

Healthy Brain Healthy Europe

A new horizon for brain research
and healthcare



CONFERENCE REPORT

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Dublin, Ireland*

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Uachtaránacht na hÉireann ar
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Healthy Brain
Healthy Europe



INTRODUCTION

This report summarises points arising from the conference *Healthy Brain: Healthy Europe – A new horizon for brain research and health care*, which took place at the Convention Centre Dublin, Ireland, on 27th and 28th May 2013. This conference was jointly organised and chaired by the Irish Presidency of the Council of the European Union and the European Commission (DG Research and Innovation). It was the main event organised in the context of the European Month of the Brain May 2013 and a key event in the Irish Presidency calendar for the Department of Health.^{1,2}

1 See EU Month of the Brain website at <http://ec.europa.eu/research/brainmonth2013>.

2 A separate EU Commission conference in Brussels on 14 May 2013 showcased EU leading EU research and outlined major progress already made in terms of understanding the brain and related disorders

EXECUTIVE SUMMARY

In recent decades, brain research has made great progress on all fronts but much more remains to be discovered. In particular, the growing prevalence of brain disorders coupled with their severe effects on society and the increasing cost of treatment make progressing research more essential now than ever before. This has to be paralleled by a revision and improvement of current research approaches and healthcare practices. The purpose of this conference was to highlight these issues and discuss how to effectively address them throughout Europe.

There was clear recognition that no single European country has the resources to achieve the scale and quality of research required. Consequently, it is considered that countries need to develop or refine and to align national strategies on brain research and healthcare within Europe.

With this in mind and arising out of the discussions, conclusions and recommendations of the conference, 10 policy principles and objectives summarising the outcomes were developed. Learning from the successful example of a national strategy for cancer that was highlighted during the conference, these recommendations address key areas of patient

engagement, exploiting full research and health care potential, and remodeling investment and innovation strategies. It is considered that these provide clear direction for the development of both national strategies and the aligning of brain research and healthcare practices across Europe. The implementation of these recommended policy principles and objectives will require further deliberation and planning.

Recommended policy principles and objectives

- 1. Promote the role of patients in all stages of research and evidence-based healthcare.** Consideration should be given to enhancing the engagement of patients in all steps of the research cycle. Patients need to be actively involved in the planning of research approaches, the execution of services and the maintenance of standards of healthcare practice
- 2. Tackle the stigmatization of patients with brain disorders.** Patient-led campaigns to raise awareness should be supported and enabled. Scientists need to engage in public debate about neuroscience, brain disorders and brain health
- 3. Continue supporting interdisciplinary research approaches.** This could be achieved, for example, by bringing together fields such as information technologies, social, environmental and educational sciences, economics, law and humanities towards neurosciences
- 4. Foster innovative and more relevant approaches to clinical development.** This could include novel trial methodologies, novel endpoints, biomarkers and diagnostics and increased involvement of population groups such as children, elderly patients and patients with co-morbidity in an ethically responsible manner. Such an approach would help achieve the necessary paradigm shift from population-based medicines to personalised medicines for the benefit of patients, healthcare systems and society.
- 5. Promote new ways of implementing healthcare solutions.** This should involve the implementation of multidisciplinary healthcare practices in caring for people with brain disorders in addition to neurological or psychiatric consultations
- 6. Encourage data sharing** by finding the right equilibrium between privacy considerations and the need to exploit data for research purposes, including anonymised healthcare data and patient registries. Regulations should facilitate the creation, maintenance and use of large data sets for research purposes
- 7. Attract and align public and private investment into brain research and healthcare.** Investment must be coordinated, aligned across Europe and re-allocated or increased where necessary to better reflect the scale of the scientific, medical and socio-economic challenges. In this context, it is essential to ensure continuous support for basic, clinical, social and other brain-related research at national and EU levels
- 8. Expand smart and innovative strategies for supporting brain research and healthcare.** Learning from existing interdisciplinary or transnational examples, this should include public-public (such as the Joint Programming on Neurodegenerative Diseases) and public-private (such as the Innovative Medicines Initiative) partnerships
- 9. Reward innovation in drug development, new technologies and healthcare delivery.** Areas of opportunity include the development of financial and tax incentives, the introduction of the EU patent, improvement of regulatory policies and support to SMEs. Incentivising collaboration between academia, industry, regulators and HTA bodies, healthcare and patients should be central to initiatives developed
- 10. Adapt the regulatory landscape.** While ensuring patients' safety, addressing some of the specific issues mentioned in the above recommendations would necessitate adapting the regulatory landscape to allow for more innovative approaches in clinical development. Those adaptations can include the use of alternative types of evidence beyond randomized clinical trials, patients' participation in decision-making and inclusion of relevant population groups such as children and elderly people, and those with co-morbidity

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MAIN REPORT

The conference was structured around five plenary sessions. Each session consisted of three-four presentations by leading representatives of different stakeholder groups: policy, funding organisations, regulatory authorities, patient organisations, researchers, industry. Opening sessions on each day set the context for discussions with the delivery of keynote/ opening addresses. A final roundtable panel discussion included presentations by the chairs of each plenary session on emerging policy recommendations and incorporated a short report on EU-supported achievements in brain research (from an earlier EU Month of the Brain conference, 14 May 2013 Brussels). The interaction with the audience solicited a lively and informed debate among the leading experts in this field.

