SEVENTH FRAMEWORK PROGRAMME
Capacities Specific Programme
Research Infrastructures

Grant agreement for Combination of Collaborative Project and Coordination and Support Actions

Annex I - "Description of Work"

Project acronym: **BBMRI**

Project full title:
Biobanking and Biomolecular Resources Research Infrastructure

Grant agreement no.: **212111**

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Date of modification (amendment n° 2): 13/11/2009

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PART A

A1. Overall budget breakdown for the project

Participant number in this project [8]	Participant short name	Estimated eligible costs (whole duration of the project)						Total receipts	Requested EU contribution
		RTD (A)	Coordination (B)	Support (C)	Management (D)	Other (E)	Total A+B+C+D+E		
1	MedUG	0.00	42,400.00	0.00	1,390,608.00	0.00	1,433,008.00	0.00	1,046,299.00
2	THL	0.00	466,560.00	0.00	0.00	0.00	466,560.00	0.00	312,012.00
3	HMGU	0.00	421,123.00	0.00	0.00	0.00	421,123.00	0.00	312,012.00
4	UU	0.00	355,520.00	0.00	0.00	0.00	355,520.00	0.00	237,754.00
5	KI	0.00	336,800.00	0.00	0.00	0.00	336,800.00	0.00	225,235.00
6	INSERM	0.00	1,167,620.00	0.00	0.00	0.00	1,167,620.00	0.00	847,924.00
7	UNIMAN	0.00	42,400.00	0.00	173,280.00	0.00	215,680.00	0.00	144,236.00
8	IARC	0.00	84,800.00	0.00	173,280.00	0.00	258,080.00	0.00	172,056.00
9	LUMC	0.00	78,880.00	0.00	128,800.00	0.00	207,680.00	0.00	138,886.00
10	UoM	0.00	21,280.00	0.00	0.00	0.00	21,280.00	0.00	14,231.00
11	NTNU	0.00	56,480.00	0.00	0.00	0.00	56,480.00	0.00	37,771.00
12	SU	0.00	42,400.00	0.00	0.00	0.00	42,400.00	0.00	28,355.00
13	UTARTU	0.00	56,480.00	0.00	0.00	0.00	56,480.00	0.00	37,771.00
14	USAL	0.00	42,400.00	0.00	0.00	0.00	42,400.00	0.00	28,355.00
15	FTELE	0.00	21,280.00	0.00	0.00	0.00	21,280.00	0.00	14,231.00
16	FHF	0.00	15,960.00	0.00	0.00	0.00	15,960.00	0.00	14,231.00
17	DMMC-ICRIN	0.00	15,960.00	0.00	0.00	0.00	15,960.00	0.00	14,231.00
18	Helmholtz	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
19	INCa	0.00	21,280.00	0.00	0.00	0.00	21,280.00	0.00	14,231.00
20	CNBBSV	0.00	21,280.00	0.00	0.00	0.00	21,280.00	0.00	14,231.00
21	MPG	0.00	33,250.00	0.00	0.00	0.00	33,250.00	0.00	14,231.00
22	ISCIII	0.00	21,280.00	0.00	0.00	0.00	21,280.00	0.00	14,231.00
23	VITRO	0.00	10,560.00	0.00	0.00	0.00	10,560.00	0.00	9,416.00
25	EMBL-EBI	0.00	14,080.00	0.00	0.00	0.00	14,080.00	0.00	9,416.00
27	NIPH	0.00	21,280.00	0.00	0.00	0.00	21,280.00	0.00	14,231.00
28	ERASMUSMC	0.00	42,400.00	0.00	0.00	0.00	42,400.00	0.00	28,355.00
29	IST	0.00	56,480.00	0.00	0.00	0.00	56,480.00	0.00	37,771.00
30	CNR	0.00	16,452.48	0.00	0.00	0.00	16,452.48	0.00	9,416.00
31	HRB	0.00	21,280.00	0.00	0.00	0.00	21,280.00	0.00	14,231.00
32	MRC	0.00	16,359.00	0.00	0.00	0.00	16,359.00	0.00	14,231.00
33	UK Biobank	0.00	52,920.00	0.00	0.00	0.00	52,920.00	0.00	47,187.00
34	OCW	0.00	15,960.00	0.00	0.00	0.00	15,960.00	0.00	14,231.00
35	RANNIS	0.00	15,960.00	0.00	0.00	0.00	15,960.00	0.00	14,231.00
36	UMCG	0.00	70,560.00	0.00	0.00	0.00	70,560.00	0.00	47,187.00
37	NFU	0.00	15,960.00	0.00	0.00	0.00	15,960.00	0.00	14,231.00
38	ZonMw	0.00	21,280.00	0.00	0.00	0.00	21,280.00	0.00	14,231.00
39	Fraunhofer	0.00	26,349.96	0.00	0.00	0.00	26,349.96	0.00	14,231.00
40	BMBF	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
41	BMWF	0.00	21,280.00	0.00	0.00	0.00	21,280.00	0.00	14,231.00
43	deCODE	0.00	194,260.00	0.00	0.00	0.00	194,260.00	0.00	94,481.00
44	LSGI	0.00	70,035.60	0.00	0.00	0.00	70,035.60	0.00	65,698.00
46	CU	0.00	98,240.00	0.00	0.00	0.00	98,240.00	0.00	65,698.00
47	ACC	0.00	21,280.00	0.00	0.00	0.00	21,280.00	0.00	14,231.00
49	GenomeSpai	0.00	15,960.00	0.00	0.00	0.00	15,960.00	0.00	14,231.00
50	HM	0.00	15,960.00	0.00	0.00	0.00	15,960.00	0.00	14,231.00
51	BBT	0.00	112,950.00	0.00	0.00	0.00	112,950.00	0.00	66,982.00
52	GSRT	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
53	BRFAA	0.00	21,280.00	0.00	0.00	0.00	21,280.00	0.00	14,231.00
54	UNI-KLU	0.00	84,800.00	0.00	0.00	0.00	84,800.00	0.00	56,710.00
55	U.TURKU	0.00	0.00	0.00	620,240.00	0.00	620,240.00	0.00	418,098.00
56	Legal Path	0.00	153,920.00	0.00	0.00	0.00	153,920.00	0.00	102,934.00
57	IPPOSI	0.00	0.00	0.00	81,240.00	0.00	81,240.00	0.00	72,439.00
58	MA	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
TOTAL		0.00	4,593,280.04	0.00	2,567,448.00	0.00	7,160,728.04	0.00	4,999,305.00

BBMRI Budget

WP1	Category	Costs
Coordination	Personnel	239.600
	Consumables	10.000
	Equipment	6.000
	Travel	43.200
	Meetings	372.800
	not allocated	31.540
	direct costs	703.140
	+ 7% indirect costs	49.220
	Subcontracting	265.584
	Requ. EC	**1.017.944**
Executive Management	Personnel	289.900
	Consumables	7.500
	Equipment	3.000
	Travel	81.000
	direct costs	381.400
	+ 7% indirect costs	26.698
	Subcontracting	10.000
	Requ. EC	**418.098**
Associate Coordinator	Personnel	79.500
	Travel	28.800
	direct costs	108.300
	+ 7% indirect costs	7.581
	Requ. EC	**115.881**
Advisory Board chair	Personnel	26.500
	Meetings	54.000
	direct costs	80.500
	+ 7% indirect costs	5.635
	Requ. EC	**86.135**
Stakeholder forum chair part of coordination	Personnel	67.700
	direct costs	67.700
	+ 7% indirect costs	4.739
	Requ. EC	**72.439**
Global integration	Personnel	79.500
	Travel	28.800
	direct costs	108.300
	+ 7% indirect costs	7.581
	Requ. EC	**115.881**

WP2	Category	Costs
	Personnel	428.100
	Travel	28.800
	Meetings	28.800
	direct costs	485.700
	+ 7% indirect costs	33.999
	per WP Requ. EC	**519.699**

WP3	Category	Costs
	Personnel	410.800
	Travel	28.800
	Meetings	81.300
	direct costs	520.900
	+ 7% indirect costs	36.463
	per WP Requ. EC	**557.363**

WP4	Category	Costs
	Personnel	216.300
	Travel	28.800
	Meetings	36.000
	direct costs	281.100
	+ 7% indirect costs	19.677
	per WP Requ. EC	**300.777**

WP5	Category	Costs
	Personnel	393.300
	Travel	31.200
	Meetings	42.000
	direct costs	466.500
	+ 7% indirect costs	32.655
	per WP Requ. EC	**499.155**

WP6	Category	Costs
	Personnel	286.563
	Travel	24.300
	Meetings	79.200
	Other costs	34.500
	Subcontracting	30.000
	direct costs	424.563
	+ 7% indirect costs	29.719
	per WP Requ. EC	**484.282**

WP7	Category	Costs
	Personnel	411.700
	Travel	28.800
	Meetings	120.000
	direct costs	560.500
	+ 7% indirect costs	39.235
	Subcontracting	202.500
	Requ. EC	**802.235**

WP 1-7	Category	Costs
	total personnel	2.929.463
	total equipment	9.000
	total consumables	17.500
	total travel	352.500
	total meetings	814.100
	not allocated costs	31.540
	other costs	34.500
	total direct costs	**4.188.603**
	+ 7% indirect costs	**293.202**
	total subcontracting	**508.084**
	total Requ. EC	**4.999.305**

A2. Project summary

GENERAL INFORMATION			
Project title 3	Biobanking and Biomolecular Resources Research Infrastructure		
Starting date 4	01/02/2008		
Duration in months 5	30		
Call (part) identifier 6	FP7-INFRASTRUCTURES-2007-1		
Activity code(s) most relevant to your topic 7	INFRA-2007-2.2-01: Preparatory phase for the projects in the 2006 ESFRI Roadmap		
Free keywords 8	biobank, antibody, affinity binder, gene clone, siRNA, protein, cell culture collection, personalised medicine, biomarker, drug development, genomics, environment, bioinformatics, legal ethics society		
Abstract 9 (max. 2000 char.)			
The Preparatory Phase for a pan-European Biobanking and Biomolecular Resources Research Infrastructure (BBMRI) will focus on technical, legal, governance, and financial issues to • prepare to construct BBMRI, building on existing biobanks, resources and technologies, specifically complemented with innovative components and properly embedded into European scientific, ethical, legal and societal frameworks, • provide the concept for a key resource to increase excellence and efficacy in biomedical sciences, drug development and public health, • expand and secure competitiveness of European research and industry in a global context, • develop a sustainable financial framework. Biomedical quality-assessed samples and data as well as biomolecular resources and molecular analysis tools are essential for academic and industry-driven research to treat and prevent human diseases. Although currently established national biobanks and biomolecular resources are a unique European strength, valuable collections typically suffer from fragmentation of the European biobanking-related research community. This hampers the collation of biological samples and data from different biobanks required to achieve sufficient statistical power. Moreover, it results in duplication of effort and jeopardises sustainability due to the lack of long-term funding. BBMRI will comprise: • biobanks of different formats (collections of blood, DNA, tissue, etc., together with medical, environmental, life-style and follow-up data), • biomolecular resources (antibody and affinity binder collections, ORF clone collections, siRNA libraries, proteins, cellular resources etc.), • enabling technologies and high-throughput analysis platforms and molecular tools to decipher gene, protein and metabolite functions and their interactions, • harmonized standards for sample collection, storage, preanalytics and analysis • harmonized databases and biocomputing infrastructure, • ethical, legal and societal			

A3. List of beneficiaries

Beneficiary Number	Beneficiary name	Beneficiary short name	Country	Date enter project	Date exit project
1 CO	Medical University of Graz (K. Zatloukal)	MedUG	Austria	1	30
2	National Institute for Health and Welfare (L. Peltonen, J. Muilu)	THL	Finland	1	27
3	Helmholtz Zentrum München – Deutsches Forschungszentrum für Gesundheit und Umwelt GmbH (E. Wichmann, T. Meitinger)	HMGU	Germany	1	27
4	Uppsala Universitet (U. Landegren, M. Taussig, T. Risch)	UU	Sweden	1	27
5	Karolinska Institutet (J.-E. Litton)	KI	Sweden	1	27
6	INSERM (G. Dagher, C. Libersa, A. Cambon-Thomsen)	INSERM	France	1	27
7	University of Manchester (M. Yuille, B. Ollier)	UNIMAN	United Kingdom	1	27
8	International Agency for Research on Cancer (M. Pasterk, P. Hainaut)	IARC	France	1	27
9	Academisch Ziekenhuis Leiden (G.J.B. van Ommen)	LUMC	The Netherlands	1	27
10	Univ. of Malta (A. Felice)	UoM	Malta	1	27
11	Norwegian University of Science and Technology (K. Hveem)	NTNU	Norway	1	27
12	Semmelweis University (A. Falus)	SU	Hungary	1	27
13	EGP of the University of Tartu (A. Metspalu)	UTARTU	Estonia	1	27
14	National DNA Bank, University of Salamanca (A. Orfao)	USAL	Spain	1	27
15	Fondazione Telethon (L. Monaco)	FTELE	Italy	1	27
16	Féderation hospitalière de France – FHF (E. Devilliers)	FHF	France	1	27
17	Irish Clinical Research Infrastructure Network (P. Doran)	ICRIN	Ireland	1	27
18	Helmholtz Gemeinschaft (S.Joos)	Helmholtz	Germany	1	27
19	Institut National du Cancer (P. Boucher)	INCa	France	1	27
20	Comitato Nazionale per la Biosicurezza, le Biotecnologie e le Scienze della Vita, Istituto Superiore di Sanita (G. D'Agnolo)	CNBBSV	Italy	1	27
21	Max-Planck-Institut für Molekulare Genetik (H. Lehrach)	MPG	Germany	1	27
22	Instituto de Salud Carlos III (R. Andrés-Medina)	ISCIII	Spain	1	27
23	VITRO Ltd (A. Fernandez)	VITRO	Spain	1	27
25	Ensembl Functional Genomics, European Genotype Archive (P. Flicek)	EMBL-EBI	United Kingdom	1	27
27	Norwegian Institute of Public Health (K. Hveem)	NIPH	Norway	1	27
28	Erasmus MC Rotterdam (P. Riegman)	ERASMUSMC	The Netherlands	1	27
29	Istituto Nazionale per la Ricerca sul Cancro, Biological Bank and Cell Factory (B. Parodi, P. Romano)	IST	Italy	1	27
30	Institute for Biomedical Technologies (L. Milanesi)	CNR	Italy	1	27
31	Research Infrastructure and Special Initiatives Unit Health Research Board (A. Cody)	HRB	Ireland	1	27
32	Medical Research Council (M. Palmer)	MRC	United Kingdom	1	27
33	UK Biobank Ltd (T.Peakman)	UK Biobank	United Kingdom	1	27
34	Ministry of Education, Culture and Science	OCW	The	1	27

	(J.W.A. Ridder)		Netherlands		
35	The Icelandic Centre for Research (K. Valgeirsdóttir)	RANNIS	Iceland	1	27
36	University Hospital Groningen (B.H.R. Wolffenbuttel, J.L. Hillege)	UMCG	The Netherlands	1	27
37	Dutch Federation of University Medical Centers (D.A. Legemate)	NFU	The Netherlands	1	27
38	The Netherlands Organisation for Health Research and Development (E. Beem)	ZonMw	The Netherlands	1	27
39	Fraunhofer IBMT (H. Zimmermann)	Fraunhofer	Germany	1	27
40	Bundesministerium für Bildung und Forschung (F. Laplace)	BMBF	Germany	1	27
41	Bundesministerium für Wissenschaft und Forschung (R. Klang)	BMWF	Austria	1	27
43	deCODE genetics (U. Thorsteinsdottir)	deCODE	Iceland	1	27
44	Life Science Governance Institute (H. Gottweis)	LSGI	Austria	1	27
46	Center for Economics and Social Aspects of Genomics (R. Chadwick)	CU	United Kingdom	1	27
47	Alleanza contro il cancro (P.L. Spagnoli)	ACC	Italy	1	27
49	Fundación para el desarrollo de la investigación en Genómica y Proteómica (J.L. Jorcano)	Genome Spain	Spain	1	27
50	Ministry of Education and Research, Estonia (I. Reimand)	HM	Estonia	1	27
51	Babraham Bioscience Technologies (M. Taussig)	BBT	United Kingdom	1	27
52	Hellenic Republic Ministry of Development, General Secretariat For Research & Technology (I.A. Tsoukalas)	GSRT	Greece	1	27
53	Biomedical Research Foundation of the Academy of Athens (D. Thanos)	BRFAA	Greece	1	27
54	Universität Klagenfurt (J. Eder)	UNI-KLU	Austria	1	27
55	University of Turku (E.Vuorio)	U. Turku	Finland	1	27
56	Legal Pathways b.v.	Legal Pathways b.v.	The Netherlands	1	27
57	Irish Platform for Patients' Organisations, Science and Industry (M.Griffith)	IPPOSI	Ireland	13	27
58	Mérieux Alliance (Ch.Bréchot)	Mérieux Alliance	France	1	27

PART B

B1. Concept and objectives, progress beyond state-of-the-art, S/T methodology and work plan

B 1.1 Concept and project objective(s)

The preparatory phase will

- develop the plan to integrate existing quality controlled biobanks, biomolecular resources and enabling technologies into a pan-European biomedical research infrastructure (WP2, 3, 4, 5),
- provide a concept for its operation and codes of conduct for European biobanks, particularly considering the different technical standards and types of health care integration currently applied (WP1-6),
- evaluate the heterogeneous European ethical and legal frameworks and find solutions how to implement a pan-European infrastructure (WP6),
- elaborate sustained funding and financing solutions for this key resource (WP7),
- deliver:
    - contracts defining the interaction and terms and conditions of members and partners with BBMRI and securing compliance with sample and data sources (D1.13, M2, 4),
    - negotiate contracts between BBMRI and/or members with funding organizations to solidify the long-term funding for this European infrastructure (D1.12M3, 4),
    - access agreements for users and associated IP and data-sharing policies (D1.8, M4),
    - in corporation of appropriate legal structure (D1.9).

The work during the preparatory phase will mainly build on achievements of previous and ongoing national, European and global projects and initiatives, such as research projects funded under FP5 and FP6 as well as new projects under FP7, public/private partnerships (PPPs) which are directly related to the needs of BBMRI, work on biobank harmonization done by the P3G consortium, the strategic research agenda of the Innovative Medicines Initiatives, the WHO, and the OECD initiative on a global network of Biological Resource Centres. Key representatives of these projects and initiatives will contribute to the goals of the preparatory phase as participants in work packages, members in various boards or as external experts. Furthermore, a large majority of European biobanks have expressed their interest in BBMRI and are involved in the preparatory phase to ensure that the solutions developed fit with their requirements. The development of the funding and financial framework for BBMRI will be facilitated by research and health ministries as well as by funding agencies. 23 ministries and research funding agencies from 13 different European countries have already committed themselves to active participation in this project.
The work packages focus on the one hand on the specific requirements of different biobank formats (WP2, 3) and biomolecular resources (WP4), and on the other hand they address issues related to the whole infrastructure such as databases and biocomputing (WP5), governance in ethical, legal societal issues (ELSI) (WP6), operation, funding and financing (WP7). This work will be performed by work package leaders and partners as well as by external expert groups. In a public consultation process, the results generated will be presented to the scientific community, to industry

and to the large group of stakeholders in order to achieve broad consensus as a basis for long-term agreements and sustained funding commitments of Member States.
The management and organizational structure of the preparatory phase foresees an open and transparent decision-making process that has already been successfully established at other trans-national organizations. Since the structure of the preparatory phase anticipates to a large extent the management structure required for the operation of BBMRI, a smooth transition from the conceptual level to its implementation is expected.

The preparatory phase will take advantage of important previous work and international consensus already achieved on several key issues (e.g., OECD best practice guidelines for the operation of Biological Resource Centres, and ISBER Guidelines on Biobanking). Furthermore, the basic concept of BBMRI has already been presented to the scientific and stakeholder community at a Partner and Stakeholder Meeting on March 17th 2007 in Vienna. At this meeting, 115 participants from 19 countries provided their comments on the concept and suggested specific issues to be addressed in the preparatory phase.

B 1.2 Progress beyond the state of the art

1.2.1 Rationale and starting point

Following the rapid progress in genomics research of humans and their ancestors, biomedical and health research has expanded from the study of rare monogenic diseases to common, multifactorial diseases (Collins et al., 2003). Innovative, high-throughput technologies are widely expected to enable a better dissection of these complex, causally heterogeneous diseases into more specific diagnostic entities, which is a requirement for the advancement of personalised medicine (Kittler et al., 2004; Sauer et al., 2005; Stelzl et al., 2005; Hoheisel, 2006;). A sharper, biology-based definition of disease categories will enhance the development of more effective treatment, reduce undesired side effects of new treatments, improve success in clinical trial design, and will lead to new concepts of disease prevention. Elucidation of complex disease aetiology is challenging because diseases are caused by a large number of small, often additive effects, representing the sum of the consequences of genetic predisposition, lifestyle and the environment. Revealing these complex interactions will depend critically on the study of large sets of well-documented, up-to-date epidemiological, clinical, biological and molecular information and corresponding material from large numbers of patients and healthy persons, collected and made available by biobanks (Kaiser, 2002; Bouchie, 2005; Hagen and Carlstedt-Duke, 2004; Manolio et al., 2006). The biological material collected in biobanks for biomedical research typically comprises DNA, tissues, cells, blood or other body fluids. Although currently established biobanks and biomolecular resources are a specific European strength, valuable and irreplaceable national collections typically suffer from fragmentation of the European biobanking-related research community, variable access rules and the lack of commonly applied standards (Hirtzlin et al., 2003; Hagen and Carlstedt-Duke, 2004). This hampers the collation of biological samples and data from different biobanks which is prerequisite to achieve sufficient statistical power. Moreover, it results in duplication of effort and jeopardises sustainability because of the lack of long-term comprehensive funding approaches. This results in a risk of these valuable resources being analyzed and emerging innovations commercially utilized outside Europe. There is also a need to strengthen the capacity to develop networks of biobanks meeting high standards of integration compatible with the design of studies structured as Phase II or

III clinical trials. This type of study design is essential for validation and translation of biomarkers into clinical practice.

