

NEWSLETTER 2



ERA-Net NEURON

ERA-Net **NEURON** was launched in January 2007 and is funded under the ERA-Net scheme in FP6 by the European Commission. The aim of **NEURON** is to promote the development of a European strategy for research in the area of disease related neuroscience. Among the many diseases affecting human health, disorders of the brain are major causes of morbidity, mortality and impaired quality of life. According to estimates by the World Health Organization (World Health Report 2001), more than one billion people suffer from disorders of the central nervous system. In Europe, disorders of the brain account for approximately one-third of the total burden of all diseases. The project envisages creating a group of relevant research funding organizations in Europe and, thereby, gain maximum added value from investment in this field. Sixteen European national research funding organizations from Austria, Finland, France, Germany, Italy, Israel, Luxemburg, Poland, Romania, Spain, Sweden and UK are cooperating under this single umbrella.

In the framework of ERA-Net NEURON a specific working group was established to give consideration to the development, provision and bottlenecks of Neuro-biobanks. The first step in this process was to convene a workshop for adequate information and discussion of the key themes (e.g. legislation, infrastructure, quality assurance, networking).

The workshop took place in Vienna in April 2008. The following pages layout the main issues and opinions expressed during the workshop.

 German Aerospace Centre, Project Management Agency	 Federal Ministry of Education & Research (BMBF), Germany	 Austrian Science Fund (FWF), Austria	 National Authority for Scientific - Ministry of Education, Research and Youth (ANCS - MECT), Romania	 Ministry of Science and Innovation (MEC), Spain
 Ministry of Health (MOH), Italy	 Academy of Finland (AKA), Finland	 National Research Agency (ANR), France	 National Center for Scientific Research (CNRS), France	
 National Institute for Medical Research (INSERM), France	 Chief Scientist Office, Ministry of Health (CSO-MOH), Israel	 National Research Fund (FNR), Luxembourg	 The National Center for Research and Development (NCBR), Poland	
 Institute of Health Carlos III (ISCIII), Spain	 Swedish Research Council (SRC), Sweden	 Medical Research Council (MRC), UK	 National Centre For Programmes Management	

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More information can be found in our web page
<http://www.neuron-eranet.eu/index.php>

“Future perspectives, benefits and bottlenecks of Neuro-biobanks”

Vienna (Austria) - April 10th, 2008

Neuro-biobanks are a subset of the general biobank concept and understanding and precise delineations are often not a simple matter. Biobanks are institutions that collect, process and store samples of human body substances or materials, amend these samples by personal or disease or treatment related medical data of patients and provide these material samples and data for research purposes. A biobank is thus (in most cases) not a stand-alone research project, but an important long-term oriented research tool for biomedical research.

Europe has well-organized biobanks and health databases of high quality. Such biobanks, sometimes also called biorepositories or tissue banks, provide both types of critical information, and have been identified as important translational bridge between research and clinical practice to accelerate the development of more personalized medicine. They are considered a major resource to enable research into the interaction between genes, environment, lifestyle and disease, and – in close cooperation between scientists and clinicians – to support the implementation of the knowledge into clinical practice through innovative diagnostics, therapeutics and preventive treatment strategies.

Particularly in the fields of disease-related neurosciences, well characterized human tissues are an essential resource for research into the etiology, diagnosis and treatment of neurological and psychiatric diseases. Tissue banks of neuropathological material, e.g. brain samples or cerebro-spinal fluid (CSF) have made an essential contribution to progress in these fields. This is evidenced by scientific breakthroughs such as the discovery of amyloid deposition in Alzheimer's Disease, Lewy bodies in Parkinson's Disease, variant Creutzfeldt-Jakob Disease (vCJD) and the role of glutamate in schizophrenia.

BMB-EUCOOP - A Legal Basis of an EU-wide Biobank-Cooperation



Dr. Thomas Pickardt, from the Competence Network Congenital Heart Defects and as member of the Working Group on Biobanks of the Telematics Platform of Medical Research Networks, introduced an ongoing project on collection and publication of recommendations and template text files including informed consents, transfer agreements, conciliation agreements and contracts for international research projects in both German and English language.

BBMRI - European research infrastructure for biobanks and biomolecular resources



Prof. Kurt Zatloukal from the University of Graz gave an overview of the Biobanking and BioMolecular Resources Infrastructure (BBMRI) project. Following the European Strategy Forum on Research Infrastructures (ESFRI) 'roadmap', BBMRI, comprising 51 participants in 21 countries and 149 associated organizations, intends to integrate biobanks in a pan-European research infrastructure.

Biobanking harmonisation – Ethical and legal challenges



Ms. Andrea Cook, from the UK Biobank Ethics and Governance Council, reviewed the establishment, aims and tasks of the EGC. In particular, the formulation and monitoring of a coherent framework for the UK biobank is aimed at engendering confidence in the public for this project. With the goal of harmonizing biobanks across Europe, the ethical and legal challenges were summarized as those relating to biobanking per se, those relating to the practical issue of trying to harmonize and find common language and those relating to ensuring adequate consent and security measures to maximise sample and data-sharing while protecting the interests of participants.

UK National network for DNA sample management



Prof. Martin Yuille from the University of Manchester described the history, structure and functioning of the UK DNA Banking Network (UDBN) project as part of a new initiative for human genome research and attempted to draw lessons from strengths and weaknesses of the project. Located at the Centre for Integrated Genomic Medical Research (CIGMR) the project aims at creating a community resource for post-genomic translational research.

BrainNet Europe



Prof. Hans Kretzschmar from the University of Munich presented the EU funded 'Network of Excellence' BrainNet Europe (BNE). He addressed principles of brain bank management and drew on the experience of the 18 brain banks that constitute the consortium, representing postmortem practice in the respective member states. Inclusion in a network fostered sharing of protocols between the brain banks, development of best practice and quality control and assistance to individual brain banks in order to effectively manage the increasingly complex legal and ethical framework for brain banking.

The Human Tissue Act - Implementation and impact on research



Prof. James Ironside from the University of Edinburgh gave, from his dual perspective as Director of a UK Brain bank and Deputy Chair of the Human Tissue Authority (HTA), an overview of the HTA and its impact on research. He explained the background to the Act that was designed to be supportive of research. The HTA, which had been established as a regulatory body, developed flexible codes of practice for researchers to follow. The implementation of licensing standards for research tissue banks had been an important step forward and provides a clear, consistent and proportionate regulatory system.

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Regulations and guidelines around biobanking



Prof. Juergen Goebel, from the Working Group on Biobanks of the Telematics Platform of Medical Research Networks, summarized current EU legislation and general legal issues relating to biobanks. The paucity of legal regulations specifically pertaining to biobanks, international differences in terms of legal regulations or different handling of the provisions of international law (e.g. data protection), together with a relative lack of practical legal experience in the field of biobanking, were considered as major bottlenecks for international cooperation and interoperability.

Conclusions

Legislation

Both legislation and ethical guidelines are currently scarce and variable and may hinder exchange of biomaterial. An encouraging development is the legislation from the Human Tissue Authority in the UK. In addition, all brain banks in EC adhere to guidelines encoded in documents such as the Helsinki declaration and the Opinion on Ethical Aspects of Human Tissue Banking.

Quality assurance

High quality clinical and biochemical data that accompany samples will become a default requirement. Data security and privacy will be ensured by adequate encoding procedures.

Networking

There are some promising examples of national and international networking although import and export regulations in some EC countries are still a challenge.

Funding

Funding solutions vary between countries, but it is widely recognized that a modus of just breaking even, aiming only to recover cost, is not realistic.