Healthy Brain Healthy Europe

OPENING SESSION: 27 May 2013



Enda Connolly



Ruxandra Draghia-Akli



Dr James Reilly



Máire Geoghegan-Quinn



Patrick Kennedy

Welcome and official opening

MC: **Enda Connolly**, Chief Executive, Health Research Board, Ireland and **Ruxandra Draghia-Akli**, Director of the Health Directorate at DG Research and Innovation (DG RTD), European Commission

Opening Addresses

Dr James Reilly, Minister for Health, Ireland

Máire Geoghegan-Quinn, Commissioner for Research, Innovation and Science

Keynote: **Patrick Kennedy**, Co-founder, One Mind for Research™ – A new horizon for brain research and healthcare

Welcoming delegates to the Conference, Enda Connolly, CEO of the Health Research Board in Ireland, said the aims of the event were to encourage EU member states and associated countries to develop or refine patient-centred strategies relating to brain health and to promote translation from research into implementation. He emphasised the need to lift the taboos associated with brain diseases and to raise awareness of the importance of early screening and diagnosis.

Irish Minister for Health Dr James Reilly officially opened the two-day conference, offering the context that diseases of the brain account for more than one-third of the overall disease burden in EU. He commented that brain health is an absolute essential, that to have a healthy economy you have to have a healthy workforce.

He highlighted that while some cognitive decline may be linked to the natural process of ageing, the evidence for the impact of lifestyle factors on our brains as we age is mounting. Eating a balanced diet, maintaining a healthy weight, reducing alcohol consumption, getting your blood pressure and cholesterol checked and not smoking can all make a difference.

The key is to work collectively, he noted, no European country alone could achieve the scale and quality of resources necessary. He also stressed the need to focus on one key objective: better outcomes for patients, and said if we do that in all we do, we will never go too far wrong.

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In her address, Commissioner Máire Geoghegan-Quinn, European Commissioner for Research, Innovation and Science, pointed out that around 165 million people in Europe are affected by some sort of brain disorder - almost every family is likely to be affected - and it is estimated that in 2010 brain disorders brought a cost burden of almost €800 billion in Europe. Business as usual is simply not an option, she said, pointing out that brain research is a smart investment that can help avoid even higher costs to society in the future.

Through the Seventh Framework Programme for Research and Development (FP7), EU has already invested close to €2 billion in brain research since 2007. The Innovative Medicines Initiative is encouraging more efficient drug development processes for safer and more efficient medicines, said Commissioner Geoghegan-Quinn. When research budgets are tight countries need to work together - transnational initiatives such as the Joint Programming on Neurodegenerative Diseases Research (JPND) and ERA-NET NEURON are a start and now more work is needed to align national programmes and activities. We will find answers more quickly by putting our heads together, she noted.

Patrick Kennedy, Founder of One Mind for Research, gave a keynote address about the need to change how we approach brain health and reduce stigma. We are all consumers of mental health, we all have brains, he noted, but he lamented how we wait until brain health is endangered before addressing it.

A former US representative for Rhode Island's 1st congressional district, Mr Kennedy described it as "challenging" to garner political support for issues relating to brain health, and also that brain-related illnesses are still "stigmatised."

We have to be of one mind on brain research, he said, and we need to have the architecture that brings people together - putting a man on the moon and return him safely could never have been accomplished if everyone had worked separately and in silos. Now instead of going to outer space we fight to go to inner space, he said, again emphasising the need for collaboration and the political will to attack this challenge.

PLENARY SESSION 1: The Fascinating Brain



Marian Joëls,



Colin Blakemore



Andreas Roepstorff



Martin Brüne

Chair: **Marian Joëls**, President, Federation of European Neurosciences (FENS)

Speakers: **Colin Blakemore**, Professor of Neuroscience and Philosophy, University of London;

Andreas Roepstorff, Professor in Cognition, Communication and Culture at Department of Culture and Society & Department of Clinical Medicine, Aarhus University, Denmark;

Martin Brüne, Bochum Professor of Psychiatry and Head of the Division of Cognitive Neuropsychiatry and Psychiatric Preventive Medicine at the LWL University-Hospital, Ruhr-University Bochum, Germany

Opening the session, Marian Joëls described how the brain is more than a potential source of illness, it is the organ that most intimately determines who we are and how we behave in our environment.