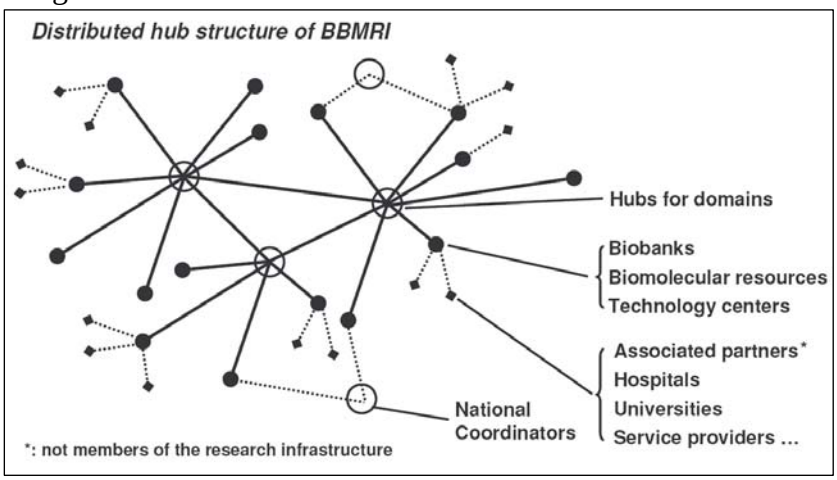
B 1.3 S/T Methodology and associated work plan

B 1.3.1 Overall strategy and general description:

Overall strategy

To overcome current limitations and to cover the needs of the scientific community a pan-European resource will be constructed by linking the individual efforts mentioned above: Key components of BBMRI are thus comprehensive collections of biological samples from different (sub-) populations of Europe, which should be linked with continuously updated data on the health status, lifestyle and environmental exposure of the sample donors. This can only be achieved in a federated network of centres established in most, if not all, European Member States (Litton et al., 2007). Therefore, the format of BBMRI should be a distributed hub structure in which the hubs coordinate activities, including collection, exchange and analysis of samples and data for the major domains. The biobanks, biomolecular resources and technology centres, which are members of BBMRI, are associated with their specific domain hub. Furthermore, a variety of public or private partners (e.g., universities, hospitals, companies), which provide biological samples, data, technologies or services, may be associated with certain BBMRI members (Figure 1). This structure provides great flexibility so that new members and partners can be connected at any time and that it can be easily adapted to emerging needs in biomedical research. The IT-infrastructure which employs federated database architecture and grid computing technology will integrate the complex network of hubs, members and partners into a single virtual infrastructure (Litton et al., 2007). Hubs will be coordinated and directed by an executive management, which is supported by a governance council as well as by a high-calibre advisory board and receives input from the Stakeholder Forum to guarantee clear responsibilities as well as open and transparent decision-finding processes.

Figure 1: The distributed hub structure of BBMRI.



Biobanks, biomolecular resources and technology centres are members of BBMRI and connected to their specific hub. Partners, who are not members, may be associated with members. In addition to domain-specific hubs there are national coordinators to address issues specific for EU Member States, such as legislation or national funding systems.

- BBMRI members represent the key providers of resources and technologies. Members are leaders in the field and drivers of innovation and scientific excellence. Membership may be on a non-exclusive basis favouring that members provide a link of BBMRI to other national, European (e.g., other FP7 programs) and global initiatives (e.g., the emerging OECD global network of Biological Resource Centres or WHO programs).

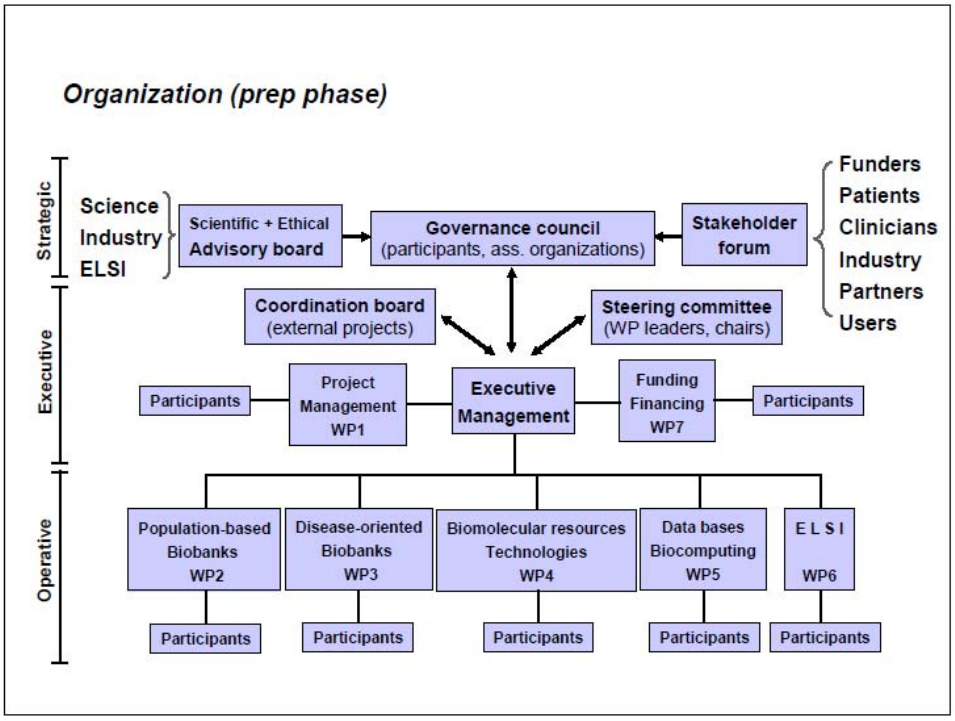
- Associated partners and subcontractors provide certain resources (services, data, samples, materials) to BBMRI. An associated partner, for instance, a hospital or research institute which provides biological samples and data, may be either reimbursed or compensated for its contribution by being granted free access to resources and technologies of the BBMRI. Associated partners may also be ministries, governments, research councils, and funding agencies from interested countries whether or not they currently support biobank or biomolecular resource projects in their country.
- Users may come from different fields of academia and industry. Access will be provided in the context of specific research projects and on the basis of secured funding. Incentives may be provided for EU Member States and for industry to enter into general user agreements.

BBMRI will integrate several ongoing international activities, such as those pursued by P3G, the Innovative Medicines Initiative, ISBER, the OECD, and the WHO, as well as research projects funded under FP5/FP6 and new projects under FP7. To avoid duplication of activities, BBMRI will exchange concepts and experience with these activities. Ultimately, this will favour the study of important biomedical research questions that are beyond the scope of a single effort. Short-term benefits will appear soon, such as increased quality and reduced cost of research through better coordination, while longer perspectives include increased efficacy of drug discovery and development, and finally novel possibilities in health care (such as personalised medicine) and secured European competitiveness in research and industry.

General process

At the beginning of the preparatory phase there will be a kick-off meeting of the governance council where the tasks for all work packages (WP) will be explained and harmonized. Furthermore, dates for upcoming council and board meetings will be defined (overview on organization Figure 2, the work flow Figure 3).

Figure 2: Organization of the preparatory phase.



This is followed by a parallel process involving WP 2-6 in which existing resources, tools and documents will be evaluated, unresolved issues on how these elements can be integrated in the infrastructure identified, solutions elaborated, and finally a concept for operation for specific domain hubs developed (Table 1). Results will be summarized in a report, which will serve as basis for the preparation of contracts, which define the relationship of BBMRI and members. This parallel process will be supported by external experts selected according to their specific expertise related to the topic addressed. This approach allows extending the contributing expertise even beyond Europe, and to include experts, who have not been included as co-applicants during the preparatory phase, and whenever unforeseen problems emerge.

Table 1: Examples of existing guidelines, procedures and recommendations applicable to BBMRI

Title	Organisation	Link
Tissue banking for Biomedical Research	National Cancer Centre	http://www.bioethics-singapore.org/resources/pdf/AppendixB-Dr%20Kon.pdf
Biorepository Protocols	Australian Biospecimen Network (ABN)	http://www.abrn.net/pdf/ABN_SOPs_Review_Mar06_final.pdf
Biological Resource Centres: underpinning the future of life sciences and biotechnology	Organization for Economic Co-operation and Development (OECD)	http://wdcm.nig.ac.jp/brc.pdf
OECD best practice guidelines for biological resource centres	Organization for Economic Co-operation and Development (OECD)	http://www.wfcc.nig.ac.jp/Documents/OECD.pdf
European Human Frozen Tumor Tissue Bank TUBAFROST	The European Human Tumour Frozen Tissue Bank (TUBAFROST)	http://www.tubafrost.org
Common Minimal Standards for Biological Resource Centers	International Agency for Research on Cancer, World Health Organization	http://www.iarc.fr/News/RecommendationsBRC.pdf
Human tissue and biological samples for use in research. Operational and ethical guidelines	Medical Research Council (MRC)	http://www.mrc.ac.uk/pdf-tissue_guide_fin.pdf
Best Practices for Repositories I: Collection, Storage, and Retrieval of Human Biological Materials for Research	International Society for Biological and Environmental Repositories (ISBER)	http://ehs.sph.berkeley.edu/Holland/Biorep/BestPractices2005.3.5.pdf
First-Generation Guidelines for NCI-Supported Biorepositories	National Cancer Institute (NCI)	http://biospecimens.cancer.gov/biorepositories/NCI_First_Generation_Biorepository_Full_Guidelines.pdf
Transport of infectious substances	World Health Organization (WHO)	http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2005_22r%20.pdf
UN Recommendations on the Transport of Dangerous Goods. Model Regulations.	United Nations Economic Commission for Europe (UNECE)	http://www.unece.org/trans/danger/publi/unrec/rev13/13files_e.html
A Cold Greeting: an Introduction to Cryobiology	Biotech	http://www.bioteach.ubc.ca/Bioengineering/AColdGreeting/
Specimen Collection, Preparation, and Handling	Labcorp	http://www.labcorp.com/datasets/labcorp/html/frontm_group/frontm/section/speccol.htm

The funding and financing work package (WP7) follows a different process since the major goal of this WP for year 1 is to prepare the documents required to ensure funding and financing of the implementation and operation of BBMRI. These documents, which

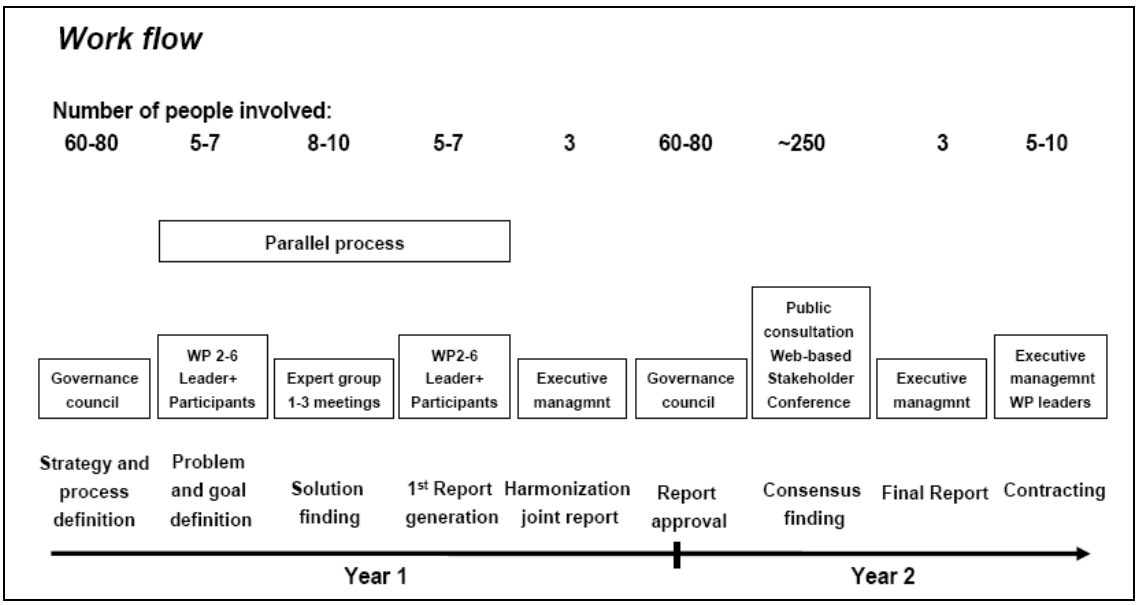
will be prepared by professional institutions on a contractual basis, will analyse the impact of BBMRI on science, industry and healthcare. Moreover, special emphasis has to be placed on the value generated for society and on the expected short-, mid-, and long-term return of investment to make possible long-term funding agreements. WP7 has to deliver a concept for funding and financing of BBMRI, which considers a variety of national and European funding schemes, financing through the health care system, income from industrial co-operations as well as contributions from patient organizations and private foundations.

The results of the work of the first year will be summarized in a joint report which, after approval by the governance council, will be subjected to a public consultation process. The joint report will be made publicly available on the internet and comments will be sought from a broad spectrum of organizations and individuals. Furthermore, public consultation will include a Stakeholder Forum meeting, which allows more interactive communication and exchange of ideas than the web-based approach. Results of this consultation process will be included into the final report by the Executive Management.
In the first quarter of year two the following documents will be available as starting points for the contract filing phase:

- Reports on the expected impact of BBMRI on science, industry and health care and the expected direct or indirect return of investments
- A report considering the input of major stakeholders on the overall concept of BBMRI including organizational, technical as well as ethical and legal issues
- A concept for operation of BBMRI
- A general framework for integrating biobanking within translational schemes of biomarker development, including phase II and phase III clinical trials on biomarkers.

The drafting of contracts will be directed by the executive manager in close cooperation with WP7 (Funding and Financing), the coordinator and by involvement of the leaders of WPs2-6 as well as external legal advice. The draft contracts, which will have been prepared by this time under direct involvement of representatives of several European ministries and funding agencies, who are participants in WP7, will then also be presented to and discussed with ministries and funding agencies of European Member States which are not participants in order to achieve broad support.

Figure 3: General work flow for the preparatory phase



After this consultation step, final contracts will be filed and made available for signature. Two types of contracts will be prepared: 1) Contracts to secure funding of construction and operation of BBMRI, 2) Contracts to define the relationship of members, such as biobanks, resource or technology centres with BBMRI. Including but not limited to;

- contracts defining the interaction and terms and conditions of members and partners with BBMRI and securing compliance with sample and data sources
- contracts between BBMRI and/or members with funding organizations
- access agreements for users and associated IP and data-sharing policies
- incorporation of appropriate legal structure

It is planned to complete the preparatory work within two years. Thereafter an additional period of 3 months is foreseen to obtain the signatures and prepare transition to the construction phase.

This fast-moving strategy is enabled by the flexible decentralized hub architecture of BBMRI, which allows starting its operation already with a small number of members representing the leading and most advanced European biobanks and resources, any of which are already engaged in national and/or international programs aimed at networking biobanks and harmonizing standards. At the same time, the architecture provides for and facilitates continuous growth and development of BBMRI by inclusion of further members at any later time point. In particular, the dynamic architecture of BBMRI makes it possible to stimulate the development of biobanking activities in new EU Members States. Finally, this architecture is highly compatible with worldwide networking, providing a model for integrating biobanks from low/middle income and emerging countries in Asia, Latin America and Africa.

General description of work packages

Work package 1 (management and coordination)

To enable this process as described above, WP1 will establish an executive management team consisting of the coordinator (leader of WP1 and chair of the executive management), the associate coordinator (participant 7 of WP1 who is responsible for coordinating all operation-related issues, the leader of WP7 (Funding and Financing), and an executive manager. Specific responsibilities of the management team are:

- Project management
- Communication with European Commission
- Public relations
- Development of operational concept
- Development of implementation plan
- Preparation of contracts
- Global integration

Work package 2 (Population-based biobanks)

The mission of WP2 of BBMRI is to provide a strategy to solve the legal, governance and financial challenges involved in the Europe-wide cataloguing and storage of the

vast amount of information collected in large epidemiological sample collections and population cohorts. The effort aims at establishing a European infrastructure for collection, storage, annotation, validation, and dissemination of the diverse data collected in national cohorts and sample collections. Such an infrastructure needs to be able to facilitate also the collection and storage of the biological data collected with '-omics' technologies from various platforms and diverse cell and tissue samples

Work package 3 (disease-oriented biobanks)

The mission of WP3 of BBMRI is to foster collaboration, harmonizing and networking of disease-oriented biobanks (which also may be referred to as clinical biobanks). These can be used to discover or validate genetic and non-genetic risk factors, without having to wait for great lengths of time and spend large efforts on longitudinal, prospective collection. The objectives of this work package are (a) to develop a long-term, strategic vision of the role and place of disease-oriented biobanking at the interface between clinical practice an research; (b) to provide solutions for networking biobanks in a way that maximizes the opportunities for the discovery of new biomarkers and their validation and translation towards clinical applications; (c) to provide support for the development of a European framework facilitating harmonization of standards through certification and accreditation procedures

Work package 4 (Biomolecular resources and molecular tools)

WP4 will develop a concept to integrate existing biomolecular resources, technologies, standards and know-how into the operational concept of BBMRI, and provide molecular tools for interrogation of biobanked samples. The focus areas will be to catalogue and ensure the availability of antibodies and other binding reagents as affinity probes for the detection of proteins in biobanked samples (e.g. as potential biomarkers), together with resources for experimental procedures to be employed in analysis of biobanked samples (Gustafsdottir et al., 2005; Taussig et al., 2007). Resources of DNA and proteins will be included where they are directly relevant to these aims, e.g. as means of raising antibodies or performing sample analyses. The WP will work towards the establishment of standards for sample analysis and develop linked web resources and databases for the reagents and technologies. The efforts will directly complement the resources of WP3 towards biomarker discovery.

Work package 5 (Database harmonization and IT-infrastructure)

The move towards a universal information infrastructure for biobanking in Europe is directly connected to the issues of semantic interoperability through standardized message formats and controlled terminologies. The information infrastructure has become a critical component in life-sciences research. The explosion of genotype data requires that data are properly loaded, accessed, managed, queried, analyzed and shared. Longitudinal research over a long period of time, for generations of researchers, demands completely new methods and systems for gathering and storing genotype and phenotype information (Totowa, 2007; Ölund et al., 2007). The biobanks bring to the fore the problems concerning the need for standardized research data and a long-term storage strategy.

Work package 6 (Ethical, legal and societal issues)

Developing an infrastructure "properly embedded into European ethical, legal and societal frameworks" requires some specific preparation on ELSI issues, both on operational questions that deals with the immediate feasibility of the endeavour and on more fundamental questions in order to understand the issues at stake and how they may impact on the organization and the public(s) perception of BBMRI and the public(s) engagement. Both aspects have to be addressed in the preparatory phase, by mean of coordination activities, and WP6 will work in these two directions: 1) rapid operationality based on existing frameworks which will result in practical tools and 2) preparatory steps for long-term solid BBMRI foundation in ethical, legal and social aspects, which will result in background paper, proposals and some level of piloting of approaches and methodologies.

Work package 7 (Funding and Financing)

The increasingly large number of biobanks that now exists provides a sound and pertinent infrastructural underpinning for a growing range of clinical research and genome epidemiology studies. However, biobanks are expensive to set up and maintain for long term studies. Lack of sustained funding has been identified as a major bottleneck in establishing long-term operation of resource centres for life sciences.
The WP will explore and summarize the current structural and operational funding of biobanks and biomolecular resources in different European countries. The information collected will be used as the starting point for discussion among different key players on the development of long-term funding concepts, which consider the whole spectrum of funding schemes including national, European and private funding organizations as well as financing solutions provided by the EIB.

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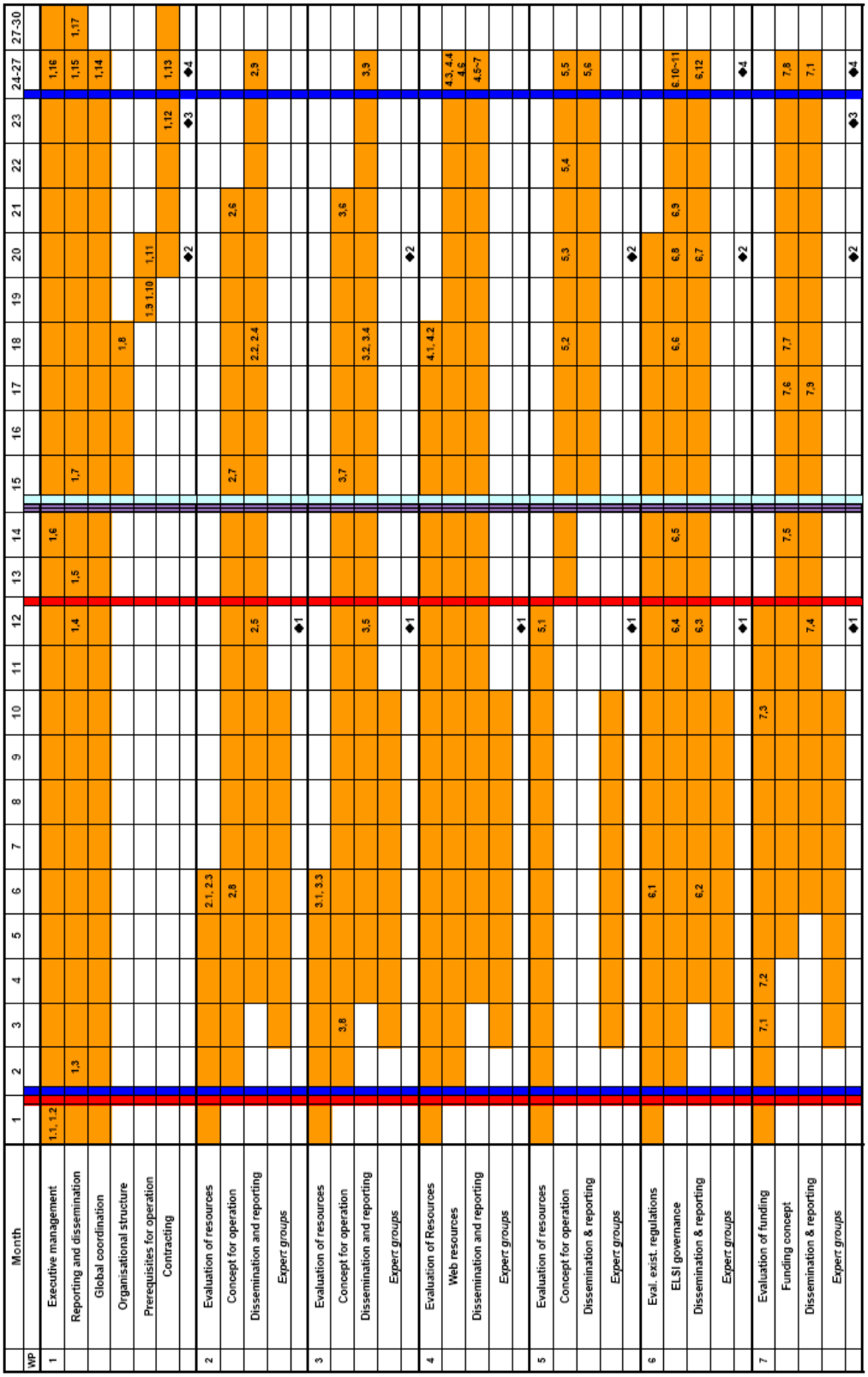
B 1.3.2 Timing of work packages and their components:



B 1.3.3 Work package list / overview:

Work Package No	Work Package Title	Type of activity	Leading Beneficiary No	Person-months	Start month	End month
WP1	Project Management and coordination	**MGT**	**1**	**162**	**1**	**30**
WP2	Population-based biobanks	**COORD**	**2**	**96**	**1**	**27**
WP3	Disease-oriented biobanks	**COORD**	**3**	**90**	**1**	**27**
WP4	Biomolecular resources and molecular tools	**COORD**	**4, 5**	**49**	**1**	**27**
WP5	Databases harmonisation and IT-infrastructure	**COORD**	**5**	**84**	**1**	**27**
WP6	Ethical, legal and societal issues	**COORD**	**6**	**65**	**1**	**27**
WP7	Funding and financing	**COORD**	**7**	**99**	**1**	**27**
			TOTAL:	**645**		

B 1.3.4 Deliverables list:

Delive-rable Number	Deliverable Title	WP no.	Lead bene-ficiary number	Estimated indicative person-months	Nature	Dissemi-nation level	Delivery date (project month)
D1.1	Employment of executive manager	1	1	2	Other	PU	1
D1.2	Establishment of all boards	1	1	3	Other	PU	1
D1.3	Release of web-site for preparatory phase	1	1	4	Other	PU	2
D3.8	Rules of involvement of scientific community	3	6	6	Report	PU	3
D7.1	WP7 participants meeting	7	6	2	Report	PP	3
D7.2	Report on current funding situation	7	6	13	Report	PU	4
D2.8	Rules of involvement of scientific community	2	3	4	Report	PU	6
D2.1	Inventory on existing population biobanks	2	13	7	Report	PU	6
D2.3	Review of technical solutions and quality criteria	2	43	6	Report	PU	6

