: Gert-Jan van Ommen**  
 14.15-15.00 **Keynote Speaker Daan Hommes:** Integrating electronic patient (ePR) records and biobanking  
 15.00-15.30 *Tea break*  
 15.30-17.00 **Examples of success stories**  
 Chair: **Erich Wichmann**  
**Heribert Schunkert:** Network-approach for the genetics of myocardial infarction  
**Tim Spector:** Use of twins in gene discovery  
**Kári Stefánsson:** Science behind deCODE Genetics  
 18.00 *Wine & Cheese party*



## Friday, September 24

- 9.30 -12:30 **Data mining, analysis and protection**  
 Chair: **Jan-Erik Litton**  
**Morris Swertz:** Biobankers and their banks – how to connect them?  
**Hakon Gudbjartsson:** Disease miner  
**Klaus Kuhn:** The BBMRI Catalogue - system and data architecture  
 11.00-11.30 *Tea break*  
 11.30-12.30 **David Goldstein:** How common are rare variants?  
**Ruth Chadwick:** Privacy in perspective  
 12.30-14.00 *Lunch*  
 14.00-15.30 **New developments and emerging technologies**  
 Chair: **Mike Taussig**  
**Thomas Illig:** New approach to combine genomics and metabolomics  
**Ivo Gut:** High-throughput genome analysis and biobanking  
**Ulf Landegren:** Protein tools for enhanced biobank analyses  
 15.30-16.00 *Tea break*  
 16.00-16.45 **Keynote Speaker Tom Hudson:** Translating cancer genomes into personalized health and disease management  
 19.00 *Conference dinner*

# BIOBANKING FOR SCIENCE

September 23-25, 2010  
 Novotel Hotel  
 Amsterdam City  
 Amsterdam, NL

## Saturday, September 25

- 9.00-10.30 Parallel Sessions:  
**ELSI-ERIC and beyond**  
**Enabling Technologies**  
 10.30-11.00 *Tea break*  
 11.00-11.45 Closing plenary session  
**Keynote Speaker David Cox:** Private-Public Collaboration and Biobanking Science  
 11.45-12.00 **Closing Remarks: Kurt Zatloukal**  
 12.00 *Lunch*





### **Upcoming Conference “BBMRI – Biobanking for Science”**

**September 23-25, 2010**

**Novotel Amsterdam City, Amsterdam, NL**

On September 23-25, 2010, the BBMRI consortium is organising the “BBMRI – Biobanking for Science” conference focusing on scientific excellence in the various aspects of biobanking at the Novotel Amsterdam City, Amsterdam, NL.

The conference “BBMRI - Biobanking for Science” brings together leading scientists in the field, young scientists, biobanking managers and practitioners to discuss the science and new approaches in cutting edge biobank research. The meeting is organised by the BBMRI Steering Committee, Work Package Leaders and Chairs, the Executive Management Team from the Medical University Graz and the University of Turku. The local organiser is Professor Gert-Jan van Ommen from Leiden University Medical Centre (LUMC), NL and scientific director of BBMRI-NL.

#### **Contacts:**

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

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[www.bbmri.eu](http://www.bbmri.eu)