Delive-rable Number	Deliverable Title	WP no.	Lead bene-ficiary number	Estimated indicative person-months	Nature	Dissemi-nation level	Delivery date (project month)
D3.1	Inventory on existing clinical biobanks	3	28	10	Report	PU	6
D3.3	Review of technical solutions and quality criteria	3	8	9	Report	PP	6
D6. 1	Report on ethics related policies for biobanks and biomolecular resources in countries of BBMRI partners and members	6	6	5	Report	PP	6
D6.2	Design of legal WIKI+ platform	6	42	6	Other	PP	6
D7.3	WP7 participants meeting	7	6	2	Other	PP	10
D1.4	Report of harmonized results from work packages	1	1	14	Report	PP	12
D2.5	System of incentives for providers of biological samples	2	6	10	Report	PP	12
D3.5	System of incentives for providers of biological samples	3	1	6	Report	PU	12
D5.1	Inventory of standard related issues, including stakeholder coordination	5	5	15	Report	PU	12
D6.3	Launch of legal WIKI+ platform and mobilising BBMRI stakeholders	6	42	3	Other	PU	12
D6.4	Background document on harmonization from an ethical point of view	6	6	3	Report	PU	12
D7.4	Reports on impact of BBMRI on science, industry and healthcare	7	6	2	Report	PP	12
D1.5	Information package (flyer, brochure)	1	1	5	Report	PU	13
D1.6	Stakeholder Forum meeting and international conference	1	57	6	Other	PU	14
D6.5	Background document on how BBMRI should address its social dimension	6	44	12	Report	PU	14
D7.5	Report on financial needs of BBMRI	7	6	18	Report	PP	14

Delive-rable Number	Deliverable Title	WP no.	Lead bene-ficiary number	Estimated indicative person-months	Nature	Dissemi-nation level	Delivery date (project month)
D1.7	Interim report	1	1	4	Report	PU	15
D2.7	Concept for national hubs of population biobanks	2	2	14	Report	PP	15
D3.7	Concept for national hubs of clinical biobanks	3	14	7	Report	PP	15
D7.6	WP7 participants meeting	7	6	2	Other	PP	17
D7.9	WP7 participants meeting	7	6	2	Other	PP	17
D1.8	Operation concept	1	7	16	Report	PP	18
D2.2	Web-based overview catalogue of existinh biobanks, collaboration with P^3G	2	2	16	Other	PU	18
D2.4	Electronic manual of existing documents for biobanking methods	2	2	18	Other	PU	18
D3.2	Web-based overview catalogue	3	3	11	Report	PU	18
D3.4	Electronic manual of existing documents for biobanking methods	3	7	13	Report	PU	18
D3.11	Education and training – European MSc/PhD in Management of Biological Resources	3	8	0	Report	PP	18
D4.1	Report on affinity reagent resources and centres in Europe with inventories and details of access, and prospective plans	4	51	8	Report	PU	18
D4.2	Reports on European technology resources for nucleic acids, proteins and metabolites, and prospective plans	4	4	8	Report	PP	18
D5.2	Strategy for unique and secure identities for specimens, subjects and biobanks	5	5	15	Report	PP	18

Delive-rable Number	Deliverable Title	WP no.	Lead bene-ficiary number	Estimated indicative person-months	Nature	Dissemi-nation level	Delivery date (project month)
D6.6	Schema of a conceptual model of governance applicable to a pan-European infrastructure for ELSI issues	6	6	12	Report	PP	18
D7.7	Funding and financing concept	7	6	16	Report	PP	18
D1.9	Definition of legal entity of BBMRI	1	1	6	Report	PP	19
D1.10	Agreement on location of executive management and hub-directors offices	1	1	6	Report	PP	19
D1.11	Implementation plan	1	1	16	Report	PP	20
D5.3	Strategy for communication between biobanks including a common nomenclature (data models/schema and coding systems/ontologies), compatible software techniques and appropriate information transmission policies.	5	5	14	Report	PP	20
D6.7	Uploading and validation of documents of BBMRI Members and Partners	6	42	1	Other	PU	20
D6.8	Strategic plan and scenarios for BBMRI interactions with various publics	6	6	12	Report	PP	20
D2.6	Concept of a pilot network of biobank infrastructures	2	2	20	Report	PP	21
D3.6	Concept of a pilot network of biobank infrastructures	3	3	11	Report	PP	21
D6.9	Flow chart of an operational integrated ELSI governance model	6	46	1	Other	PP	21
D5.4	Requirements for a general information management system for European biobanks.	5	5	14	Report	PU	22
D1.12	Contracts for funding organizations	1	1	22	Other	PP	23

Delive-rable Number	Deliverable Title	WP no.	Lead bene-ficiary number	Estimated indicative person-months	Nature	Dissemi-nation level	Delivery date (project month)
D1.13	Contracts for BBMRI partners	1	1	18	Other	PP	27
D1.14	Global status and consensus report	1	8	18	Report	PU	27
D1.15	Scientific and Ethical Advisory board meetings	1	9	4	Other	PP	27
D1.16	Governance Council, Coordination board, and Steering committee meetings	1	1	12	Other	PP	27
D2.9	Final report	2	2	2	Report	PU	27
D3.9	Final report	3	3	17	Report	PU	27
D3.10	Clinical biobanking in the field of cancer research	3	8	0	Report	PP	27
D4.3	Report on quality standards to be adopted for reagents in Europe	4	51	4	Report	PP	27
D4.4	Reagent database with common ontology standards	4	51	4	Other	PU	27
D4.5	Technologies database	4	4	15	Other	PU	27
D4.6	Website for resources and molecular technologies	4	4	7	Other	PU	27
D4.7	Final report, including foresight on the construction phase of BBMRI	4	4	3	Report	PU	27
D5.5	Strategy for a federated hub and spoke structure for European Biobanking.	5	5	14	Report	PP	27
D5.6	Final report	5	5	12	Report	PU	27
D6.10	Overall report and recommendations for BBMRI ELSI, including educational proposals	6	6	3	Report	PU	27
D6.11	Implementation and monitoring of gender issue plan	6	46	2	Other	PP	27
D6.12	Final report	6	6	5	Report	PU	27
D7.8	Contracts ready for signature	7	6	20	Other	PP	27

Delive-rable Number	Deliverable Title	WP no.	Lead bene-ficiary number	Estimated indicative person-months	Nature	Dissemi-nation level	Delivery date (project month)
D7.10	Final report	7	6	18	Report	PU	27
D1.17	Final report and memorandum of understanding	1	1	6	Report	PU	30
			total	645			

B 1.3.5 Work package descriptions:

WP1 Project Management

Work package number	**1**	**Start date or starting event:**			Mo 1
Work package title	Project Management				
Activity Type	MGT				
Participant number **Participant short name**	**1** MedUG	**7** UNIMAN	**8** IARC	**9** LUMC	**57** IPPOSI
Person-months per participant:	54	18	18	6	6
Participant number **Participant short name**	**55** U.TURKU				
Person-months per participant:	60				

Objectives: WP1 coordinates and supervises all processes of the project. It is responsible for reporting to the EU, and coordinates and supervises all contract negotiations. In particular, WP1 organizes the advisory board, governance council and Stakeholder Forum meetings, prepares documents for and reports of these meetings, and is responsible for public relations. Furthermore, it coordinates the activities of BBMRI with that of other external projects and takes care of proper integration of BBMRI in the global context.

Description of work

Task 1: Establishment of the executive management team. It will consist of the coordinator (leader of WP1 and chair of the executive management), the associate coordinator (participant 9 of WP1) the leader of WP7 (Funding and Financing), and of an executive manager. The executive manager will be employed immediately after start of the project. An executive management office will be established.

D1.1: (MedUG, UNIMAN, IARC, LUMC, U.TURKU)

Task 2: General project management. WP1 is responsible for the smooth interaction of all parts of the project and the assurance of the workflow. In particular, it is responsible for establishing and maintaining efficient communication between the individual bodies of the project and supervises the progress in the work packages according to their work plan.

D1.4: (MedUG, UNIMAN, U.TURKU)

Task 3: Reporting to the EU. WP1 will collect the information from the project partners and prepare the reports for the European Commission as requested, including an ethics section, and pertinent documents (approval by the local Ethics Committees involved in the project and Consent Forms to be used for the collection of samples from the donors and subsequent uses).

D1.7: Interim report (MedUG, UNIMAN, U.TURKU)

D1.17 Final report (MedUG, UNIMAN, U.TURKU)

Task 4: Organization of meetings: WP1 will be responsible for the organization of several meetings

including 2 Governance Council meetings, 2 Advisory Board meetings, 1 Stakeholder Forum conference, 1 international scientific conference, 2 Coordination Board meetings, and ca. 4 Steering Committee meetings. The Steering Committee meetings may also be held as conference calls. To reduce the number of events and travel expenses 1 Governance Council meeting, 1 Advisory Board meeting, the Stakeholder Forum Conference and the international scientific conference will be combined to one large event scheduled for the first quarter of year 2. For these meetings, the program, information packages, working documents and meeting reports will be prepared by the executive management.

D1.2: (MedUG, LUMC, IPPOSI, U.TURKU)

D1.6: (IPPOSI, MedUG, U.TURKU)

D1.15 (LUMC, MedUG, U.TURKU)

D1.16 (MedUG, U.TURKU)

Task 5: Dissemination and public relations. In addition to scientific publications and publications of the project partners and the international conference, WP1 will generate flyers and brochures for experts and lay public to inform about the importance of BBMRI for Europe. Furthermore, a web-site will be set up for internal as well as external communication. The content of the documents will be prepared in close collaboration with the work package leaders. The design of the documents and hosting of the web-site will be outsourced to professional providers.

D1.3: (MedUG, U.TURKU)

D1.5: (MedUG, UNIMAN, U.TURKU)

Task 6: Coordination with other European and global initiatives. The Coordinator also chairs the Coordination Board of external projects. This board is established to develop synergies with other biomedical sciences research infrastructures and to avoid duplication of efforts. Furthermore, the concept of BBMRI will be harmonized with the biobanking needs of the Innovative Medicines Initiative. To monitor the progress made in external projects and to fine tune the activities with the various projects and programs, representatives of the external projects will participate in the Coordination Board. Global networking and integration of BBMRI is a specific task of participant 8 who will be responsible for knowledge transfer and harmonisation of the strategies, guidelines and recommendations of the project into other inter- or supranational organisations like the OECD or non-European national institutions like NIH (U.S.A.) or MOST (Japan).

D1.14 (IARC, MedUG, U.TURKU)

Task 7: Operational concept. Work packages 2-6 will deliver biobank format- and resource-specific recommendations for the operation of BBMRI. Participant 9 will integrate the recommendations made into an operational concept, which also forms a basis for contracts defining the relationship of individual members within BBMRI.

D1.8: (UNIMAN, MedUG, U.TURKU)

Task 8: Legal entity and location of executive management office for the operation phase. The best legal entity will be identified by support of legal advisors and in collaboration with WP6 and WP7. In addition to legal and logistic issues, the agreement on the final location of the executive office will take into account the specific support provided by Member States and local governments in hosting the office.

D1.9: (MedUG, U.TURKU)

D1.10: (MedUG, UNIMAN, U.TURKU)

Task 9: Implementation plan. Based on the operational concept and the results of the work of WPs 2-7 an implementation plan for BBMRI will be developed.

D1.11 (MedUG, UNIMAN, U.TURKU)

Task 10: Contracting. The executive management will be in charge of drafting and negotiating the contracts with ministries, funding agencies, other funding sources, and industry. All funding and financing-related issues will be performed in close interaction with WP7. Furthermore, contracts which regulate the relationship (funding, contribution of materials and resources, access to infrastructure, general support and services, success-dependent incentives, etc.) between members and BBMRI will be provided. The drafting of contracts will be outsourced to lawyers.

D1.12: (MedUG, U.TURKU)

D1.13: (MedUG, U.TURKU)

Deliverables (month of delivery)

D1.1: Employment of executive manager (mo1)

D1.2: Establishment of all boards (mo1)

D1.3: Release of web-site for preparatory phase (mo2)

D1.4: Report of harmonized results from work packages (mo12)

D1.5: Information package (flyer, brochure) (mo13)

D1.6: Stakeholder Forum meeting and international conference (mo14)

D1.7: Interim report (mo15)

D1.8: Operation concept (mo18)

D1.9: Definition of legal entity of BBMRI (mo19)

D1.10: Agreement on location of executive management and hub-directors offices (mo19)

D1.11: Implementation plan (mo20)

D1.12: Contracts for funding organizations (mo23)

D1.13: Contracts for BBMRI partners (mo24)

D1.14 Global status and consensus report (mo 24)

D1.15 Scientific and Ethical Advisory board meetings (mo24)

D1.16 Governance Council, Coordination board, and Steering committee meetings (mo24)

D1.17 Final report and memorandum of understanding (mo 30)

WP2 Population-based biobanks

Work package number	**2**	**Start date or starting event:**		Mo 1
Work package title	Population-based biobanks			
Activity Type	COORD			
Participant number **Participant short name**	**2** NPHI	**3** GSF	**6** INSERM	**11** NTNU
Person-months per participant:	41	7	8	8
Participant number **Participant short name**	**13** UTARTU	**33** UK Biobank	**36** UMCG	**43** deCODE
Person-months per participant:	8	8	8	8

Objectives

Large population-based cohorts of Europe containing samples and reliable phenotype and epidemiological information are critical when the population impact of an identified genetic variants or joint effects of genes and environment/life style is being evaluated. Such analyses in large prospective cohorts are necessary before any translational use of the genome or other '-omics' information in early diagnosis, or prediction of disease progress, mortality or response to treatment. For this, coordination of European biobanks and better availability of their samples/data for the research community are imperative.

WP2 will coordinate collaborative activities between population-based European biobanks, including prospective cohorts and twin cohorts. It will deliver guidelines for harmonized data structures for both existing biobanks and new collections. For this, WP2 addresses questions of construction and operation of the infrastructure, quality criteria, availability of samples and data, including rules of access, and incentives for participation. The strategy builds on previous work like existing cataloguing efforts by the P^3G observatory and the OECD guidelines. Regarding practises of consent, data protection and rules of access and release there will be close co-ordination with ethical and IRB boards of EU countries as well with developing policy documents of NIH and funding agencies like Wellcome trust. Corresponding activities, such as P^3G and FP7 biobank-related research networks will be integrated.

Description of work

The major effort will be on the existing population biobanks, due to high immediate demands on data harmonization and codes of conduct. From their experience as well as evaluating infrastructures of new biobanks (such as UK biobank), reflecting the state-of-the-art in data collection and storage, we will define recommendations for all the components of data collection and harmonization, to be set as a standars for future biobanking efforts..

Task 1: Integrate existing European population biobank datasets into the operational concept of BBMRI. (i) At the beginning, an inventory on existing population biobanks, including prospective studies and twin cohorts in Europe will be made. (ii) The initial list of population biobanks (see Table 7) of BBMRI will be complemented with additional biobanks, interested to join and capable to provide datasets of high quality. A web-based overview catalogue will be established (a close collaboration with the observatory element of P^3G) , which describes the available data and resources (DNA, blood, urine, tissue, cells) and the possibilities for access according to informed consent, etc. (iii) Review of technical solutions and quality criteria for storage, retrieval and transfer of biological samples in the collaborating biobanks. (iv)

Electronic manual of existing guidelines and other relevant documents for biobanking methods (general considerations for laboratory infrastructure, sample collection and transport, sample processing and storage, DNA extraction and storage, DNA measurement and normalisation).

D2.1 (UTARTU, NPHI, GSF)

D2.2 (NPHI, INSERM, UK Biobank, UMCG)

D2.3 (deCODE, NTNU, NPHI)

D2.4 (NPHI, UMCG, deCODE, NTNU)

Task 2: Identify unresolved issues: (i) The lack of common rules, how access to existing biobanks is possible, how the review process of applications for access to and use of samples could be organised, what the criteria are for scientifically sound study protocols, how competing interests of different groups in the same samples can be met in a transparent and fair way, which fees are appropriate for academic and industrial users etc. (ii) Standards for new collections are needed which should be based on best knowledge and on modern technical solutions, from preparation of the sample to storage, retrieval and transfer. (iii) Organizing of the data on existing biobanks in such a way, that the areas where there is need for new collections can easily be identified

Task 3: Find solutions to motivate existing population biobanks to make their resources available to qualified investigators, (i) a system of incentives for providing biological samples within BBMRI shall be developed (model of incentives for contributors, contribution points, internal budget). (ii) The concept of a pilot network of biobank infrastructures shall be developed. It aims at providing a framework for training, testing and assessing proposed standards, and at developing networking/tissue and specimen transfer protocols. (iii) For some countries it might be helpful to develop a structure for their national biobanks and collections of biological samples which then could serve as a national hub. This might allow to deal more specifically with the given rules of ethics, data confidentiality etc. which can be quite different between different countries. The final goal should be a document providing rules for quality criteria which can be monitored and audited.

D2.5 (INSERM, NPHI, UTARTU)

D2.6 (NPHI, UK Biobank, INSERM, NTNU, deCODE)

D2.7 (NPHI, GSF, UTARTU, UMCG)

Task 4: Proper involvement of the scientific community: (i) The partners of WP2 will closely collaborate with the WP2 participants and the other organisations comprising a broad spectrum of major European biobanks (Table 7) and the members of the expert groups. Regular information via e-mail, teleconferences and meetings are planned. (ii) WP2 is open for new groups not yet listed in the tables of the preparatory phase.

D2.8 (GSF, UK Biobank, NPHI)

Deliverables

1) Report on existing resources and assets (inventory)

D2.1: Inventory on existing population biobanks (mo 6)

D2.2: Web-based overview catalogue of existing biobanks, collaboration with P^3G (mo 18)

D2.3: Review of technical solutions and quality criteria (mo 6)

D2.4: Electronic manual of existing documents for biobanking methods (mo 18)

2) Operation concept (including access rules and models for incentives for contributors)

D2.5: System of incentives for providers of biological samples (mo 12)

D2.6: Concept of a pilot network of biobank infrastructures (mo 21)

D2.7: Concept for national hubs of population biobanks (mo 15)

D2.8: Rules of involvement of scientific community (mo 6)

3) Final report and recommendation for contract filing.

D2.9: Final report (mo 27)

WP3 Disease-oriented biobanks

Work package number	**3**	**Start date or starting event:**		Mo 1
Work package title	Disease-oriented biobanks			
Activity Type	COORD			
Participant number **Short name**	**3** GSF	**3** GSF	**1** MedUG	**6** INSERM	**7** UNIMAN
Person-months per participant:	23	13	6	6	6
Participant number **Short name**	**8** IARC	**12** SU	**14** USAL	**28** ERASMUS MC	**29** IST
Person-months per participant:	6	6	6	6	6
Participant number **Short name**	**37** NFU	**53** BRFAA			
Person-months per participant:	3	3			

Objectives

WP3 will coordinate the activities on disease-oriented biobanks. It will deliver recommendations for the construction and operation of the infrastructure and address questions of availability, quality criteria, rules of access, and incentives for participation. It will also provide concepts for developing networks of biobanks aimed at supporting prospective collections compatible with the requirements of Phase II/III clinical trials on biomarkers. The strategy mostly builds on previous work and on existing resources with special emphasis on the OECD best practice guidelines. Corresponding activities, such as P^3G will be integrated as well.

Description of work

The focus will be on existing clinical biobanks, but we will also address future new biobanks.

Task 1: Integrate existing resources, technologies, standards and know-how into operational concept of BBMRI. (i) At the beginning, an inventory on existing clinical biobanks and clinical sample collections (including clinical culture collections) in Europe will be made. (ii) The biobanks interested to collaborate in BBMRI will be identified. For these a web-based overview catalogue will be established, which describes the available data and resources and the possibilities for access. (iii) Review of technical solutions and quality criteria for storage, retrieval and transfer of biological samples. (iv) Electronic manual of existing documents for biobanking methods.
D3.1 (ERASMUSMC, GSF, USAL, SU)
D3.2 (GSF, UNIMAN)
D3.3 (IARC, GSF, IST, SU)
D3.4 (UNIMAN, GSF, SU, IST, ERASMUS, NFU, BRFAA)
D3.9 (GSF, ERASMUS, IARC, UNIMAN, MedUG, USAL, INSERM, IST, SU, NFU, BRFAA)

Task 2: Identify unresolved issues: (i) missing common rules, how access to existing biobanks is possible, how the review process of applications for access to and use of samples could be organised, what the selection criteria are for scientifically sound study protocols, how competing

interest of different groups in the same samples can be met in a transparent and fair way, which fees are appropriate for academic and industrial users etc. (ii) Standards for new collections are needed which should be based on best knowledge and on modern technical solutions, from preparation of the sample to storage, retrieval and transfer.
D3.8 (INSERM, GSF, MedUG)
D3.9 (GSF, ERASMUS, IARC, UNIMAN, MedUG, USAL, INSERM, IST, SU, NFU, BRFAA)

Task 3: Find solutions: (i) to motivate existing biobanks to make their resources available to others, a system of incentives for providing biological samples within BBMRI shall be developed (model of incentives for contributors). (ii) The concept of a pilot network of biobank infrastructures is planned. It aims at providing a framework for training, testing and assessing proposed standards, and at developing networking/tissue and specimen transfer protocols. (iii) For some countries it might be helpful to develop a structure for their national biobanks and collections of biological samples which could serve as a national hub. This might allow to deal more specifically with the given rules of ethics, data confidentiality etc. in different countries.
D3.5 (MedUG, GSF)
D3.6 (GSF, MedUG, IARC, IST, NFU, BRFAA)
D3.7 (USAL, GSF, INSERM)
D3.9 (GSF, ERASMUS, IARC, UNIMAN, MedUG, USAL, INSERM, IST, SU, NFU, BRFAA)

Task 4: Proper involvement of the scientific community: (i) WP3 will closely collaborate with the participants (List of beneficiaries), the other organisations comprising a broad spectrum of major European biobanks (Table 7) and the experts. Regular information via e-mail, teleconferences and meetings are planned. (ii) WP3 is open for new groups not yet listed in the tables of the preparatory phase.
D3.1 (ERASMUS, GSF, USAL, SU)
D3.8 (INSERM, GSF, MedUG)
D3.9 (GSF, ERASMUS, IARC, UNIMAN, MedUG, USAL, INSERM, IST, SU, NFU, BRFAA)

Task 5: Outline the structure of a “biomarkers discovery and translation pipe-line” based on the rationale use of biobanking resources. This pipe-line will allow to progress from discovery studies essentially based on retrospective case-series to validation and translation studies using large series of well-annotated specimens with information on patient’s follow-up and outcomes. These validation studies, structured as clinical trials, will require the development of large, integrated networks capable of prospectively recruiting a large number of participants and collection specimens in a minimal amount of time. Such a “pipe-line” may anticipate the missions or a European Agency for Biomarker Translation.
D3.3 (IARC, GSF, IST, SU)
D3.7 (USAL, GSF, INSERM)
D3.9 (GSF, ERASMUS, IARC, UNIMAN, MedUG, USAL, INSERM, IST, SU, NFU, BRFAA)

D3.10 (IARC, INSERM, GSF, USAL) is concerned with the clinical biobanking in the field of cancer research. This, because during the kick-off meeting WP3 group members realized that the cancer research field is already far more developed than other disease fields. It was therefore suggested to pool that expertise into a separate new deliverable. In comparison with the two other pilot (deliverables 3.6 and 3.7) the new deliverable will not only pilot a structure but will do some concrete work (agreeing on a pilot study with common protocol, new samples collected).
The tasks that need to be performed for this deliverable are:

1. Identify a small number of existing national or regional cancer biobank networks with demonstrated capacity to collect large number of cancer tissue and blood sample according to high quality standards. Criteria for inclusion in the network will include (1) collection capacity; (2) compliance with quality standards; (3) capacity to operate as regional/national hub; (4) capacity to

engage into the assembly of specific collection;

2. Adopt a common set of procedures for data annotation and sharing, specimen collection and quality control, and for network coordination;

3. Set-up a cluster structure with decentralized collection of tumour tissues and centralized storage of blood samples giving access to genomic DNA

4. Identify collaborations with existing consortiums in particular in the field of genomics and set up an operational platform for assembling DNA specimen series that can contribute to large-scale, multicentric studies focusing on Genome-Wide Associations.

5. Write a report on the structure, standards and procedures and scientific questions

D3.11 (IARC, INSERM, GSF, SU, ISCII) shall concern the education and training – European MSc/PhD in Management of Biological Resources. Both existing and even more new biobanks need the appropriate educated and trained personnel. There are no biobanking specific curricula in Europe developed or already in place. Therefore a new deliverable was introduced to fill that gap. Moreover, as it is the development of a new concept, it is different from training opportunities covered by Marie Curie Actions.

The tasks that need to be performed for this deliverable are:

1. To review the contents of recent national and international courses on biobanking to identify the areas in which training currently provided;

2. To develop a questionnaire to be circulated across BBMRI to identify

(1) Expectations of biobanks in terms of training and know how of their future staff, and

(2) Capacity of biobanks to offer practical training to students

3. Identify the main components and teaching programme of a 1-to 2 years Master Degree that will combine lectures, courses and on site-training with preparation of a Master Thesis on a biobank-related issue.

4. Develop a PhD programme for future BRC managers

5. Make contact with teaching institutions and Universities across Europe to evaluate and discuss the implementation of a pilot programme in defined centres.

6. Write a report on the curricula and its modules

Deliverables (brief description and month of delivery)

D3.1: Inventory on existing clinical biobanks (mo 6)

D3.2: Web-based overview catalogue (mo 18)

D3.3: Review of technical solutions and quality criteria (mo 6)

D3.4: Electronic manual of existing documents for biobanking methods (mo 18)

D3.5: System of incentives for providers of biological samples (mo 12)

D3.6: Concept of a pilot network of biobank infrastructures (mo 21)

D3.7: Concept for national hubs of clinical biobanks (mo 15)

D3.8: Rules of involvement of scientific community (mo 3)

D3.9: Final report (mo 27)

D3.10: Clinical biobanking in the field of cancer research (mo 24)

D3.11: Education and training – European MSc/PhD in Management of Biomedical Resources (mo 18)

WP4 Biomolecular resources and molecular tools

Work package number	**4**	**Start date or starting event:**	Mo 1
Work package title	Biomolecular resources and molecular tools		
Activity Type	COORD		
Participant number **Participant short name**	**4** **UU**	**9** **LUMC**	**51** **BBT**
Person-months per participant:	28	9	12

Objectives

The focus will be on binding reagents (antibodies and others) as affinity probes for detection of proteins, together with advanced methods for molecular analyses at the levels of nucleic acids, proteins and metabolites in biobanked samples. The issues to be addressed for biomolecular resources have to be mutually compliant with requirements of biological samples. Issues for affinity reagents will include standards, quality control, availability, access, dissemination of information and database requirements. Issues for molecular tools will include establishing standard operating procedures, web resources, and a database. The work will directly complement WP3 towards building a resource for biomarker discovery.

Description of work

Task 1. To review European resources for affinity binding reagents (antibodies and others) for detection of human proteins, by identifying all centres willing to place reagents in the public domain, inventorising the available reagents and assessing the level of coverage of the relevant proteome (e.g. plasma, cancer) for application in biobanked samples. The task will include a review of the archiving and distribution of affinity binding reagents across Europe in order to establish a uniform system of access to the reagents, e.g. through national hubs or networks of reagent suppliers. Centres will be contacted initially with an electronic questionnaire for information and plans for implementation of such resources in the construction of BBMRI, followed up by meetings or site visits.

D4.1 (BBT, LU)

Task 2. To review existing European technology resources for advanced molecular procedures for detection of nucleic acids, protein and metabolites in large series of biobanked samples, including resources of DNA and proteins where they are directly relevant to these aims, and to develop plans for implementation of such resources in the construction of BBMRI.
D4.2 (UU, LUMC)

Task 3: To establish rigorous standards for quality control of affinity reagents in relation to their application in analysis of biobanked samples. Quality standards are recognised as central to the use of the reagents. The task will be to review existing criteria and to specify procedures which will establish a ‘gold standard’ for quality control to be adopted by both academic resources and other suppliers.
D4.3 (BBT)

Task 4: To integrate data on antibodies and similar reagents into a major public database currently being established by the EBI for the ProteomeBinders consortium. The data storage and exchange structure being created includes a controlled vocabulary and ontology for description of binders and binding events. The task will be to link all European sources of antibodies and other relevant molecules into this database and to ensure adoption of the common standard ontology, in

preparation for full-scale population of the database in the construction phase.
D4.4 (BBT)

Task 5: To create a publicly accessible database for technologies and methods, including standard protocols and data storage, for analysis of DNA, protein and metabolites, applicable biobanked samples.
D4.5 (UU, LUMC)

Task 6: To establish a publicly accessible, common web-based portal as a centralised electronic information site for European technology resources and platforms serving the major biobanks (in co-operation with WP2 and 3). This will include links to inventories of available resources, reagents and molecular technologies for interrogating biobank samples at the DNA, protein and metabolite levels.
D4.6 (UU, LUMC, BBT)

Task 7: To construct a final report on European biomolecular resources, integrating existing resources, technologies, standards, know-how, and and prospective plans into the operational concept of BBMRI.
D4.7 (UU, LUMC, BBT)

Deliverables

D4.1: Report on affinity reagent resources and centres in Europe with inventories and details of access, and prospective plans (mo 18).

D4.2: Report on European technology resources for nucleic acids, proteins and metabolites, and prospective plans (mo 18).

D4.3: Report on quality standards to be adopted for reagents in Europe (mo 27).

D4.4: Reagent database with common ontology standards (mo 27).

D4.5: Technologies database (mo 27).

D4.6: Website for resources and molecular technologies (mo 27).

D4.7: Final report, including foresight on the construction phase of BBMRI (mo 27).

WP5 Database harmonisation and IT-infrastructure

Work Package number	**5**	**Start date or starting event:**		Mo 1
Work package title	Databases harmonisation and IT-infrastructure			
Activity Type	COORD			
Participant number **Short name**	**5** KI	**2** NPHI	**4** UU	**54** UNI-KLU
Person-months per participant:	24	12	12	12
Participant number **Short name**	**43** deCODE	**23** VITRO	**25** EMBL-EBI	**29** IST
Person-months per participant:	12	2	2	2
Participant number **Short name**	**30** CNR	**33** UK Biobank	**36** UMCG	
Person-months per participant:	2	2	2	

Objectives

WP5 coordinates and supervises all processes of the IT, informatics and infrastructure in the project. The IT-infrastructure, which employs federated database architecture and grid computing technology, will integrate the complex network of hubs, members and partners enabling the user to interact with a single virtual infrastructure, which provides access to a broad spectrum of resources, tools and services. To perform these tasks, a professional IT/ informatics group will be established and work with different themes.

Description of work

Emphasis will be put on providing best practice-based standard protocols for different types of sample collection so that samples can be utilised well into the future. Protocols will be made public. Standardisation of the whole sample handling process including the infrastructure required should lead to certification of BBMRI members.

In BBMRI, a complementary approach to the traditionally used centralized repository model using strict data submission models will be suggested where data is accessed on demand from participating centres, using direct database connections. This strategy offers flexible infrastructure for data sharing and collaboration between centres, providing the possibility to adapt the informatics infrastructure easily to different research needs.

Before data can be federated, a European expert group will be established. The expert group will then produce a number of reports that will address the key issues underpinning the objectives detailed above.

Task 1 in this work package will be to arrive at a consensus on the requirements for a general information management system for biobanks in Europe. The participants will meet in order to, before month 12, have completed an inventory of standard related issues and how this can be used in a federated hub-and-spoke network.
D5.1 (KI, all partners)
D5.2 (KI, all partners)

Task 2 will be to explore systems for maintaining unique and secure identities (object models) for

specimens, subjects and biobanks, as well as for keeping track of the handling of permissions for use, analytical results and statistical output. Meta-information on quality of specimens and phenotypes will be integrated. The FP6 PHOEBE project is also looking into identifiers for biobanks and BBMRI can benefit from that as Professor Litton is one of the WP leaders in both projects.
D5.3 (KI, all partners)

Task 3 will be to explore a complete strategy for communication between biobank including a common nomenclature, compatible software techniques and appropriate information transmission policies. This all relates to information on specimens, laboratory results, phenotypes, exposures and genealogical data. This is partly going to be a collaboration with the P^3G project where Professor Litton is leading the international working group of IT-curation.
D5.4 (KI, all partners)
D5.5 (KI, all partners)
D5.6 (KI, all partners)

Task 4
See WP 6: G – Data Protection (page 42f)
G – Data Protection:

Deliverables
D5.1: Inventory of standard related issues, including stakeholder coordination. (mo 12)
D5.2: Strategy for unique and secure identities for specimens, subjects and biobanks. (mo 18)
D5.3: Strategy for communication between biobanks including a common nomenclature (data models/schema and coding systems/ontologies), compatible software techniques and appropriate information transmission policies. (mo 20)
D5.4: Requirements for a general information management system for European biobanks. (mo 22)
D5.5: Strategy for a federated hub and spoke structure for European Biobanking using deliverables from above. (mo 27)
D5.6: Final report (mo 27)
D5.7: Data Protection working group (mo18)

WP6 Ethical, Legal and Societal Issues

Work package number	**6**	**Start date or starting event: Contract signature**		**Mo 0**
Work package title	Ethical, Legal and Social issues			
Activity Type	COORDINATION			
Participant number Short name	**6** INSERM	**56** Legal Pathways	**44** LSGI	**46** CU
Person-months per participant:	27	12	13	13

Objectives:

General objective

To design an agreed, harmonized and implementable ethical, legal and social framework for the establishment of a biobanking and biomolecular European infrastructure and to propose corresponding strategies and scenarios as basis for the operational concept and contractual agreements.

Specific objectives

1. To manage and to oversee ethical and corresponding legal aspects in practice within the BBMRI preparatory phase
2. To develop an online platform on legal aspects for uploading and validating existing legal documents in use with BBMRI Members and Partners
3.a To work out the concept of harmonisation as compared to standardization as regards to ethics and
3.b - to present practical mechanisms to achieve it in the context of BBMRI
4. To provide mechanisms for BBMRI to interact openly and transparently with the European citizenry - means to assess the debate regarding such an infrastructure in the population and among the relevant stakeholders in the different countries
5. To define, describe and demonstrate an integrated conceptual and operational model for ELSI approaches of BBMRI
6. To prepare proposals for training in the domain of ELSI relevant for BBMRI in Europe.

Description of work:

General methodology: the competencies and experience represented by the 4 partners of this WP is opening on a large network of experts in each of the main domains and disciplines involved (ethics, law, social sciences); this core group will interact frequently and in a dynamic way with a group of about 20 experts covering the three domains in order to produce efficient deliverables. The core group is able to interact in an interdisciplinary way in order to construct truly integrated and balanced ELSI governance proposal for the future of BBMRI.

WP ELSI will work according to 2 avenues: 1) short term operational level, based on existing frameworks which will result in practical tools and 2) preparatory steps for long term solid BBMRI foundation in ethical, legal and social aspects. The core group will produce first background documents, template, methodological considerations on each of the questions, targeting the needs for BBMRI to be launched; these documents will be used to assess the existing situation and identify gaps through expert consultation and they will be systematically communicated to the other functional bodies of the BBMRI preparatory phase for comments and integration. For legal aspects a bottom up approach will be set up through an on line platform.

A-Legal aspects for the realization of BBMRI:

The legal part of the WP will be principally targeted on operational issues and be tool oriented, rather than directed towards a conceptual-critical approach, as a more in depth normative research on biobank norms will be carried out at other projects. The legal part of the ELSI WP will pioneer a novel and experimental take at overcoming the challenges due to diversity of country level legal requirements. Rather than providing a centralised top down approach, it will organise a bottom up, decentralised WIKI platform. The platform will focus on the specific and current needs of the BBMRI. It will be tailored so as to help achieve the goal of the BBMRI preparatory phase, i.e. to have signature ready contracts with all applicants being legally compliant.

The platform is to unearth any existing knowledge, expertise and templates currently in use by (prospective) BBMRI Members and Partners. Examples include informed consent forms, material transfer agreements, collaborative research agreements, and copyright notices. Using the WIKI method, the aim is to provide a dynamic, online, 24h/d-7d/w accessible, grass roots platform for uploading, comparing those documents prior validation. Thus, a virtual legal data room will be created for easy reference by the BBMRI community and the Stakeholder Forum. As some topics may be controversial the WIKI format in its pure form may not suffice, as it is liable to vandalism and quality issues. Instead, a WIKI+ (Plus) format could be established which will allow for authorisation by a designated editorial board that will be established in close collaboration with P^3G and relevant FP7 projects (e.g. ASSIST). The platform will be piloted in the BBMRI preparatory phase and may be evolved and used then in other relevant projects as they require.

Building this platform will be the primary responsibility of LegalPathways and will be tested and commented in priority by INSERM and the law specialists of the expert group, before launching. This platform will contribute to objectives 1 and 2 and would involve the following steps:

Task A1: Mo1 – Mo6. Development of the design of the platform. The exact format in which to present the platform is to be determined and will have to reflect the complexities presented by the goal of BBMRI. Topics to be addressed include:

- Establishment of BBMRI and EU competence: Does the realization of the BBMRI require the adoption of a specific legal framework. Should this framework be a specific piece of enabling legislation or could self-regulation suffice?
- Documentation of the following issues as a test of the concept of such a platform and of its ability of providing a means to compare situation in different countries, for countries of partners and member of BBMRI in its preparatory phase:
    - Terms of Participation: the complex issue of whether and how to obtain informed consent of the sample sources and data subjects whose samples and data will be involved, their right to withdraw from participation and the implications of withdrawal, any obligations to feedback research results back to constituent biobanks and/or back to the patient, and ownership of data and samples
    - Data Protection: policies and methods for coding, access control, security and prohibitions of use of data collected, processed and generated by the biobanks.
    - Access: various access policies developed by prospective BBMRI members. Specific issues include research use, conditions of access to data, access to samples, cross-border data and sample flows.
    - Commercialisation: nature of the applicable intellectual property rights, manner in which the contents of the BBMRI could be commercialised, and the approach to benefit sharing.

D6.2 (LegalPathways, INSERM)

Task A2: Mo6 – Mo20. To get the platform off the ground and to ensure continuous uploads and support, publicity must be sought through appropriate channels, e.g. presentations and posters at conferences etc. In fact, to be truly grass roots and to yield the best results, the WIKI model only works if there is a high level of participation. Prior to this step and in order to get secure and quality level start of the process this will be first triggered by contribution from experts chosen by the core group and the platform editorial board as will be discussed at a specific expert meeting that will

constitute an important milestone (Mo6).
D6.3 (LegalPathways, INSERM)

Task A3: Mo10 – M018. The platform would provide the opportunity (or perhaps obligation) for BBMRI Members and Participants to upload any 'tried-and tested' forms and documents on a WIKI platform. These uploads could then be discussed and refined by the BBMRI Partners and Members, the Stakeholder Forum and the public at large, using the WIKI method and technology; a specifically interesting aspect will be the documentation in the platform on existing tools allowing to take into account legal – ethical aspects in practice, as this could be a source of best use of existing resources to achieve BBMRI goals; (Mo12);

Task A4: Mo18 – Mo20. The resultant documents could then be validated by peer reviewing, under the supervision of the editorial board (Mo20);
Having taken stock of existing, specific expertise and forms of BBMRI Partners and Members, the platform could then be used for uploading the norms and harmonised consensus forms that are being produced in the meantime by other projects by (such as P^3G). The Platform could also join forces with the platform to be established by the proposal for Support Action on Data Protection and Biobanking.
The results of Task 4 will contribute to objective 5.
D6.7 (LegalPathways, INSERM)

<u>B- Ethical dimension raised by the concept and the realisation of BBMRI</u>
Task B1: Mo1 – Mo6. Assess the situation regarding the issues that are the bases of ethics related policies for biobanks and biomolecular resources in countries of BBMRI partners and members. This will be done by reviewing the results or interacting with other projects in the field (like GenbanC, PHOEBE, GenomeEUtwin, P^3G, etc.) and will have the aim to identify issues relevant for the pan-European dimension of BBMRI that are not addressed or if considered are conflicting. A first internal WP meeting (Mo1) and an expert group meeting at Mo4 will result in a document (Mo6) to be then deepened and enriched, through task 2.
Task 1 will be under the primary responsibility of INSERM in collaboration especially with CU. It will serve objective 1.
D6.1 (INSERM, CU)

Task B2: Mo4 – Mo12. Address the questions oriented on the harmonisation in the domain of ethics and produce for Mo12 a corresponding background document
How should 'harmonisation' in ethics be interpreted? How does it differ from 'standardisation'?
To what extent is either practically feasible in ethics, from an ethical point of view?
To what extent is ethics in this area dependent on social context?
What are the acceptable margins of deviation from standards in relation to BBMRI?
What are the challenges in making BBMRI congruent with 'European values'?
To what extent are ethical traditions in tension with new developments in this area?
Task 2 will be under the primary responsibility of INSERM in collaboration with CU. It will serve objective 3a and will involve an expert meeting at Mo8.
D6.4 (INSERM, CU)

Task B3: Mo12 – Mo20. Identify mechanisms to translate into EU level policy the relevant recommendations and clarify the relevant chain of implementation, allowing appropriate consultation. It will be important to examine the extent to which ethical procedures need to be standardised e.g. informed consent, and which ones can be more context-sensitive while still protecting important interests. This task will be further performed through analysis of decision making processes in various forums and relevant bodies and through policy analysis based on documents provided at the expert group meeting at Mo8. The produced background document at Mo12 will serve objective 3b and this task will be under the primary responsibility of CU in

collaboration with INSERM. The document will be then circulated and amended before being considered as a basis for Objective 5.
D6.9 (CU, INSERM)

C- Social dimension of BBMRI

What corresponds to BBMRI as a European infrastructure on the societal level? In the absence of a "European society" we want to think in terms of varied "European publics", and discuss possible strategies of BBMRI to interact with these various publics. Our basic assumption is that it will be key for BBMRI to interact openly and transparently with the European citizenry. Any other strategy would be conceived against the assembled wisdom of science and society studies on Europe conducted during the last decades. This part will be developed in close coordination with the Stakeholder Forum activities.

Task C1: Mo1 – Mo12. to examine best practice examples and failed examples of engaging society into the building of biobanks on the national level. In particular, we want to compare experiences such as from the UK Biobank, the Icelandic Health Sector database, the Western Australian Genome project, and the HAPMAP project. The lessons that can be drawn from these national experiences for BBMRI and its future interaction with European publics will be the basis of a document that will be circulated among experts in the field, discussed at a specific social sciences expert meeting at Mo10, further amended and be generally discussed at the general ELSI expert meeting at Mo12. This task will be under the primary responsibility of LSGI in collaboration with INSERM.

Task C2: Mo6 – Mo14. to prepare a survey of the public perception of biobanks in Europe, including a study of the perception of larger collaborations in this field, such as BBMRI. While this WP will not have the time and resources to actually conduct a full survey, strategies to develop such a survey will be presented and piloted in 2 sites. We also want to discuss and present an array of other instruments than surveys to locate the public perception of biobanks, in particular focus groups and citizen forums. We will study the complementarities of instruments used in sociology and in psychology. This task will be under the primary responsibility of LSGI in collaboration with INSERM. This task will be developed in close collaboration with the ELSI component of the EUGEPO proposal if successful (HEALTH-2007-2.1.1-3: Comparative studies of genetic variation in humans: towards a reference population in Europe) that also addresses public perception of a European dimension of a specific biobank and with the DG SANCO project POSEIDON that addresses especially perception and modalities of engagement in European minorities. This will contribute to objective 4 and will be the bases of the report delivered at Mo14.
D6.5: (LSGI, INSERM)

Task C3: Mo12 – Mo20. To discuss various strategies of citizen engagement in BBMRI, and strategies of science communication based on a specific expert meeting on such issues at Mo18 in relation with the relevant projects of the Science in society line in DG Research. This task will be under the primary responsibility of LSGI in collaboration with INSERM and CU. It will generate an outline of a BBMRI strategy for interaction with European publics, and allow to present different strategic scenarios for how such an interaction could look like at Mo20. It will contribute to objective 5.

D- An integrated conceptual and operational model for the ELSI approaches of BBMRI

This part of the work will start at Mo12 and will build on the first year work of A, B and C. It aims at producing the model of ELSI governance that could be proposed as the base for properly embedding BBMRI into European ethical, legal and societal frameworks. It will concentrate on 4 steps, first a methodological one, second a conceptual model one, third a translation into an operational model and fourth a validation phase through a demonstration of its operability on some of the considered biobanks.

Task D1: Mo12 – Mo15. Set up the methodology to integrate the various aspects of ELSI into one model (M15, internal WP meeting).

Task D2: Mo15 – Mo18. Construct according to this methodology a conceptual model of governance applicable to a pan-European infrastructure. This will be presented and accordingly modified at a general ELSI expert meeting at Mo18 that will also take into account in the discussions the results of the public consultation and the Stakeholder Forum input.
D6.6 (INSERM, all partners)

Task D3: Mo18 – Mo21. Construct on the basis of previous results and consultations an operational integrated ELSI governance model that will be integrated in the final report.
D6.8 (INSERM, all partners)

Task D4: Mo21 – Mo23. An attempt to pilot the model in practice using 2 to 4 representative biobanks will be done as a demonstration of operability before contract signatures. This will involve a specific meeting with representatives of the chosen biobanks.

Task D5: Mo23 – Mo27. Finalise the redaction of the ELSI part of the final report.
This part of the work will be the primary responsibility of INSERM and will involve all the other WP partners, given the integrative objective. It will allow achieving objective 5.
D6.10 (INSERM, all partners)
D6.12 (INSERM, all paertners)

<u>E- Training in ELSI for BBMRI operation</u>
As the stakeholders are very different, the domains of applicability of biobanks and biomolecular resources very diverse and the levels of organisation of national contexts highly variable, an element of training and education seems indispensable to include in such an endeavour. This dimension has been isolated here to insist on its importance but it will actually be included in each of the parts A to D just described. It will be the responsibility of partner 6 (Cambon – Thomsen) to check that the needs of education or training in each dimension (legal, ethical, social) are adequately addressed in part A to D and that adequate proposals to meet these needs will be included in the final report.

<u>F – Gender Issues:</u>
A gender issue plan will be implemented and monitored during the preparatory phase of BBMRI.
D6.11 (CU, LSGI)

G – Data Protection:
General objective for both WP 5 and 6. Both within and without BBMRI (partners, participants, European Parliament, European Commission) concerns have been voiced as to the data protection (DP) issues associated with the cross-border features of BBMRI. Achieving a pan-European solution for cross-border DP issues is a prerequisite for the realization of the BBMRI objective.

Specific to WP 6: To provide a pan-European solution for the cross-border data protection issues associated with BBMRI. BBMRI's achieving of a pan-European solution would demonstrate that:

- cross-border health research across EU borders is actually possible;
- European resources can actually be used for the benefit of EU health;
- the Lisbon goal of establishing the EU Research Area (ERA) in the life sciences can actually be achieved within the limits and safeguards set by EU law.

Tasks

The DP group will (MO12-18):

1. *identify* cross-border data protection issues associated with the deliverables of BBMRI;
2. *prioritise* the identified issues;
3. *Map* existing parallel projects on data protection issues, including but not limited to:
    - Privireal
    - Eurogentest
    - Genebanc
    - Privileged
    - Tiss.ue
4. *seek* for synergies between parallel projects
5. *apply and customize* existing knowledge to BBMRI specific situation: infrastructure and cross border dimension
6. *explore* potential solutions provided by EU DP law;
7. *convert* the results of this exploration into a 'BBMRI *data protection standard';*
8. *seek* to consult with the appropriate EU Body.

D5.7: Data Protection Standard to govern cross border DP issues that is compliant with the EU Data Protection Directive (mo 18)

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Deliverables (brief description and month of delivery)

D6.1: Report on ethics related policies for biobanks and biomolecular resources in countries of BBMRI partners and members (mo 6)

D6.2: Design of legal WIKI+ platform (mo 6)

D6.3: Launch of legal WIKI+ platform and mobilising BBMRI stakeholders (mo 12)

D6.4: Background document on harmonization from an ethical point of view (mo 12)

D6.5: Background document on how BBMRI should address its social dimension (mo 14)

D6.6: Schema of a conceptual model of governance applicable to a pan-European infrastructure for ELSI issues (mo 18)

D6.7: Uploading and validation of documents of BBMRI Members and Partners (mo 20)

D6.8: Strategic plan and scenarios for BBMRI interactions with various publics (mo 20)

D6.9: Flow chart of an operational integrated ELSI governance model (mo 21)

D6.10: Overall report and Recommendations for BBMRI ELSI, including educational proposals (mo24)

D6.11: Implementation and monitoring of gender issue plan (mo 27)

D6.12: Final report (mo 27)

D5.7: Data Protection Standard to govern cross border DP issues that is compliant with the EU Data Protection Directive (mo 18)

WP7 Financing and funding

Work package number	**7**	**Start date or starting event:**		Mo1	
Work package title	Funding and Financing				
Activity Type	COORD				
Participant number **Participant short name**	**6** INSERM	**58** Meriéux Alliance	**10** UoM	**15** FTELE	**16** FHF
Person-months per participant:	24	3*	3	3	3
Participant number **Participant short name**	**17** ICRIN	**18** Helmholtz	**19** INCa	**20** CNBBSV	**21** MPG
Person-months per participant:	3	3	3	3	3
Participant number **Participant short name**	**22** ISCIII	**27** NIPH	**31** HRB	**32** MRC	**34** OCW
Person-months per participant:	3	3	3	3	3
Participant number **Participant short name**	**35** RANNIS	**38** ZonMw	**39** Fraunhofer	**40** BMBF	**41** BMWF
Person-months per participant:	3	3	3	3*	3
Participant number **Participant short name**	**47** ACC	**49** Genome Spain	**50** HM	**52** GSRT	
Person-months per participant:	3	3	3	0	

* no funding requested

Objectives: WP7 will develop a concept for funding and financing of the construction and operation of BBMRI, considering the full spectrum of national, European and private funding schemes as well as financing through industrial co-operations. The concept will be elaborated in a cooperative effort actively involving Research and Health Ministries as well as national funding organisations from several European Member States. The concept for funding of the first 3 years will focus on better trans-national coordination of current financial spending for biobanks and biomolecular resources, whereas the concept for later funding will explore possibilities to increase funding budgets on the basis of expert reports evaluating the expected direct or indirect return of investments made in BBMRI. The work of WP7 should lead to contracts for funding of construction and operation of BBMRI, in cooperation with WP1 and supported by lawyers.

Description of work (all participants of WP7 will be implicated in the discussion and definition of funding concepts, meetings will be organized and reports will be written by Inserm)

Task 1: Assessment of current funding situation of biobanks and biomolecular resources. The current funding situation will be assessed by using specific questionnaires. The information obtained will be validated and complemented by data available at ministries and funding organizations.

D 7.1 (Inserm, all participants)

D 7.2 (Inserm)

Task 2: Preparation of reports on impact of BBMRI on science, industry and healthcare. As starting point for this report a description of key features of BBMRI will be prepared by WP7 on the basis of information provide by WP1-6. The production of the reports will be outsourced to independent professional organizations. The report has to describe in detail the impact of BBMRI on science, industry and health care and to evaluate the expected direct or indirect return of investments made in BBMRI.

D 7.3 (Inserm, all participants)

D 7.4 (Inserm, independent professional organizations)

Task 3: Development of a concept for sustained funding and financing. The concept will follow different strategies for short-, mid- and long-term funding. Short-term funding, which should cover expenses for construction and operation for the first 3 years, will mainly come from better trans-national coordination of current funding expenditures. The basis for the short-term concept comes from the work done in task 1. Mid-term funding should allow further development and enlargement of BBMRI and will require increased financial resources. The justification for increased funding should come from the reports generated by task 2. Long-term funding should in addition to public funding be increasingly based on income generated from industrial co-operations. For all funding concepts the full spectrum of available national, European and private funding schemes including structural funds, financing solutions provided by the EIB as well as income from the industry will be evaluated.

D 7.5 (Inserm)

D 7.6 (Inserm, all participants)

D 7.7 (Inserm)

D 7.9 (Inserm, all participants)

D 7.10 (Inserm)

Task 4: Drafting and negotiating of contracts. Task 3 provides the basis for drafting contracts between ministries and/or funding organizations and BBMRI for funding construction and operation for the first 3 years. Task 4 will be performed in close collaboration with WP1 and supported by lawyers.

D 7.8 (Inserm)

Deliverables

D7.1: WP 7 participants meeting (ministries, funding agencies, research institutions…) (mo 3)

D7.2: Report on current funding situation. (mo 4)

D7.3: WP 7 participants meeting (ministries, funding agencies, research institutions…) (mo10)

D7.4: Reports on impact of BBMRI on science, industry and healthcare. (mo 12)

D7.5: Report on financial needs of BBMRI. (mo 14)

D7.6: WP 7 participants meeting (ministries, funding agencies, research institutions…) (mo17)

D7.7: Funding and Financing concept. (mo 18)

D7.8: Contracts ready for signature. (mo 27)

D7.9: WP 7 participants meeting (ministries, funding agencies, research institutions…) (mo22)

B 1.3.6 Efforts for the full duration of the project:

Participant no. / short name	WP1	WP2	WP3	WP4	WP5	WP6	WP7	Total
1 - MedUG	54		6					60
2 – THL		41			12			53
3 - HMGU		7	36					43
4 - UU				28	12			40
5 - KI					24			24
6 - INSERM		8	6			27	24	77
7 - UNIMAN	18		6					24
8 - IARC	18		6					24
9 - LUMC	6			9				15
10 - UoM							3	3
11 - NTNU		8						8
12 - SU			6					6
13 - UTARTU		8						8
14 - USAL			6					6
15 - FTELE							3	3
16 - FHF							3	3
17 - ICRIN							3	3
18 - Helmholtz							3	3
19 - INCa							3	3
20 - CNBBSV							3	3
21 - MPG							3	3
22 - ISCIII							3	3
23 - VITRO					2			2
25 - EMBL-EBI					2			2
27 - NIPH							3	3
28 - ERASMUSMC			6					6
29 - IST			6		2			8
30 - CNR					2			2
31 - HRB							3	3
32 - MRC							3	3
33 - UK Biobank		8			2			10
34 - OCW							3	3
35 - RANNIS							3	3
36 - UMCG		8			2			10
37 - NFU			3					3
38 - ZonMw							3	3
39 - Fraunhofer							3	3
40 - BMBF							3*	3
41 - BMWF							3	0
43 - deCODE		8			12			20
44 - LSGI						13		13
46 - CU						13		13
47 - ACC							3	3
49 - Genome Spain							3	3
50 - HM							3	3
51 - BBT				12				12
52 - GSRT								0

Participant no. / short name	WP1	WP2	WP3	WP4	WP5	WP6	WP7	Total
53 - BRFAA			3					3
54 - UNI-KLU					12			12
55 – U.TURKU	60							60
56 - Legal Pathways b.v.						12		12
57- IPPOSI	6							
58 – Mérieux Alliance*							3	
Total	168	96	90	49	84	65	90	651

* no funding requested

B 1.3.7 List of milestones and planning of reviews:

Milestone number	Milestone name	Work package(s) involved	Lead beneficiary	Delivery date	Comments
1	Reports from expert groups available	1-7	1	Mo 12	Reports approved by executive management
2	Consensus achieved on operational concept for BBMRI	1-7	7	Mo 20	Concept approved by Governance Council
3	Consensus achieved on funding and financing concept	1, 7	6	Mo 23	Term-sheets for contract approved by Governance Council
4	Contracts for funding and financing of construction phase available	1, 6, 7	1	Mo 27	Contracts approved by Governance Council

B2. Implementation

B 2.1 Management structure and procedures

The overall management structure of the preparatory phase is designed as a precursor of the final organization of BBMRI, to ensure a smooth transition to the construction phase. It consists of specialized bodies which integrate into BBMRI the diverse types of resources on the one hand and the differing expectations and needs of the broad user community on the other. This complex management structure is designed to facilitate decision-finding by consensus, which is reflected in the work flow of the preparatory phase. After the preparatory phase most of the operative work packages will develop into hubs of the BBMRI network and, in principle, the executive manager might continue as the CEO of the infrastructure. Also the Scientific and Ethical Advisory Board and Stakeholder Forum should find their extension in the construction and operation phases.

The **Project Management** (WP1) is responsible for communication with and reporting to the European Commission as well as for the coordination of all elements of the project during the preparatory phase. The management tasks will be addressed by a management team which will consist of the coordinator (K. Zatloukal, leader of WP1 and chairman of the executive management), the associate coordinator (M. Yuille, participant 7 of WP1 and coordinator for all operation-related issues), the leaders of WP7 (G. Dagher: academic and non-profit organisations relations, C. Bréchot: industrial relations), a responsible person for global integration (M. Pasterk, FR) and an executive manager (E. Vuorio, FI). The executive manager will be searched during the evaluation phase of the proposal and should be employed immediately after the start of the project. The executive manager should have long experience with the management of large international academic, governmental or industrial organizations and profound insight into European funding systems.

During the whole preparatory phase, the executive management will supervise the progress of individual work packages, manage the flow of information between all applicants, and will be responsible for reporting to the European Commission. To facilitate internal communication a secured web site will be established. For all meetings an agenda will be distributed, minutes will be prepared and made available to all participants. Project progress will be monitored quarterly on the basis of the pre-defined deliverables and milestones. The steering committee decides on the need for corrective actions and, if necessary, decides on the involvement of the Governance Council.

The executive management will organize meetings, and is responsible for public relations. Furthermore, it coordinates the activities of BBMRI with that of other external projects and takes care of proper integration of BBMRI in the global context. This will be achieved by input obtained from the Advisory Board and its experts from several non-European countries, and through the active participation of WHO/IARC in this work package (participant 8). A proactive global integration strategy will guarantee that solutions developed within BBMRI will be compatible with biological resource infrastructures worldwide or that it might even become a model for them.

The global integration process will be fostered by close collaboration with the following global organizations:

- The OECD, which introduced in 2001 with its report “Biological Resource Centres: Underpinning the Future of Life Sciences and Biotechnology a new concept of repositories and providers of high quality biological materials and information: the Biological Resource Centre (BRC). In 2007 the OECD`s Committee of Science and Technology Policy declassified a new report on best practice guidelines on BRCs. Four sets of guidelines are included dealing with (i) general quality aspects, (ii) biosecurity-related issues, (iii) specific guidelines for BRCs holding and supplying micro-organisms, and; (iv) specific guidelines for BRCs holding human-derived materials. In this report it is stated, that the facilitation of international co-ordination among BRCs by creating an agreed system of linkage, and the establishment of a global BRC network is planned for a third report foreseen for 2008. As of today, however, an implementation plan yet is missing.
- The World Health Organization (WHO) is more and more interested in research aspects in general and defined in its 11th General Programme of Work, 2006-2015 six core functions, out of one calls “shaping the research agenda and stimulating the generation, translation and dissemination of valuable knowledge”. This is especially important for Biobanks. Furthermore the International Agency of Research on Cancer (IARC) in Lyon – being a WHO

Agency – developed and brought to international discussion a document on "Recommendations on Common Minimal Technical Standards for Biological Resource Centres for Cancer Research". By that it opens the door into the medium- and low income countries R&D repositories, which will be of increasing importance in the future. In practical terms, the IARC Cancer Control Forum, whose membership is National Cancer Institute Directors globally, has prioritized the establishment of guidelines for BRCs to enable future research collaboration.

- The Public Population Project in Genomics (P3G) is a non-for-profit international consortium to promote collaboration between researchers in the field of population genomics. This platform has been launched in order to provide the international population genomics community with the resources, tools and know-how to facilitate data management for improved methods of knowledge transfer and sharing especially developing research tools for effective collaboration between biobanks so as to enable the international research community to share expertise and resources and facilitate knowledge transfer for the health of populations.

The executive management will also be responsible for drafting and negotiating the contracts with future members of BBMRI, ministries, funding organizations, and industrial partners. To perform these tasks, the executive management will be supported by a full-time assistant and secretary as well as by external legal advisors and lawyers.

The **Governance Council** (Chair: Leena Peltonen, FI) consists of full members, who are all participants (co-applicants of the project; List of beneficiaries) and of associated members. Associated members are, for instance, biobanks which have submitted an Expression of Interest and a detailed description of their biobank, and fulfilled certain quality criteria regarding the size of the biobank, specific assets, and secured funding (all associated members are summarized in Table 7 below). Full members will decide on formal issues related to the proposal in addition to scientific ones. Since most biobank members are associated members, they have no official vote on formal issues but their input and active involvement in the project is required to ensure that the solutions developed will be suitable for future integration of the biobanks into the BBMRI structure. The Governance Council is responsible for the definition of the appropriate strategy and processes, and is required for the approval of reports and any changes of the work plan. It is advised by the Advisory Board and the Stakeholder Forum.

The **Scientific and Ethical Advisory Board** (Chair: Gert-Jan van Ommen, NL) consists of global leaders of the scientific community, from industry and the fields of ethical, legal and societal issues. It ensures scientific excellence as well as compliance with the needs of industry and society. Since Advisory Board members will mainly come from non-European countries, the board will also provide guidance for proper global integration of BBMRI. Another important aspect is that the board members who are international leaders in the fields of ethics will act as independent body to provide guidance for ethical issues thereby complementing the expertise and work of the project participants of WP6.
The following board members have already agreed to participate: Karima Boubekeur (Hoffmann-La Roche Ltd, CH), Jean-Jacques Cassiman (Eurogentest, BE), David R. Cox (Perlegen Sciences, USA), Mark J. Daly (Broad Institute, Harvard, MIT, USA), Bartha M. Knoppers (Université de Montréal, Centre for Public Law, CA), Klaus Lindpaintner (F. Hoffmann-La Roche AG, CH), Bela Melegh (University of Pecs, HU), Lyle J Palmer (University of Western Australia).

The **Stakeholder Forum** (Chair: Michael Griffith, IE) collates the input and requirements of the broad and heterogeneous stakeholder community of BBMRI, comprising patients, clinicians, funding organizations, associated project partners, industry, and users. Stakeholders have already been contacted during the drafting phase of the proposal and participated in the Partner and Stakeholder Meeting (Vienna March 17th, 2007). To extend the representation of stakeholders, major stakeholder groups will be actively approached by the chair and invited to participate in the Stakeholder Forum. A specific web-site section of BBMRI will be set up for stakeholders where relevant information will be provided and stakeholders are invited to submit comments. Furthermore, there will be a Stakeholder Forum conference as a central element in the public consultation process.

The **Steering Committee** (Chair: Leena Peltonen, FI) is the assembly of all work package leaders and chairs of the Advisory Board, Governance Council and Stakeholder Forum. The Steering Committee is designed as a small and flexible committee for coordinating activities of the work packages and to find and agree on solutions related to the planned work. This committee also decides whether an issue raised should be presented to the Governance Council.

The **Coordination Board** (Chair: Kurt Zatloukal, AT) is set up to coordinate activities and requirements of BBMRI with external ongoing and proposed projects and initiatives (e.g. P3G, the Innovative Medicines Initiative, other biomedical sciences research infrastructures, FP6-7 projects). This is of particular importance since on the one hand the concept of BBMRI builds on achievements made in external projects, and on the other hand BBMRI delivers resources and services for other projects. For instance, there are major synergies with other biomedical sciences research infrastructures and the Innovative Medicines Initiative (IMI) in the field of biobanking including standardization, bioinformatics, knowledge management as well as ethical, legal and societal issues. Furthermore, BMRI will coordinate its activities with relevant projects that will be funded in upcoming calls of FP7. Members of the coordination board are leaders and key partners of external projects and WP leaders of BBMRI (Table 2). This board monitors the progress and tunes the activities in projects which develop solutions in joint efforts.

Table 2: Proposed members of the Coordination Board

Project	Shared solution	Board member
P3G	Harmonization of sample and data collection	I. Fortier, CA
PHOEBE	Harmonization of population-based biobanks	P. Burton, UK
IMI	Biobanking, knowledge management	NN
Research Infrastructures		
ELIXIR	Databases, data analysis	D. Clark, UK
INSTRUCT	Protein repository	I. Bertini, IT
EATRIS	Biobanking	R. Balling, GER
INFRAFRONTIER	Biobanking	M. Hrabe de Angelis, GER
ECRIN	Biobanking, ELSI	J. Demotes-Mainard, FR

B 2.2 Beneficiaries

Table 3: Specific expertise and assets contributed by beneficiaries

Partici-pant #	Principal investigator, nationality	Role in prep. phase	Specific expertise, assets
1	K. Zatloukal, AT	WP1 leader, coordinator, Chair Coordination Board, participant WP3, national contact	Molecular pathology; Coordinator Genome Austria Tissue Bank, member Bioethics Commission at Federal Chancellery, member OECD task force on biological resource centres, member ESFRI BMS road map working group, member Steering committee of P^3G; co-founder of OridisBiomed,115 publications on cancer and metabolic diseases; 12 patents
2	L. Peltonen, FI	WP2 leader, Chair Governance Council, Chair Steering Committee, national contact	Human Genetics; Current President of HUGO, Member of the UNESCO Bioethics Committee, Vice-Chair of P^3G Board, Foreign Associate Member of the National Academy of Sciences USA, Institute of Medicine (IOM), Member of ERC Scientific Council; > 400 publications on population and diseases; 1 patent, 3 applications
2	J. Muilu, FI	WP5 participant	Design and development of database and data integration systems, standards for genetic epidemiological studies, bioinformatics; Head informatics group in GIU, systems architect in collaborative programs like GenomEUtwin, 1996-2002: European Bioinformatics Institute
3	E. Wichmann, DE	WP3 leader, WP2 participant, national contact	Genetic Epidemiology, BBMRI-Coordinator Germany, Member of Steering Committee and Working Group Leader of P3G
3	T. Meitinger, DE	WP3 associate leader	Human Genetics; Research on disease gene mapping, co-coordinator of NGFN genotyping platforms, member of scientific advisory boards of EU projects (MolPage, AnEUploidy), expertise in biobank- and genomic technologies
4, 51	M.Taussig, UK	WP4 associate leader	Proteomics and affinity reagent resources: antibodies, ribosome display, protein arrays, protein structure; Coordinator of ProteomeBinders, FP6 Research Infrastructure CA (affinity binding reagents for the human proteome); Board member and Head of Applied Functional Genomics section of the European Federation of Biotechnology; Chair of European Science Foundation Functional Genomics Programme; Patents on ribosome display technology, and protein array methods
4	U. Landegren, SE	WP4 leader	Leader of Molecular Medicine research group at Rudbeck Laboratory at Uppsala University, Coordinator European Integrated Project "MolTools", cofounder of Olink AB and ParAllele Inc.; Member of the Royal Swedish Academy of Sciences and the European Molecular Biology Organization (EMBO), visiting senior scientist at the RIKEN Genomic Sciences Centre, Yokohama, Japan; >120 scientific publications, 22 patents and patent applications.
4	T. Risch, SE	WP5 participant	Professor of Database Technology at Uppsala University, previously Professor at Linköping University (Sweden); > 100 technical publications and 5 US patents. General Chair of two international scientific conferences.
5	J.E. Litton, SE	WP5 leader, national contact	Professor of Biomedical Computing Technology, Director of Informatics, Karolinska Institutet Biobank, Head of IT and Computing (Department of Medical Epidemiology and Biostatistics, Karolinska Institutet). Member of the steering group in the P^3G project and co-director and responsible for the Swedish LifeGene initiative, a prospective cohort based biobank. Head of development of e-epidemiology; > 130 publications.
6	A. Cambon-Thomsen, FR	WP 6 leader	Genomics and public health. MD, DR CNRS, head of "Genetics and society platform" GIS Genopole - Inserm U558, Toulouse. Member European Group of Ethics, Pres. "Operational ethics committee" (COPé) of CNRS, member P3G, resp. ELSI issues in FP6 projects (Riset, PHOEBE), 20 publications on biobank issues.
6	G. Dagher, FR	WP7 leader (academic and	Director for clinical research infrastructures. Member of OECD task force on biological resource centres,

		non-profit organisations relations) WP2 participant national contact	Member of Inserm bioethics committee, 90 publications on Hypertension, Cardiovascular diseases.
6	C. Libersa, FR	WP3 participant	MD, PhD in Pharmacology, Coordinator Hospital University Biological Resource Center, Clinical Investigation Center, Lille; Responsible of the WP2 of the European Helena CSS (Good Clinical Practices); Participant as a French representative to ECRIN (European Clinical Research Infrastructures Network),90 publications in pharmacology
7	M. Yuille, UK	WP1 associate leader	Molecular genetics; biological resources management; Director, UK DNA Banking Network. 90 publications in human genetics and immunology.
7	B. Ollier, UK	WP3 participant	Professor of Immunogenetics, Director of Centre for Integrated Genomic Medical Research, The University of Manchester. Board Member of P^3G. Co-PI of UK DNA Banking Network. 405 publications in the field of genetics and epidemiology.
8	P. Hainaut, FR	WP3 participant	Coordinator, Cluster of Molecular Carcinogenesis; head of IARC Biological Resource Center (EPIC Biobank), head of Gambia Hepatitis Intervention Study. Author of WHO "Recommendations on common minimal standards for BRC". Member of Marble Arch think tank on Biobanks. Past board member of ISBER (International Society for Biological and Environmental Repositories). Coordinator of IARC TP53 mutation database; > 200 publications.
8	M. Pasterk, FR	WP1 participant (global affairs)	IARC Scientific coordinator, nominated WHO representative at OECD-WPB, research policy background at both national (Austria) as well international level (EU, OECD); research management experience from 10 years Science Ministry duties
9	G-J.B. van Ommen, NL	WP1 and WP4 participant, Chair Advisory Board, national contact	Past HUGO, ESHG and NLSHG president, member HUGO IP committee, Editor EJHG, director CMSB, Chair SAB GenomEUtwin, member ISAB CartAgene/P^3G, member of ESFRI expert group genomics/bioinformatics, expertise in biobank- and genomics technologies, discovered several disease genes, >350 papers, 6 patent families.
10	A. Felice, MT	WP7 participant	Professor (Biomedical Sciences) in the University of Malta, director of Laboratory of Molecular Genetics, the Molecular Genetics Services at St. Luke's / Mater Dei Hospital, director of the development of a Molecular Biotechnology Program (incl. Malta BioBank). Research papers on the genetics of haemoglobin disorders, human molecular genetics.
11	K. Hveem, NO	WP2 participant, national contact	Clinical Epidemiology and Gastroenterology, Leader HUNT biobank and of the National Norwegian Population Based Biobank, associate leader Biohealth Norway, Major publ. in gastro empidemiology, hemochromatosis and functional dyspepsia
12	A. Falus, HU	WP3 participant, national contact	Immunology, medical genomics, Coordinator Hungarian Biobanking Network, member Ethical Committee of Scientific Research, Representative of ESFRI for Hungary, member of P^3G. Member of Hungarian Academy of Sciences, Professor and Chairman of Department of Genetics, Cell- and Immunobiology at Semmelweis University, Head of Semmelweis Genomics Network. 279 publications
13	A. Metspalu, EE	WP2 associate, national contact	Vice president of European Society of Human Genetics, member of HUGO, ASHG, founder and director (treasurer) of P^3G and steering committee member of ESF Functional Genomics, acting director of the Estonian Genome Project and Head of the Dept. of Biotechnology of the Inst. of Molecular and Cell Biology at University of Tartu. > 70 publications
14	A. Orfao, ES	WP3 participant, national contact	Cytomics: Haematology and cancer; Professor and Scientific Director of the National DNA Bank of Spain; Member of Editorial board of 8 international journals; Member of 7 evaluation commissions of research projects; Member of P^3G; 335

			publications; 10 patents
15	L. Monaco, IT	WP7 participant	Research program manager, Italian Telethon Foundation, peer review and management of Telethon Genetic Biobanks. Member of the Working Group for the preparation of guidelines on biobanks certification of the National Committee for Biosafety and Biotechnology
16	E. Devilliers, FR	WP7 participant	Head of research and innovation department
17	P. Doran, IE	WP7 participant	Molecular medicine, biobanking, virus host interaction, integration of genomic and clinical data; Director, UCD Genome Resource Unit, Scientific Director, UCD Clinical Research Centre, Member Health Research Board Ethics Committee, Member ECRIN data management group
18	C. Schippers, DE	WP7 participant	Scientific Management, Responsible for the Helmholtz-Research Field Health (Berlin office of the President)
19	L. Borella, FR	WP7 participant	Director, department of canceropôles, biobanks and innovative drugs, French National Cancer Institute; coordination of the French network of cancer biobanks; former counsellor of the Ministry of health for cancer topics
20	G. D'Agnolo, IT	WP7 participant, national contact	Member of the OECD Working Party on Biotechnology, and of Istituto superiore di sanità group on cancer research (Alleanza contro il cancro)
21	H. Lehrach, DE	WP4 and WP7 participant	genome analysis, neurobiology, cancer research and systems biology, in particular generation of biological resources and technological advances; Head of MPIMG; Chairman of the SAB of RZPD and GEN-AU, member of the HUGO Council, the Human Genome Center, Shanghai, the NGFN Project Committee; 557 publications, 80 active patents, co-founder of 6 companies, including RZPD
22	M. Posada	WP7 participant	Head of Research Institute for Rare Diseases Instituto de Salud Carlos III, member Eurobiobank
23	A. Fernandez, ES	WP5 participant	Technical Manager of VITRO, S.A. (Industrial Engineer). Project Manager of: Spanish National DNA Bank Network, National Tumor Registries Network, Tumor Bank Networks and International Laboratory QC Network.
25	P. Flicek, UK	WP5 participant	Project Leader, European Genotype Archive and Ensembl Functional Genomics Team at the European Bioinformatics Institute. 16 publications in genomics and bioinformatics.
27	K. Hveem, NO	WP7 participant	Cf. #11
28	P. Riegman, NL	WP3 participant	Head Erasmus MC Tissue Bank, Chair OECI Pathobiology work group. Coordinator OECI TuBaFrost and Chair of the EORTC Tissue Bank Steering Committee. Several publications in Cancer Research and 9 relevant to Biobanking.
29	P. Romano, IT	WP5 participant	Bioinformatics, Information Systems for Biological Resource Centres, Curator of CABRI network services, Coordinator of the National Network of Oncology Bioinformatics 29 publications in international peer-reviewed journals
29	B. Parodi, IT	WP3 and WP4 participant	MD, curator BRC IST, member of the Board of the European Culture Collection Organization; responsible for validation and accreditation of the IST cell factory, Qualified Person for the production of cells for therapy, delegate of the Italian Minister of Research at the OECD Task Force on BRCs and member Steering committee OECD work-shop on BRCs; 35 publications
30	L. Milanesi, IT	WP5 participant	PhD in Health Physics (University of Milan). Researcher of the Italian National Research Council – Institute of Biomedical Technologies (CNR-ITB), coordinator of projects CNR-Bioinformatics, BIOINFOGRID and LITBIO. Editorial board member of the IEEE Transactions on Nanobioscience and Briefings in Bioinformatics; > 150 publications (Bioinformatics, Systems Biology, Medical Informatics)
31	A. Cody, IE	WP7 participant	Research funding agency with special interest in research infrastructure. Will set up national biobank for control samples to support all biobanking initiatives, which will be tied in with

			BBMRI.
32	M. Palmer, UK	WP7 participant	MRC has experience of providing infrastructure at the national, European and international level. MRC is one of the funders of UKBioBank and supports many other biological banks and resources. MRC is participating in a number of ESFRI projects in the biomedical area and is well placed to contribute to discussion on developing viable infrastructure for this project.
33	S. Walker, UK	WP2 and WP5 participant	CIO UK Biobank, Information Systems Programme Director, National Institute of Health Research; Co-leader of EU work package 'Biobank databases and Information Management Systems'.
34	J.W.A. Ridder, NL	WP7 participant	Ministerial contact person for the Academic Biobank Netherlands; Council member of EMBL; delegate in FP7 PC-Research Infrastructures; secretary of the National roadmap commission in The Netherlands
35	R. Valsdottir, IS	WP7 participant	Ph.D. Biochemistry, MBA. Senior Advisor, International Division of RANNIS, National expert and NCP in FP7 Cooperation Themes 1 and 2. NCP in the ERC programme Ideas.
36	B.H.R. Wolffenbuttel, NL	WP2 participant	Professor of Endocrinology and Metabolism; University Groningen, Scientific Director LifeLines Cohort and Biobank, member P3G, >150 publications.
36	J.L. Hillege, NL	WP5 participant	Associate Professor Cardiology, member of the management board of the Department of Epidemiology, Clinical Assessor for the Medicines Evaluation Board, The Netherlands, Clinical Expert for the European Agency for the Evaluation of Medicinal Products, founding director of the Trial Coordination Center at the University Medical Centre of Groningen; Member of several steering committees and advisory boards including LifeLines.
37	D.A. Legemate, NL	WP3 participant	Scientific Director, Dutch Academic Patient Data and Biobank Consortium (Pearlstring Initiative). Professor of surgery and clinical epidemiologist
38	E. Beem, NL	WP7 participant	Co-director, health research funding, access to expertise on every subfield of health research; specific: biochemistry of rare diseases, member of International Stem Cell Forum, member of EMRC
39	H. Zimmermann, DE	WP4 and WP7 participant	Head of Cryotechnology department, Professor of Cryobiophysics & Cryobioinformatics, Principal investigator in Bill&Melinda Gates Foundation biobanking project, Research & demonstration cryobank (first and only with permission for embryonic stem cells), >30 cryobanking related patents files, >30 scientific papers, founding member of "Gemeinschaft Deutscher Kryobanken e.V."
40	F. Laplace, DE	WP7 participant	Federal Ministry for Education and Research, Head of Unit Molecular Life Sciences
41	R. Klang, AT	WP7 participant	Austrian Ministry for Science and Research, Head of Division Research Policy and Life Sciences; Lawyer
43	K. Stefansson, IS	WP2 and WP5 participant, national contact	M.D., Dr. Med., President, CEO and Co-founder of deCODE genetics, Reykjavik, Iceland. Former Professor of Neurology, Neuropathology and Neuroscience (Harvard), Director of Neuropathology (Beth Israel Hospital, Boston), Professor in Neurology, Neuropathology and Neurosciences (University of Chicago); 184 publications
44	H. Gottweis, AT	WP6 participant	Professor, department of Political Sciences, research associate at the BIOS Centre, London School of Economics (LSE), director LIFE-SCIENCE-GOVERNANCE INSTITUTE, recent FP6 projects are BIONET, a China-EU network on ethical governance in bio-medical research (2006-2008,) and GENBanC (2006-2008), a project on biobank governance.
46	R. Chadwick, UK	WP6 participant	Ethics, especially Human Genetics and Genomics Director, CU – ESRC Centre for Economic and Social Aspects of Genomics, Member of UK MRC Steering Committee on DNA Banking. Chair, Ethics Committee of the Human Genome Organisation
47	P.L. Spagnoli,	WP7 participant	Full Professor and Director of Anatomic Pathology, University of

	IT		Rome "Tor Vergata", Director-General of "Alleanza contro il cancro", Member of the Working Group for Biobanks Certification, National Committee for Biosafety and Biotechnologies, Presidency of Italian Council of Ministers 328 publications, Atherosclerosis and vascular pathology, Clinical and experimental oncology, Histopathology applied to pharmacotoxicology.
49	J. Jorcano, ES	WP7 participant	General Manager Genome Spain
50	I. Reimand, EE	WP7 participant	PhD in optics and spectroscopy, head of research policy department of Estonian Ministry of Education and Research, member of CREST, member of ESFRI, member of e-IRG
52	I.A. Tsoukalas, GR	WP7 participant	Representative of the Hellenic Republic Ministry of Development
53	D. Thanos	WP3 participant	Director of the Center of Basic Research II and the Vice-Chairman of the Scientific Board at the Biomedical Research Foundation of the Academy of Athens, Greece., AAdjunct Professor in the Department of Biochemistry and Molecular Biophysics at the College of Physicians & Surgeons of Columbia University,
54	J. Eder, AT	WP5 participant	Databases and information systems; PI Data management in Biobanks (Austria, GEN-AU), Partner EU NoE Interop; VP Austrian Science Funds; >100 publications (data bases, information systems, workflow)
55	E.Vuorio	WP1 participant	Professor of Molecular Biology, has served as the Chancellor of the University of Turku since September 2003, 2002-2006: Chair of the European Molecular Biology Laboratory (EMBL) Council, expert duties at the European Commission and the European Science Foundation (ESF), in 2008 appointed to chair the ER C Identification Committee
56	J. Bovenberg, NL	WP6 participant	Practicing attorney in bio-law, founder of the "Legal Pathways Institute for Bio-Law b.v.", an independent private research institute. Legal counsel to Dutch, European and Global public and private bio-medical Research Community, including the OECD, the Human Genome Organization (HUGO), the Public Population Project in Genomics (P^3G) and the Netherlands Royal Academy of Sciences. Privacy committee Netherlands National Pathology Archives and METC of Netherlands Cancer Institute (NKI)
57	M.Griffith	WP1 participant, Stakeholder Forum chair	Has served as Chief Executive of Fighting Blindness, active in the European Platform for Patients Organisations, Science and Industry (EPPOSI). Currently he is board member of the Irish Platform for Patients' Organisations, Science and Industry (IPPOSI)
58	C. Bréchot, FR	WP7 leader (industrial relations)	MD, PhD, Cancer Research; Executive Director of INSERM since 2001, Head of the National Reference Center on the molecular epidemiology of viral hepatitis, Pasteur Institute and Inserm U370, Paris (1998-2001) President of the French National Consortium for Research in Genomics-CNRG (2002-2006), sevaral awards and nominations including the academy of medicine,1996; Jean Valade award, 2000.more than 350 publications in medical and scientific journals. Since 2008 at Merieux.

B 2.3 Consortium as a whole

Work package leaders and participants (List of beneficiaries, Table 3) form a consortium which comprises European leaders in the field of biobanking, biomolecular resources as well as ethical and legal issues. Furthermore, several ministries (research and health) and funding agencies form European Member States are co-applicants and participate actively in the funding and financing work package (Table 4).

Table 4: Ministries and funding organizations contributing to the preparatory phase

Participating organisation	Country

Alleanza contro il cancro (ACC)	Italy
Bundesministerium für Bildung und Forschung (BMBF)	Germany
Bundesministerium für Wissenschaft und Kultur (BMWF)	Austria
Comitato Nazionale per la Biosicurezza e le Biotecnologie, Presidenza del Consiglio dei Ministri (CNBBSV)	Italy
The Icelandic Centre for Research (RANNIS)	Iceland
Dutch Academic Biobank Consortium (NFU)	The Netherlands
Dutch Ministry of Education, Culture and Science (OCW)	The Netherlands
Féderation hospitalière de France (FHF)	France
Fraunhofer Institute of Biomedical Engineering (Fraunhofer)	Germany
Genoma España (Genome Spain)	Spain
Head of Research policy department, Ministry of Education and Research (HM)	Estonia
Research Infrastructure and Special Initiatives Unit Health Research Board (HRB)	Ireland
Helmholtz Association (Helmholtz)	Germany
The Norwegian Institute of Public Health (NIPH)	Norway
Institut National de la Santé et de la Recherche Médicale (INSERM)	France
Institut National du Cancer (INCa)	France
Irish Clinical Research Infrastructure Network hosted by the Dublin Molecular Medicine Centre (ICRIN)	Ireland
Max-Planck Society (MPG)	Germany
Medical Research Council (MRC)	United Kingdom
Research Institute on Rare Diseases (ISCIII)	Spain
Telethon, Comitato Telethon Fondazione ONLUS (FTELE)	Italy
The Netherlands Organisation for Health Research and Development (ZoMw)	The Netherlands
Univ. of Malta, Laboratory of Molecular Genetics, Dept. of Physiology and Biochemistry (UoM)	Malta
Hellenic Republic Ministry of Development (GSRT)	Greece
Organisations with letter of support	**Country**
International Research Programmes Department	Spain
Ministère Education Nationale Enseignement Supérieur Recherche	France
Ministerio de Educacion y Ciencia	Spain
Ministry of Social Affairs and Health	Finland
National Office for Research and Technology – NKTH	Hungary
The Government of Romania, Ministry of Education, Research and Youth, National Authority for Scientific Research Cabinet of the President	Romania
The Research Council of Norway	Norway
Vetenskapsradet Swedish Research Council	Sweden

A specific challenge of the preparatory phase is that in order to address the emerging need of providing access to biological materials from sufficiently large cohorts representing the different European populations, the infrastructure has to integrate many biobanks and biological resources across Europe. To develop an operational concept and standards, which can be applied in existing biobanks and resources, 104 major European biobanks have expressed their interest in contributing to the preparatory phase and becoming member of BBMRI (see Table 6). These biobanks would contribute enormous resources as building blocks for construction of BBMRI (Table 5).

Table 5: Summary of samples and resources contributed by associated biobanks. Results from questionnaires provided by biobanks listed in Table 6 and from List of beneficiaries (Table 3).

Biobank format	Number of biobanks	Number of samples	Funding invested	Funding approved
Population-based	36	2.4 million		
Disease-	67	10 million		

oriented				
Others	1	1,500		
Total	**104**	**12.5 million**	**340 M€**	**138 M€**

Representatives of these biobanks as well as industrial partners from biotech and pharma industry will contribute to the preparatory phase as participants in the work packages, in expert groups as stakeholders or as board or council members. Of particular importance for an infrastructure containing human samples and data is expertise in ethical societal and legal issues, which is provided by partners of WP6 and complemented by subcontracting of lawyers.
The specific expertise and assets provided by the work package leaders, partners and chairs of the boards and councils are summarized above in Table 3. Full CVs will be published on the BBMRI website (currently: www.biobanks.eu). Further organisations from the scientific community, stakeholders and funding organisations are listed in Table 6.

Table 6 - List of **other organisations*** involved in the Preparatory Phase (as of 5/11/2007)

**: Other organizations comprise major European biobanks the integration of which into BBMRI has to be considered in the preparatory phase, ministries and funding agencies as well as industrial partners and service providers. The table does not include biobanks of beneficiaries listed in Table 3.*

Organisation Name	**Country**	**Description of the Organisation / Specific role or contribution to the preparatory phase**
University of Sydney, Dept. of Sociology and Social Policy	Australia	Ethical, legal and social issues (C. Waldby)
AKH Biobank	Austria	Disease-focused Biobank (ageing & lifestyle diseases) (C.Marsik)
CLST Cryo Life Science Technologies	Austria	Cryo-Logistics Provider Company, (G.H. Thiessen)
IMBA – Institute of Molecular Biotechnology GmbH	Austria	Functional genomics (J. Penninger)
Institute of Clinical Neurobiology	Austria	Probes from VITA aging study, assessment of amyloid, paraffin-embedded blocks of degenerative diseases, frozen half-brains from Alzheimer disease and aged controls (A. Jellinger)
Oridis-Biomed GmbH	Austria	Development and implementation of in-vitro diagnostics, in vitro prognostics and companion diagnostics (N. Wick)
Pathology Institute, Otto Wagner Hospital	Austria	Paraffin embedded tissue of central nervous system from neurodegenerative diseases (J. Attems, F. Lintner)
VETBIOBANK	Austria	Disease-focused biobank (animal disease models) (I. Walter)
Public Population Project in Genomics - P^3G	Canada	Non-for-profit organisation promoting collaboration between researchers in the field of population genomics (I. Fortier)
The Cyprus Institute of Neurology and Genetic	Cyprus	Disease-focused & population-based biobank (genetic and neurological disorders)(P.C. Patsalis)
Genetics Resource Centre – GRC, Ministry of Health and Social Affairs	Faroe Islands	Tissue bank, Genealogy & Diagnosis Registry (S.O. Vang)
Ministry of Social Affairs and Health	Finland	Ministry (K. Leppo)
National Public Health Institute	Finland	Population-based biobank (M. Perola)
Air Liquide, Société Anonyme pur l'Etude et l'Exploitation des Procédés Georges Claude	France	Cryo storage, sample preservation and logistics (M. Lemaire)
APHP Saint Louis Paris	France	Disease-focused biobank – cancer tissue (A. Janin)
APHP, Centre Hospitalier de la Pitié-Salpetrière	France	Biobank (A. Brice)
Biological Resource Center of Dijon, University Hospital CHU Dijon	France	Disease-focused biobank (A. Bonnin)
BRC Créteil	France	Disease-focused biobank – rare diseases (B. Ghaleh-Marzban)
BRC Epigenetec Paris	France	Biobank (P. Laurent-Puig)
BRC Hôpital Cochin Paris	France	Biobank (J. Chelly)
BRC Marseille FNLCC	France	Disease-focused biobank – tumour tissue (C.Chabannon)
BRC Strasbourg	France	Disease-focused biobank – tumour tissue (A. Neuville)
BRC-Centre Léon Bérard,Lyon	France	Disease-focused biobank – cancer tissue and blood (M. Rousseau-Tsangaris),

CARDIOBIOTEC- CRB Hospices Civils de LYON	France	Disease-focused Biobank (C. Perrin)
Centre Hospitalier Universitaire d'Amiens, Biobanque de Picardie	France	Disease-focused Biobank, BRC platform, proteomics (F. Betsou),
Centre Paul Strass Strasbourg	France	Disease-focused biobank – tumour tissue (D. Ghnassia)
Centre René Huguenin, Pathology Department	France	(F. Bertrand)
CHU CAL UNSA Human biobank	France	Disease-focused biobank (C. Ducord)
Clinical Investigation Centre INSERM CIC-0502 Brest	France	Disease-focused biobank, diagnostics & imaging of venous thromboembolism (E. Oger)
Clinical Investigation Centre Marseille	France	Biobank (O. Blin)
DNA and Cell Bank – Federative Institute for Research in Neurosciences (IFR70)	France	Disease-focused biobank – DNA & cell lines (A. Brice)
E3N Biobank	France	Population-based biobank (V. Hélin),
ESF Centre Atlantique, CRBT	France	(I. Desbois)
GENETHON, Banque ADN Evry	France	Disease-focused biobank – DNA (S. Saker-Delye)
Genopole	France	Analysis platforms, stem cell research(F. Russo-Marie)
GIE Neuro CEB Paris	France	Disease-focused biobank – brain tissue (M.V Artaud)
Hôpital Beaujon Clichy	France	Disease-focused biobank – tumour tissue (P. Bedossa)
Hopital Cochin, Paris, Service d'Anatomie Pathologique	France	Disease-focused biobank – tumour tissue (B. Terris)
Hôpital Maison Blanche Reims	France	Toxoplasma gondiistrain collection (I. Villena)
Hôpital Necker Paris	France	Disease-focused biobank – tumour tissue (L. Boccon-Gibod)
Hôpital Necker Paris	France	Disease-focused biobank – tumour tissue, DNA, RNA (N. Brousse)
Hôpital Necker Paris – Necker DNA bank	France	Disease-focused & population based biobank – rare diseases, familiy cohorts (C. Antignac)
Hôpital Pierre Zobda-Quitman Fort de France	France	Disease-focused biobank – tumour tissue (M. Landau-Ossondo)
Hospices Civils de Lyon	France	Disease-focused biobank - tumour tissue, blood, CSF (M.C. Mazé)
Human Genome Diversità Project-Centre d'Etude du Polymorphisme Humain (HGDP-CEPH)	France	Lymphoblastoid cell lines (H. Cann)
IAC Angers	France	Disease-focused biobank – tumour tissue (J.-P. Saint Andre)
Inserm ERI 20 Villejuif	France	Population-based biobank – blood (F. Clavel-Chapelon)
Inserm Toulouse	France	Biobank (C. Cambon)
Inserm UMR S 546 Paris	France	Disease-focused biobank – DNA (B. Fontaine)
Inserm, Nantes	France	Biobank (D. Riochet)
Institut Curie, Centre de Ressources Biologiques, Départment Biologie des Tumeurs	France	Biological resources (X. Sastre-Garau)
Institut Jean Dausset Paris	France	Population-based biobank – DNA, BPL (H. BlancheBlanché)
Institut Jean Godinot	France	Disease-focused biobank – tumour tissue (Ch. Delvincourt)
Institut Mutualiste Montsouris Paris	France	Dsease-focused biobank – tumour tissue (P. Validire)

Institut Pasteur Paris	France	Biobank (M.-N. Ungeheuer)
ITERT-Uro-Néphro, INSERM U643	France	(M. Giral)
L'Institut du Thorax – UMR 533 (Biocollection Cardiovasculaire et Métabolisme « BC2M »)	France	Population-based & disease-focused biobank – CVD tissue & DNA (C. Petit Petit-Le Manach),
Leishmania Cryobank of Montpellier	France	Disease-focused biobank – Leishmania strains (J-P Dedet)
NEUROBIOTEC BANQUES-CRB Hospices Civils de LYON	France	Disease-focused biobank (N. Dufay)
Stanislas Cohort (IGE-PCV), INSERM U525 Nancy	France	Disease-focused biobank – CVD blood, blood cells & DNA (S. Visvikis-Siest)
The Nancy Teaching Hospital Center for Biological Resources	France	Disease-focused biobank (N. Martinet)
Tumorothèque - CRB des Hospices Civils de Lyon	France	Disease-focused Biobank (J.Y. Scoazec)
Tumorothèque de l'Hopital Cochin	France	Disease-focused biobank (B. Terris),
Tumorothèque Nationale Franche Comté	France	Tumor Biobank (B. Kantelip)
Tumorothèque St Etienne	France	Disease-focused biobank – tumour tissue (M. Peoch'h)
University Hospital Angers	France	Disease-focused biobank – rare diseases (A. Barthelaix)
University Hospital Cimiez Nice	France	Biobank - tissue (C Ducord)
University Hospital Morvan brest	France	Disease-focused biobank – tumour tissue (A. Volant)
University Hospital Rouen	France	Disease-focused biobank – tumour tissue (J.-C. Sabourin)
EURORDIS – European Organisation for Rare Diseases	France (EU-worldwide organisation)	Euro-Biobank – European Network of Rare Disease Biobanks (F. Bignami)
BrainNet Europe	Germany	Consortium of 18 European brain banks (H.A. Kretzschmar)
Central Biomaterialbank of the German Competence Network for Heart Failure (GHFN) [Kompetenznetz Herzinsuffizienz (KNHI)]	Germany	Disease-focused biobank - CVD blood(C. Özcelik)
Competence Net Pediatric Oncology and Hematology; Biobank for Embryonal Tumors	Germany	Disease-focused biobank – tumour tissue (F. Berthold)
Competence Network for HIV/AIDS	Germany	Disease-focused biobank (A. Skaletz-Rorowski)
CRIP (Central Research Infrastructure for Molecular Pathology)	Germany	Disease-focused Biobank network (Germany-Austria), internet acess (C. Schröder)
Danubian Biobank Consortium	Germany	Population-based & disease focused biobank – metabolic diseases (G. Schmitz)
DNA-Collection of Juvenile Idiophatic Arthritis	Germany	DNA collection (J.P. Haas)
DPZ, Deutsches Primatenzentrum GmbH	Germany	Primates, animal repository (R. Teepe)
DSMZ-Deutsche Sammlung von Mikroorganismen und Zellkulturen GmbH	Germany	Biomolecular resources, cell line collections (E. Stackebrandt, H. Quentmeier)
Friedrich-Baur-Institute and Department of Neurology, Ludwig-Maximilians-University of Munich	Germany	Disease-focused Biobank - Muscle Tissue Culture Collection (H. Lochmüller)
GEDEK Gemeinschaft Deutscher Kryobanken Fraunhofer IBMT	Germany	Biobank Cryo Technology (H. Zimmermann)
GENEMOVE University of Tuebingen, Department of Medical Genetics	Germany	Disease-focused biobank – neurological & psychiatric diseases, DNA (P. Bauer)

GEPARD (Gene Bank Parkinson's Disease Germany) in the German Competence Network on Parkinson's disease (CNP e. V. - charity)	Germany	Disease-focused biobank – movement disorders (U. Wüllner)
German Competence Network for HIV, AIDS	Germany	Sera collection (N. Brockmeyer)
German Dementia Competence Network	Germany	Population-based & disease-focused biobank – cognitive disorders, DNA, blood (W. Maier)
Heinz Nixdorf Recall Study	Germany	Population-based biobank – CVD, cancer, mental disorders, blood DNA (K.H. Jöckel),
IKC, Institute of Clinical Chemistry Medical Faculty Mannheim University of Heidelberg	Germany	Disease-focused biobank, quality assurance (M. Neumaier)
ImaGenes GmbH	Germany	Gene clone collection (J. Maurer)
Institute of Science and Ethics, University of Bonn	Germany	Biobank ELSI (M. Fuchs)
Klinik für Chirurgische Onkologie, Robert-Roessle-Klinik, Charité Universitätsmedizin Berlin	Germany	Disease-focused biobank (W. Kemmner)
KORA-gen (Cooperative Health Research in the Region of Augsburg)	Germany	Population-based biobank – blood, DNA (H.E. Wichmann),
NFGN Working group "Quality management and Standards" (AGQM) of the National Genome Research Network (NGFN)	Germany	Biobank Quality Management (S. Wiemann)
Philipps-Universität Marburg	Germany	ELSI for Biobanks (P. Dabrock)
POPGEN University Hospital Schleswig-Holstein, Campus Kiel	Germany	Population-based biobank, (M. Krawczak)
Qiagen GmbH	Germany	Biotech industry, sample processing and preparation (A. Quandt)
SHIP, SepNet Central Sample Bank	Germany	Disease-focused biobank - blood (M. Kiehntopf)
SNiP, Research Network Community Medicine, "Survey of Neonates in Pommerania" DNA-Collection on Juvenile idiopathic arthritis	Germany	Population-based biobank – neonates, blood, placenta, DNA (J.-P. Haas)
Study of Health in Pomerania	Germany	Population-based biobank (H. Völzke)
TMF Telematikplattform Medizinischer Forschungsnetze	Germany	ELSI, Quality, Harmonisation, Standardization of Biobanks (S. Semler)
Unabhängiges Landeszentrum für Datenschutz (LD)	Germany	IT security for Biobanks (L. Gundermann)
Foundation for Biomedical Research of the Academy of Athens	Greece	Disease-focused biobank – blood, tissue, rare diseases, cancer (C. Stavropoulos)
Institute of Biological Research and Biotechnology, National Hellenic Research Foundation	Greece	Coordination of Greek Cancer Research Network (A. Pintzas)
The Hellenic National Biobank	Greece	Population-based biobank - (A. Papassavas)
Hungarian Biobank	Hungary	Disease-focused biobank – cancer, rheumatoid arthritis, asthma; DNA (A. Falus),
National Institute of Environmental Health (NIEH)	Hungary	Disease-focused biobank – DNA, blood, neuromuscular & mitochondrial diseases (M. Karcagi)
University of Pécs	Hungary	Disease-focused biobank – DNA, rare diseases, metabolic diseases etc. (B. Melegh)
Islensk Erfdagreining ehf (deCODE genetics ehf)	Iceland	Population-based biobank – population isolates (G. Einarsson, K. Stefánsson)
Landspitali – University Hospital, C13	Iceland	K. Erlendsson
Health Research Board	Ireland	(R. Barrington)
Trinity Biobank	Ireland	Population-based & disease-focused biobank - DNA (J. McPartlin),

Bank of DNA, Cell Lines and Nerve-Muscle-Cardiac Tissues. UOS Servizio di Diagnostica delle Malattie Neuromuscolari. Fondazione Ospedale Maggiore Policlinico IRCCS, Universitá degli Studi Milano	Italy	Population-based & disease-focused biobank – neuromuscular diseases, tissue, DNA, muscle cell culture (M. Moggio)
Biobanca Istituzionale Istituto Tumori Giovanni Paolo II – Bari	Italy	Disease-focused biobank (G. Pelagio)
Biobanca Italiana, Center of Transfusion Medicine, Cellular Therapy and Cryobiology (CMTC), Department of Regenerative Medicine, Foundation Ospedale Maggiore Policlinico, Mangiagalli e Regina Elena	Italy	Disease-focused biobank (P.Rebulla)
Biobanking Network and Molecular Evidence Medicine Group (BN-MEM)	Italy	Virtual archive tissue bank (G. Stanta)
BioRep S.r.l.	Italy	Cell culture banking (P. de Blasio)
Centro Substrati Cellulari, Istituto Zooprofilattico della Lombardia e dell'Emilia Romagna, Brescia	Italy	Disease-focused biobank (M. Ferrari)
Comitato Nazionale per la Biosicurezza e le Biotecnologie	Italy	(LoS, L. Santi)
Da vinci European biobank, Pharmacogenomic foundation FiorGen onlus	Italy	Collections of urine, serum and plasma samples (P. Turano)
Department of Public Health Sciences, Sapienza University of Rome	Italy	Organisation (S. D'Amelio)
Fondazione I.R.C.C.S. Istituto Neurologico C. Besta	Italy	Disease-focused biobank – neuromuscular disease, muscle tissue, DNA (M. Mora)
Memory Clinic, NeuroBioGen Lab, IRCCS S. Giovanni di Dio Fatebenefratelli	Italy	(G. Binetti)
Neuromuscular Bank of Tissues and DNA Samples, Telethon	Italy	Population-based & disease-focused biobank - neuromuscular disease, muscle tissue, DNA, cultured cells (C. Angelini),
Research Laboratories Catholic University	Italy	Population-based & disease-focused biobank (M. B. Donati),
Second University of Naples – Cardiomiology and Medical Genetics	Italy	Disease-focused biobank – (cardio)myopathies, tissue, DNA (L. Politano)
Telethon Network of Genetic Biobanks	Italy	Coordination of seven Italian biobanks (F. D. Bricarelli)
VAS - Vascular - Independent Research and Education - European Organisation - c/o Research Centre of Vascular Diseases, University of Milan	Italy	Disease-focused biobank – vascular diseases (M. Catalano)
Thalassemia DNA Biobank, Unersity of Malta, Molecular Genetics Lab	Malta	Euro-Biobank Member (A. Felice)
Oslo Clinical Research Biobank Consortium, Ullevaal University Hospital Trust	Norway	Population-based biobank - blood (R. Bjugn)
The Research Council of Norway	Norway	(LoS, A. Hanneborg)
International Hereditary Cancer Center	Poland	Cancer biobank, biological samples, clinical data (J. Lubinski)
Laboratory of Glycobiology, instituto de Tecnologia Química e Biológica	Portugal	Disease-focused biobank, bank of plasma and cerebrospinal fluid (J. Costa)
"Victor Babes" National Institute of Pathology and Biomedical Sciences	Romania	Disease-focused biobank – tumours, tissue, bone marrow, blood (C. Ursaciuc)
Fundeni Clinical Institute	Romania	Disease-focused biobank - colonic and rectal cancer (I. Popescu)
Neuroscience Research Department of Clinical Hospital "Bagdasar-Arseni" – Brain Tumours Bank	Romania	Disease-focused biobank – brain tumours, tumour cell culture (F. Brehar)
The Government of Romania, Ministry of Education, Research and Youth	Romania	LoI (A. Anton)
King Abdulaziz Medical City – National Guard Health Affairs	Saudi Arabia	Extracted DNA, amniotic fluid for prenatal diagnostics, tissues, muscle biopsy (I. Alabdulkareem)

Neuromuscular Biobank of the University of Ljubljana, Medical Faculty, Institute of Anatomy	Slovenia	Population-based & disease-focused biobank (M. Meznaric-Petrusa),
European Commission, Institute for Prospective Technological Studies	Spain	Organisation (E. Zika)
Fundación Istituto Valenciano de Oncología	Spain	Disease-focused biobank – cancer tissue (J. A. LopezLópez-Guerrero),
Institut de Recerca Biomedica de Lleida (IRBLLEIDA)	Spain	Biobank (X. Matias-Guiu), Disease-focused
Instituto de Investigacion de Enfermedades Raras – IIER-ISCIII	Spain	Euro-Biobank member, Organisation, rare diseases (M. Posada)
Spanish National Cancer Centre (CNIO) Tumor Bank Network	Spain	Disease-focused biobank – tumour tissue (M.M. Morente)
Subdirección General de Evaluación y Fomento de la Investigación (SGEFI), Instituto de Salud Carlos III	Spain	Fund for Health Research (R. Andrés-Medina)
Swedish Research Council – VR	Sweden	Government agency under the Ministry of Education and Research (P. Ormling)
Uppsala Akademiska Sjukhus, Department of Genetics and Pathology, Uppsala University	Sweden	Human tumor tissues for somatic mutational analyses of human cancer (T. Sjöblom)
Stiftung biobank-suisse / foundation biobank-suisse	Switzerland	Network of disease-oriented research biobanks (D. Simeon-Dubach)
Swiss Biobank	Switzerland	Cell bank, R&D services in regenerative medicine sector: hematopeitic, mesenchymal and progenitor cells (D. Medjahed)
Amsterdam Medical Center	The Netherlands	Disease-focused biobank, Dyslipidemia (Kastelein)
Center for Medical Systems Biology	The Netherlands	Population-based and disease focused biobank, isolates, genotyping and phenotying infrastructure, NA/Serum (GJB van Ommen, LUMC)
Center for Medical Systems Biology, Leiden University Medical Center	The Netherlands	Population, isolate and disease-focused biobanks, genotyping and phenotying infrastructure DNA/Serum (GJB van Ommen,)
CLB/ Amsterdam Medical Center	The Netherlands	Diseasefocused biobank,. Longitudinal HIV/AIDS (Amsterdam Cohort) (H. Schuitemaker)
Erasmus Rucphen Family Study	The Netherlands	Population-based biobank (w. fam. Structure, isolate), DNA / Serum, deep-clinically phenotyped (C van Duijn, ErasmusMC)
ErasmusMC	The Netherlands	Population-based biobank (cancer, cardiovascular, neurological, psychiatric, endocrine, locomotor and ophthalmological disorders) ERGO/EPOZ, (Hofman, van Duijn)
Leiden University Medical Center	The Netherlands	Disease-focused biobank, CVD risk factors, Intervention trial. (W. Jukema)
Leiden University Medical Center	The Netherlands	Disease-focused biobank, 3 cohorts, migraine & headache (Ferrari)
Leiden University Medical Center	The Netherlands	Disease-Based, dyslipidemia (Smelt)
Leiden University Medical Center & ErasmusMC	The Netherlands	Disease-focused & population-based biobank, Osteoathritis (Slagboom / van Duijn)
LifeLines Cohort and Biobank	The Netherlands	Population-based & disease-focused biobank (B.H.R. Wolffenbuttel)
NL Epidemiological Study on Depression and Anxiety (NESDA)	The Netherlands	Disease-focused biobank, (B Penninx, VU)

NL Twin Registry	The Netherlands	Population-based, deep-phenotyped (D.I. Boomsma, VU). DNA / Serum/ RNA). Various diseases
Radboud University Nijmegen Medical Center, Department of Epidemiology and Biostatistics	The Netherlands	Nijmegen biomedical study – age-stratified random sample of the population, polygene-Nijmegen study – population-based collection of germline DNA (A. Kiemeney)
Rheumatoid arthritis	The Netherlands	Disease-focused, (Huizinga LUMC)
UMC Utrecht, department of cardiology	The Netherlands	Disease-focused biobank – CVD cardiomyocytes (P.A. Doevendans)
UMCU/ UMCG	The Netherlands	Disease-focused biobank, Type 2 Diabetes (C.Wijmenga)
UMCU/ UMCG	The Netherlands	Disease-focused biobank, Coeliac disease (C.Wijmenga)
University Medical Center Gent	The Netherlands	Disease-focused biobank, longitudinal, Asthma, allergy: 4 Cohorts (Postma)
University Medical Center Utrecht, Julius Center for Health Sciences and Primary Care	The Netherlands	DNA-collection (S.S. Soedamah-Muthu)
Dkuz Eylül University Faculty of Medicine	Turkey	Contact person for biobanks in Turkey (M. Özgören)
AstraZeneca Charnwood, BIOSES	United Kingdom	Pharmaceutical industry, biobanks in industry (J. Corfield)
Biobank Services, National Health Service Greater Glasgow & Clyde	United Kingdom	Biobank ELSI and logistics (J. Hair)
Division of Cell Biology and Imaging, NIBSC	United Kingdom	Cell Culture Collections (G. Stacey)
Dubowitz Neuromuscular Centre Neuromuscular Biobank	United Kingdom	Disease-focused iobank – muscle and skin tissue and primary cell cultures (F. Muntoni)
European Collection of Cell Cultures - ECACC	United Kingdom	Cell Culture Collections (D. Lewis)
Geneservice Ltd.	United Kingdom	Gene and clone collections (A.J. Walker)
Human Genome Diversity Project-Centre d'Etude du Polymorphisme Humain, HGDP-CEPH	United Kingdom	Lymphoblastoid cell lines from blood samples (H. Cann)
National Cancer Research Institute	United Kingdom	Consortium of institutions: development, management & use of cancer biobanks (J. Cope)
onCore, National Cancer Research Institute NCRI	United Kingdom	Biobanking organisation, prevention, diagnosis and treatment of cancer (A. Carter)
University of Leicester, Department of Health Sciences	United Kingdom	Leadership role in international biobank harmonization initiatives – P^3G, PHOEBE (P. Burton)

Sub-contracting:

Subcontract 1:
For public relations including the design and print of information material as well as hosting the BBMRI web site professional agencies will provide the necessary services as subcontractors. For these services a total of € 100,000.- are foreseen.

Subcontract 2:
For an expert report by WP7 on the impact of BBMRI on science, industry and heath care will require € 202.500.--. The expert opinions and reports will be produced by

independent professional organizations as subcontractors. Specific aspects to be elaborated in these documents are the impact of BBMRI on:

- Improvement of efficacy and quality of research in the field of life sciences. Both basic and applied life sciences research rely on access to human biological samples and data. The progress of such projects is often hindered by the difficult and limited access to human materials and data. Furthermore, the quality of these projects is critically dependent on the quality of the materials and data analysed.
- Improved efficacy in drug discovery and development. The high attrition rate in drug development is a major cause of increase in heath care costs. There is an urgent need for biomarkers for early prediction of drug safety and efficacy (see also strategic research agenda of the Innovative Medicines Initiative). BBMRI is a key resource for the development of such biomarkers, which requires large numbers of standardized human biological samples, including detailed medical data as well as innovative analysis tools.
- Advancement of personalized medicine. To understand the multitude of factors that contribute to the large variability in human diseases and to the differences in responses to therapy, large population-based and disease-oriented biobanks are a prerequisite. For most diseases, a sufficient number of cases in a given disease subgroup can only be provided by collation of resources from a large network of biobanks applying common standards. This also explains why BBMRI has a distributed hub structure, which allows connecting many biobanks across Europe. Since BBMRI is the only provider which will be able to cover the emerging needs of personalized medicine for standardized human samples and data, it should be seen as a key resource for the improvement of healthcare in Europe.

Subcontract 3:
WP1 requires professional legal advice in the contract filing process (€ 165,584.--), which must be done by an external attorney office.

Subcontract 4:
WP 1 requires professional web support for € 10.000,-.

Subcontract 5:
WP 6 requires professional support for the execution of focus groups for € 30.000,-.

Additional beneficiaries / Competitive calls:

To be able to involve additional experts and stakeholders a budget of € 32,576.- is foreseen to cover their expenses.

In case one or more beneficiaries cannot perform their tasks any more, the coordination will nominate substitutes among the beneficiaries or involve new participants to perform these tasks.

B 2.4 Resources to be committed

The coordinator will require an academic employee and a part-time secretary (24 PM, and 18 PM, respectively) and the assistant coordinator will be supported by one part-time academic employee (18 PM). WP1 requires the appointment of a full-time

Executive Manager with pertinent management experience in industry or international organizations. Budget for such an expert are is foreseen for 27 PM. This person will be supported by an academic employee (24 PM) and part-time secretary (18 PM). Costs for office and secretarial expenses (stationery, computers, communication) are also foreseen.

The Associate Coordinator as well as the responsible person for global integration require support by a part-time academic employee (18 PM each).

For travel costs for the coordinator, executive manager and assistants to support international cooperation, 3 journeys per month are budgeted (for one of these persons in turn). The Associate Coordinator will require a travel budget for one monthly journey as well as the partner for global integration.

Several meetings have to be organized by WP1 and are budgeted according to the number of estimated participants per event. Two Governance Council meetings (60 PE each), four Steering Committee meetings (10 PE each), and two Coordination Committee meeting with 20 participants each (40 PE) are budgeted. In addition, an international conference will be organised in combination with the Stakeholder Forum meeting, to save on cost. Conference organization is budgeted and will be outsourced.

Within WP1, there will be subcontracting costs for the legal advice and contracting and public relations activities to be outsourced to professional agencies.

For the Chair of the Scientific and Ethical Advisory Board an academic part-time assistance (6 PM) is required. To cover travel costs for the international board members (9 persons) for two journeys (to cover the increased expenses of overseas flights) is budgeted.

For the Chair of the Stakeholder Forum, part-time assistance (6 PM) and contributions to travel cost for the Stakeholder Forum (ca. 250 participants) are required.

A travel budget for global integration (Coordination Board) will be required to support the necessary international contacts (travel expenses for incoming experts and for traveling to other organaisations, respectively).

WP1 will keep a budget for travel, subcontracting or other cost, which is not allocated to a specific work package, in order to allow new experts or organizations to become involved in the preparatory phase in case unforeseen topics have to be addressed or increased capacities are required in a particular work package.

Work packages 2-7 follow similar cost schemes. The work package leaders will require an assistant to support their work. The work package partners will be supported by part-time assistance (1/2 – 1/4 FTE for 3-9 partners per work package, except WP7 for which 1/4 FTE assistant per participant has been calculated, for details see Table 7). A basic travel budget will be allocated to all work packages leaders to cover travel cost of the leader as well as WP Participants and the expert group members (1 journey per month per work package leader, except wp6 that has an additional budget for expert meetings).

Three expert meetings with 8 participants are calculated in work package 2. Work package 3 will host 5 expert meetings with 7 participants. Work package 4 and 5 will hold 3 expert meetings with 10 participants each. In work package 6 three expert

meetings (á 10 participants) and two more comprehensive meetings with 18 participants are planned with additional budget not allocated costs. Four meetings with 25 members are calculated in work package 7.

Furthermore WP7 requires a budget for an expert report on the impact of BBMRI on science, industry and health care.

B3. Impact

B 3.1 Strategic impact

Over the last two decades, Europe has lost some ground in scientific issues, especially in the life sciences. By introducing a global networking component into this project, this will ensure that what will be developed in Europe will have an important global impact. Europe will serve as a model for other regions and thereby regain scientific credibility. Other regions and international institutions will be given new and improved implementation modules for their own development. To balance the need, on one hand, for Europe to become once again a leader in science and, on the other, to provide global solutions, thus sustaining the development and the use of biological resources, is one aim of this project.

- BBMRI will contribute to the technological development capacity in ERA by creating an infrastructure with a focus on research and development in sample and data management processes. In existing infrastructure components, such research and development has tended to take second place to the pursuit of investigations into the biological resources themselves, rather than into their management. As a result, improvements in basic laboratory processes (e.g. purification techniques) have tended not to be developed beyond proof of principle and data management systems have been developed with single locations in mind. The BBMRI Preparatory Phase will plan coordination between these infrastructure components and create a unique body of expertise with the capacity to make such improvements.
- BBMRI will contribute to the scientific excellence of Europe as a whole by providing
    - Investigators' access to high quality biological resources and data for:
    - Participants in current and future EU framework programme Health projects.
    - Epidemiologists, clinicians, geneticists, pathologists and molecular biologists in national centres of excellence.
    - Pharmaceutical and biotech industry
- BBMRI will provide a competitive advantage and fruitful environment for development of service and technology providing companies in that BBMRI will act as R&D partner as well as customer
- The implementation and development of its "distributed hub structure" which is designed to allow the extension of the infrastructure by incorporating existing and new components that meet the criteria of excellence of BBMRI and that have physical locations in the convergence regions as well as the outermost regions thus providing a pan-European solution.

B 3.2 Plan for the use and dissemination of foreground

The results and standards generated by BBMRI will be disseminated in public meetings, most importantly the stakeholder meeting, through various public reports and a dedicated website. One of the central aims of BBMRI is the dissemination of its work, to reach stakeholders, scientific community and general public as widely as possible. This work is shared between all workpackages, with central roles of WP1, WP6 and WP7. BBMRI will in this role contribute to policies, and harmonize standards, with emphasis on international standardization. This role will be achieved by cooperation

with various international standardization organizations (P3G, IMI, OECD, WHO), in which WP1 plays a specific role. The assessment of risks is integrated in the 'operative' workpackages (WP2, WP3, WP4 and WP5) and will be monitored by WP6 with respect to ELSI.

Public relations and dissemination are also major tasks of the executive management and will be addressed in addition to organizing an international conference in the context of the public consultation process at the beginning of year two. This will be done by establishing and hosting a web-site, preparation of flyers and brochures (for professionals and the general public) as well as press releases. For the various documents, input will be received from the respective work package leaders with special emphasis on scientific as well as on ethical and societal issues. The design of information materials and the hosting of the web-site will be outsourced.
For further details see description of WP1.

Contributions to standards:
The goal of the 'operative' workpackages WP2 – WP6 is to integrate and harmonize existing standards and if required to generate new standards in their respective fields on a European level (see workpackage descriptions). Within WP1, this harmonisation is taken to the international level by involving previous efforts within international consortia, such as the WHO, OECD and P3G.

- BBMRI will have a catalytic effect in this respect because standardisation will reduce the organisational and financial barriers for the design and implementation of experimental research projects using BBMRI's resources across the biomedical sciences.
- the scientifically justified further development of infrastructure (especially in the outermost regions of the EU).
- BBMRI will have an optimising effect because, in order to function, it is essential that it implements agreed standards for biological resources and data so as to enable distribution. BBMRI will adopt the best practice guidelines for biological resource centres of the OECD and will comply with and develop appropriate standards in the framework of the International Standards Organisation

Contribution to policy developments:

BBMRI will contribute to EC policy developments by

- Harmonization of existing standards
- Preparing the ground for harmonized legislation with respect to use and exchange of biological samples, and
- Lead to harmonization of funding shemes throughout Europe, with respect to the access to biological resources

Specifically, BBMRI will contribute to policy development in

- Work Package 1. Deliverable 1.16 includes the creation and operation of a Coordination Board. This will develop synergies with other biomedical sciences research infrastructures, in particular those proposed through the ESFRI process. By seeking to avoid duplication of effort between different research infrastructures policy will have been developed for the future harmonisation of operations and policy-making between the research infrastructures.

- Work Package 6. A number of is deliverables will contribute to policy development. We may refer particularly to Deliverable 6.4 which will make proposals for biobanking harmonisation from an ethical point of view; to Deliverable 6.6 which will produce a conceptual model of governance applicable to a pan-European infrastructure for ELSI issues; and to Deliverable 6.10 which will recommend the appropriate ELSI policy for BBMRI.
- Work Package 7. Deliverable 7.7 will develop a concept for funding and financing of BBMRI acceptable to European funders.

Risk assessment and related communication strategy:

A specific risk identified for the success of the preparatory phase of constructing BBMRI is that legislation in certain countries may have restrictions for the exchange of certain biological samples with partners from other countries, and that legislation cannot be changed within short time. In such a case a workaround may be sought, e. g. in such a way that the required analyses are performed within the country of origin of the material, and that only anonymized data are exchanged.
No risks for the public are foreseen for the preparatory phase. Risk avoidance in the subsequent construction and operation phases will be considered throughout the preparatory phase.

B4. Ethical issues

ETHICAL ISSUES TABLE

	YES	PAGE
Informed Consent		
• Does the proposal involve children?	X	Possibly in WP2 and 3
• Does the proposal involve patients or persons not able to give consent?	X	Possibly in WP3
• Does the proposal involve adult healthy volunteers?	X	Yes in WP2
• Does the proposal involve Human Genetic Material?	X	Yes in WP2 and WP3
• Does the proposal involve Human biological samples?	X	Yes in WP2 and WP3
• Does the proposal involve Human data collection?	X	Yes in WP2, WP3, WP4 and WP5
Research on Human embryo/foetus		
• Does the proposal involve Human Embryos?		x
• Does the proposal involve Human Foetal Tissue / Cells?	X	Possibly in WP3 and WP4
• Does the proposal involve Human Embryonic Stem Cells?	X	Possibly in WP4
Privacy		
• Does the proposal involve processing of genetic information or personal data (eg. health, sexual lifestyle, ethnicity, political opinion, religious or philosophical conviction)	X	Yes in WP2, WP3
• Does the proposal involve tracking the location or observation of people?	X	Possibly in WP2 and WP3 for cohort studies
Research on Animals		
• Does the proposal involve research on animals?		x
• Are those animals transgenic small laboratory animals?		X
• Are those animals transgenic farm animals?		X
• Are those animals cloning farm animals?		X
• Are those animals non-human primates?		X
Research Involving Developing Countries		
• Use of local resources (genetic, animal, plant etc)		X
• Benefit to local community (capacity building ie access to healthcare, education etc)		X
Dual Use		
• Research having potential military / terrorist application		x

The BBMRI application in its preparatory phase aims at establishing the bases for the construction of the pan-European biobank and biomolecular research infrastructure, where ethical aspects will have an important role. Common standards for informed consent, data protection as well as biosafety and biosecurity measures will be developed during the preparatory phase as an integral element of the operational concept and have to implemented before the start of operation. As a matter of fact, presently the sharing and exchange of samples, data and various biomolecular resources between European countries are being made complicated not so much because of technological obstacles but more so because of the large heterogeneity of ethical and legal frameworks, as regards to informed consent requirements, variety of the institutions and ethics committees involved and of their attributions and competencies, variable rules for exporting and importing samples and data, different rules for different kinds of samples, heterogeneity of definition of anonymization procedures etc.. A certain level of uncertainty and a lack of knowledge of standards and rules in this domain across borders are a source of practical difficulties. Unlike technical standards that involve mainly professionals and well identified agencies, biobanks and biomolecular resources ethical frameworks (that may be translated into legal framework, at least partially in some of the EU countries and for some aspects in certain Directives) rely on a more heterogeneous group of principles, traditions, regulation bodies and stakeholders. No agreed and binding framework at pan-European level exists in the domain that embraces all possible cases covered by BBMRI. Because of the variety and importance of such issues, a full WP has been devoted to ELSI in order to plan at best how to deal with all ethical and legal issues of relevance for networking and harmonizing frameworks of biobanks. Thus the consortium is fully aware of the importance of these dimensions. The ethical, legal and societal coordination work that will be performed in the BBMRI preparatory phase will itself contribute to the construction of the European framework for this domain. Although the topic of the BBMRI preparatory phase is to construct operational ways for networking activities that may include highly sensitive ethical issues related to long term biobanking, exchanges of samples and data etc., the preparatory phase itself will actually involve few of these issues in the course of its own development.

The issues ticked in the table above are thus not actually issues that will be directly encountered in the first year of the preparatory phase. But they represent largely the extent to which ethical issues are diverse when considering all the cases that will be encountered if one wants to include all sorts of existing and future biobanks and biomolecular resources in the scope of BBMRI. The production of the WP (WP6) dealing with ethical, legal and societal aspects will be an integrated part of the output of this preparatory phase. As mentioned in the WP6 description, it will operate at two levels, an operational one and a more reflexive one. That should allow meeting the objectives of high level of awareness, true reflexion and development of procedures and rules that will translate not only into a “ticking box” attitude regarding ethical aspects, but in a true embedment of such dimensions in the activities. The objectives (see WP6) are:

1. To manage and to oversee ethical and corresponding legal aspects in practice within the BBMRI preparatory phase in order to come out with a fully operational schema that can be agreed upon by BBMRI members and partners with regard to the legal, ethical and cultural background in their own countries
2. To develop an online platform on legal aspects for uploading and validating existing legal documents in use with BBMRI members and partners that will allow monitoring such issues in the future BBMRI
3a - To work out the concept of harmonisation as compared to standardization, as regards to ethics

3b - To present practical mechanisms to achieve it in the context of BBMRI
4. To provide mechanisms for BBMRI to interact openly and transparently with the European citizenry and means to assess the debate regarding such an infrastructure in the various publics and among the relevant stakeholders in the different countries
5. To define, describe and demonstrate an integrated conceptual and operational model for ELSI approaches of BBMRI
6. To prepare proposals for training in the domain of ELSI relevant for BBMRI in Europe.

Only from the second year in order to test and pilot the feasibility of the systems on real cases, issues of exchanging samples and data, coding, extracting data will occur etc. It is foreseeable from the list of partners and that of proposed biobanks and biomolecular resources given in Table 7, that more than 20 countries are already concerned and willing to involve their biobanks in the endeavour; it is expected that biobanks in countries outside the present consortium will join at the construction phase. All samples potentially used in this phase will come from existing biobanks and will not be specifically sampled for BBMRI, although for new biobanks the European dimension may be described from the start.
The executive BBMRI bodies and the partners involved in the ELSI WP will set up an internal procedure in order to check that at least the following measures are taken:
a) an appropriate consent has been obtained (a copy of the original information and template consent form will be asked for and/or the copy of the ethical approval from the relevant committee)
b) the use envisaged upon submission to BBMRI is in agreement with the information given at the time of original consent
c) the process for anonymization is secure: details on the process will be asked for and, if this is necessary in the country of origin of the data, a copy of the local approval for the anonymization process will be asked.
d) transfer of data will only involve anonymized data in agreement with the definition given in the Council of Europe recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin.

Anonymization of the samples being exchanged will refer to the definition given by the Council of Europe in 2006. The Council of Europe's Recommendation Rec(2006)4 on research on biological materials of human origin gives the following definition;
"Identifiable biological materials are those which, alone or in combination with associated data, allow the identification of the persons concerned either directly or though the use of a code. In the latter case, the user of the biological materials may either
a) have access to the code: .."coded materials"; or
b) not have access to the code, which is under the control of a third party: …"linked anonymised materials"
and 2) Non-identifiable biological materials are…"unlinked anonymised materials": those which, alone or in combination with associated data, do not allow, with reasonable efforts, the identification of the persons concerned."

These categories are referred to under different names in various texts, but the above definitions are the only European level operational and official definition one can refer to, so far. The materials used will be linked anonymized or unlinked anomymized; they will consist of extracted nucleic acids, blood, biopsies, urine or other fluid. The aim in the preparatory phase is not to generate new data or biobanks, but rather design a quality assurance system validation and a process for the future BBMRI.

A proper consent will have been obtained for inclusion in the given biobank of origin and it covers the use that is done of the sample or the principle of non-opposition to secondary use where it can be legally applied (France). In particular the fact that a sample might be sent across borders will be investigated in the original information and consent form. Verification that the conditions to export or import samples are respected, especially the existence of a specific authorization if needed (case in France).

Regarding data, no identifiable data will be exchanged and if such data would be used for example to test the compatibility of two computer database systems they will be anonymized.

The issues involved that will have to be considered precisely in any document produced to become operational are:

- the identification, description and exchange of existing biological material and of data on already tested population samples or patients cohorts in various countries, including minorities; these countries are EU or other European countries but also country of origin of migrant populations relevant for EU [North Africa, India, Sub Saharan Africa]. They may be healthy populations of adults, children or patients; the case of other non competent persons for consenting may also occur, for example in Alzheimer patients.
- the exchange and the statistical analysis of sensitive data, genetic and non genetic
- the additional testing of new biomarkers (genetic or not) on part of these biological materials the re-sampling of some of the individuals previously studied when there is not enough material left and the sampling of new individuals
- the data management of demographic data, clinical information, other phenotypes, sensitive data on origin, cultural traits and genomic markers the exchange across borders of biological samples and data associated
- the potential exploitation of results by industry and the issue of benefit sharing
- the conditions to make such results widely available while continuing protecting individuals
- the issues of possible misuse of results and concepts produced or used.

In order to assure a proper management of such issues all along the project as well as the generation of new knowledge allowing to better address such dimensions in the future, several measures have been taken:

- the ethical aspects have been taken into consideration as part of the management structure and in addition to the specific WP6 activities, international external and independent experts in ethical and legal aspects of population genomics and biobanking-related be part of the BBMRI Scientific and Ethical Advisory Board (Bartha Maria Knoppers, Université de Montréal, Canada has already agreed to act on the board);
- educational activities that will be proposed and sometimes made a requirement within the consortium and external to it fully include ethical and societal aspects
- collaboration with other projects in the field addressing ethical aspects relevant for BBMRI is already set up, through contacts with the ELSI components of previous FP5/FP6 projects that have addressed similar issues (PHOEBE, GenbanC, GenomeEUtwin, GAALEN); also contacts will be taken with successful applications for FP7 calls that address specifically issues of human samples and data banking and exchanges in various contexts in order not to duplicate the work of comparative analysis of the legal/ethical contexts related

to such applications (HEALTH-2007-1.1-1: Unifying human and model organism genetic variation databases.; HEALTH-2007-2.1.1-1: Networking biobanking initiatives across Europe: developing standards and norms for existing and future human sample biobanks; HEALTH-2007-2.1.1-2: Molecular epidemiological studies in existing well characterised European (and/or other) population cohorts; contacts with bids GEN2PHEN, EUGEPO are established.

Such an organisation should allow a timely and coordinated management of such issues at the highest level.

Ethical, legal, regulatory or other societal problems which could hinder the realisation of BBMRI:

Obstacles of an ethical nature are not related to the ethical concerns per se, but to the fact that these are not translated into ad hoc regulations and guidelines at the EU level and that harmonization of national regulations may be difficult or may imply subsequent steps that might delay the project.

- As a rule, an informed consent form will have been signed in the first study that has generated the data (copy asked for; description of the consent process in the local context); the consent will have to include the description of the original study mentioning the aim for studying that specific population/group of patients; the possibility to refuse; to withdraw, with practical information on how to do so; the policy for anonymization; the possibility for additional genetic markers testing and exchange of data and samples.
- If the information and consent form are in a language not understood by relevant members of the consortium, a translation (in English, French, Spanish, German or Dutch) will be provided in order to allow appreciation of the content.
- If the consent does not cover the use in BBMRI, different policies will be applicable according to the legal context in the country of origin (to be described precisely in each case with laws applicable for sampling populations, patients, specific measures for minorities if applicable)
    - an approval by a local committee plus anonymization; and only existing data will be analysed
    - an approval by a local committee plus anonymization, with possibility of testing new markers
    - a new consent when new markers are envisaged to be tested
    - a non opposition to a further use of the samples after information has been provided.
    - If minorities are involved the specific laws and regulations will have to be respected (ex: special authorisation for exporting data, approval by a specific relevant authority; impossibility to export samples from minorities if not for their own interest ; the situation varies between countries and specifying this will be a requirement)
    - Specific criteria for importation/exportation of samples and data will be respected in each country.

Specific work will be done regarding the conditions to be applied for children involved in biobanks, persons not able to consent and the guiding text will be the Oviedo Convention and the recommendation of the Council of Europe.

For populations of non EU countries if any, in addition to the respect of their legal requirements, the same level of information about the consent process will be required,

and the same level of protection of persons and data as is in EU. Explicit consent will be asked for any new tests.
For additional populations/patients groups outside EU, a guide will be proposed as a general BBMRI document, including provisions for information, consent, return of results and benefit sharing or policies to provide help in case of developing countries.

These criteria will be part of the decision mechanism for the final choice of partners of BBMRI.
Apart from the national legal provisions, the guiding principles and reference texts that will be considered are as follows:

- transfer of data will only involve anonymized data in agreement with the definition given in the Council of Europe recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin in March 2006; at EU level the opinion of the European group of ethics (EGE) Opinion Nr. 11 "Ethical Aspects of Human Tissue Banking", published on 21 July 1998, as well as the relevant measures in the directive GMP (directive 2001/0/EC) and the directive “cells” (directive 2004/23/EC), and its technical annexes from 2006 will be applied.
- the provisions of the HELSINKI declaration in its last amendment of 2002 and the Convention of Oviedo where applicable, UNESCO international declaration on the Human Genome and Human Rights (1997) and the UNESCO international declaration on Human genetic databases (2003) will be respected as well as the guidelines of the OECD for human biological resource centres (2007). An update to this will be made, taking into account the provisions of the guidelines of the OECD HGRD (Human genetic research databases), as soon as they are public.
- Sensitive data like religion will not be stored unless specifically justified and authorized and reliable degree of anonymization ensured; any information that could lead to discrimination against a group will be avoided
- the “Statement of Principles on the Ethical Conduct of Human Genetic Research Involving Populations” from the “Réseau de médecine génétique appliquée au Québec” will be taken as additional guiding principles, when relevant for population studies.

The data analysis exploitation plan for any BBMRI resource will be carefully reported in order that no result could be used as a discriminant element against a group or a minority. Especially a reading of the redacted results by ELSI specialists in order to check the language used and to specify the meaning of the terms used in order to avoid possible erroneous interpretations that could hamper the communication of results of the project will be worked out.
In this sense the specific questions worked out in the context of the preparatory phase will help for the use of the data and the communication about the project.

The conditions for re-sampling of some of individuals previously studied when there is a need for more material will be examined.

For such cases the above principles will be applied; detailed information will be provided and a policy for communication of general results will be applied.
A mechanism for dealing with incidental discoveries that could be useful for individual health purposes, (although unlikely) will be set up, through a medical contact at the site where link is kept, especially in the context of potentially sampled minorities, where

possibilities to use and derive information useful for health purposes is seen as a priority.

The data management of demographic data, phenotypes, sensitive data on origin, cultural traits and genomic markers

The provisions of EU directive 95/46/EC on the protection of individuals with regard to the processing of personal data and the free movement of such data will be applied in all cases. This directive is implemented in all EU countries. An equivalent degree of data protection will be applied to all data being imported. The definition of the phenotypes that will be documented will take into consideration that the maximum of data should be made publicly available, The exchange across borders of biological samples and data associated will be restricted to anonymized data and samples (linked anonymized or fully anonymized according to the cases). Where necessary the data protection specific authority will be consulted for getting approval.

The potential exploitation of results by industry and the issue of benefit sharing;

Given the major impact of diversity studies in the context of pharmacogenetics a policy for sharing results as part of a governance system dealing with benefit sharing will be worked out as part of the project.

The conditions to make such results widely available while continuing protecting individuals

This is an important question and the principle in accordance with the “philosophy” of making this resource publicly available will be especially worked out in order to balance with the theoretical possibility of identification of individuals through their genetic data. Especially the strict availability for research will be promoted (no police use).

The issues of possible misuse of results and concepts produced or used is always a possibility that one cannot rule out completely in the domain of exploitation of biobanking resources and it is through careful communication policy and promotion of a democratic governance involving stakeholders that this issue will be addressed.

Regarding fetal tissues and cell lines derived from stem cells, there are special issues associated with the cell lines of embryonic origin. As a centralised resource of this kind would allow a maximized use of such established cell lines, all efforts will be made to include the Registry of such cell lines, that has just been launched and the corresponding biobanks, among BBMRI partners. Any resource that would involve cell lines of human embryonic origin would follow the provisions of the EGE Opinion Nr. 12 "Ethical Aspects of Research Involving the Use of Human Embryo in the Context of the 5th Framework Programme", published on 23 November 1998; the EGE Opinion Nr. 15 "Ethical Aspects of Human Stem Cell Research and Use", published on 14 November 2000; in addition, all measures that will be included in the opinion presently in preparation on ethical reviews of research protocols involving the use of cell lines derived from human embryos will be considered in the BBMRI documents.

Thus given all these ethical issues and the questions that will rise in the course of the project the system in this section with its different instruments (WP, management structure including ethics, advisory board including ethical/legal competencies), education in research ethics is an essential tool for the achievement of the project with an integration of not only “operational and normative ethics” in the course of the research, but also a true reflexion and innovative governance through openness and interdisciplinary integration.

B5. Consideration of gender aspects

The Consortium or individual beneficiaries have the option to give an indication of the type of actions that will be undertaken during the course of the project to promote gender equality in the project, or in the specific research field.

Relevant activities might include actions related to the project consortium (e.g. improving the gender balance in the project consortium, measures to help reconcile work and private life, awareness raising within the Consortium) or, where appropriate, actions aimed at a wider public (e.g. events organised in schools or universities)

The gender dimension of the research content should also be considered.

Gender Aspects should be addressed in a work package or task within a work package. See Appendix 8 for more details.

Women are increasingly participating in most socio-economic areas in Europe. However, they are still somewhat under-represented in the science and technological domains. A greater involvement of women in research would enrich European science, in terms of its methods, the investigations targeted, and the objectives of the research. The BBMRI Consortium is aware of this situation and is committed to promote the participation of women in the project, as a goal of the preparatory phase. This goal will be achieved and monitored by a Gender Equality Plan (GEP), designed as follows:

a) Establish and track objective parameters in order to assess the success of the GEP.
These parameters should take into account quantitative data, such as number of women directly
involved in BBMRI (both in coordination activities and in management), number of women
participating in expert activities, organised by BBMRI, speakers/presenters in conferences, women answering project surveys, etc.; as well as qualitative measures, such as the meaningfulness of gender-relevant research promoted by BBMRI, degree of interaction with networks of scientist women, etc. Early in the project, a member of the Executive Management Team will be assigned as the manager of gender issues. He/she will prepare a report reviewing and auditing the gender dimension of the project. The report will be presented at the Stakeholder Conference and circulated to promote and enhance gender equality in participants' legal entities. This person will also build statistics on the key parameters mentioned above, in order to test the tools of gender balance measurement for the future BBMRI.

b) Promote the participation of women in the project.

- The Executive Management Team will request all BBMRI participants to provide:
- Their current information on gender breakdown of workforce by occupation and status (full-time / part-time) in their legal entity.
- Their policy statements on gender equality and training
- Their policy statements on the reconciliation of work and private life

During the course of the preparatory phase, several actions will be implemented to increase the female gender balance in BBMRI. For instance, transparent and fair selection of recruitment practices will be adopted (the advertisements for researchers should include positive sentences that encourage equal opportunities), and the same will

apply for activities involving external parties (workshops, open meetings, etc.); local, national and European networks of Women in Science will be used to advertise any vacant positions; family-friendly policies will be promoted. The Consortium will guarantee that equal resources and involvement in decision-making are given to women that participate in the project and it will help young recruited female scientists to progress in science in order to increase their chances for an academic career in Europe.

The Executive Management Team will review all proposals and contracts arising during the Preparatory Phase to identify plans to attain gender equality, to provide gender equality training and to facilitate reconciliation of work and private life. Where no such plans can be identified, the Executive Management Team will draw the attention of the authors of the proposals and contracts to this fact.

Already in the proposal phase, two WP leaders among the 5 technical WP are female scientists (Leena Peltonen, Finland and Anne Cambon-Thomsen, France); in addition the head of the Governance council and of the Steering Committee is also female. In addition, a significant number of women scientists and managers will be working in BBMRI from the start of the project.

c) Consideration of the gender aspects in the future infrastructure.
Special care will be taken to ensure that gender-based variability is appropriately considered in the coordination work itself and gender related considerations will be included in the parameters to be documented by the various biobanks candidates to become members of BBMRI. This includes recording gender information in datasets, indicating sex-chromosome origin of tested markers, including optional gender filters in search interfaces, emphasizing gender parameters in phenotype data and genetic effects, and strong support for database partnership proposals that deal with sex-linked Mendelian disease or gender-biased common disorders. This will help enable male-centric, female-centric, and gender-neutral views of BBMRI based studies to be independently examined.