Colin Blakemore spoke about the complexity of the brain and how some of our fundamental views on its organisation, plasticity and function have changed. He outlined some of the technologies and often visually stunning approaches that allow us to analyse and better understand the brain at the levels of cells, circuits and regions. There is a vital need for investment in fundamental brain research, said Professor Blakemore, including in clinical areas and also in other areas of potential relevance such as neuroethics, neuroeconomics, neuroeducation, social neuroscience and law, and that Europe should seize the opportunities for research at interfaces between fields.

Andreas Roepstorff spoke about the multi-dimensional brain and how our experiences, such as learning new skills, can be located in changes in structures in the brain. He described how cultural products affect us and how bodily processes, cognition and emotions integrate. The story of our brain and ourselves are two narratives that are getting closer, and interdisciplinary research is key.

Martin Brüne delved into the social brain, and talked about how human brains appear to thrive on social interaction, showing early development and performance in the social domain beyond non-human primates. Social environments can be both cause of stress or help to prevent stress, noted Martin Brüne, and he emphasised the need to study impact of virtual social networks.

Conclusions

1. Neuroscience is at a critical phase in its maturation. Remarkable new techniques promise a rapid increase in our understanding of the normal functioning of the brain and of the causes of many brain disorders. The alarming increase in prevalence and cost of brain disorders make progress in neuroscience a necessity, not an optional luxury.
2. Environmental stimulation and social interactions are of eminent importance for the health of the brain, especially during brain development but also throughout an individual's lifetime.
3. Great opportunities exist for innovative research and the application of knowledge at the interface of neuroscience, information technologies, social sciences, educational science, economics, the law and the humanities, in addition to the more well-known approaches of neuroscience from the angle of biomedical research, natural sciences and/or technical sciences.

Recommendations

1. The overall proportion of funding for neuroscience in Europe is not proportionate to the scientific opportunity and the clinical need. Funding should be raised, given:
 - the scale and significance of both the scientific and the medical challenges
 - the high quality of European neuroscience as exemplified by the comparatively high success in personal programs, including European Research Council (ERC) grants
 - the potential of exciting new technologies in neuroscience
 - its enormous attraction to new generations of scientists. Europe should extend its efforts to transform human potential into capacity: supporting high-level training for talented young neuroscientists is key to success and to the continued development of neuroscience in the whole of Europe
2. Given the brain's sensitivity during development to the (social) environment and the important implications thereof for prevention of brain disorders during aging, dedicated and balanced research investments into social and environmental influences throughout life are warranted
3. There is a need for new incentives and new programs that support genuine, investigator-driven interdisciplinary research consortia, bringing the latest insights from hitherto separated research fields together, such as neuroscience, information technologies, social sciences, educational science, economics, the law and the humanities. Administrative hurdles and bureaucratic burdens should be minimised
4. The nature of both basic and clinical neuroscience research demands special attention to ethical issues, including such topics as data sharing in clinical and preclinical research, treatments involving genetic modification and cell transplantation, new interventions for the treatment of brain disorders, and invasive research on normal human brain function. Neuroscientists and clinicians should recognise the need to inform and engage with the public and governments to ensure that regulations are proportionate and are based on evidence

PLENARY SESSION 2: The Brain Challenge



Richard Hughes



John Golding



Charles Normand



Mary Baker

Chair: **Richard Hughes**, President, European Federation of Neurological Societies (EFNS)

Speakers: **John Golding**, President European Multiple Sclerosis Platform;

Charles Normand, Edward Kennedy Professor of Health Policy and Management, Trinity College Dublin;

Mary Baker, MBE, President, European Brain Council

John Golding gave a personal perspective on the human dimension of brain disorders. He described how he was diagnosed with multiple sclerosis, how it affected him physically, mentally and emotionally and how he has handled the changes the condition brings, both through self-management and with the support of a multi-disciplinary team.

He emphasised the need for a European register of people with multiple sclerosis for research not just on medical factors but also on socioeconomic considerations, and he called for more focus on research into progressive multiple sclerosis.

Charles Normand spoke about the challenges of 'measuring the immeasurable' in brain disorders: brain disorders bring particular challenges - including patients having difficulty in expressing impacts, care of patients with multiple morbidity and also that recovery over time may not bring the patient back to the pre-disease state. Costs fall on health services, individuals, families and informal carers, and providing robust evidence on effectiveness and cost-effectiveness of interventions is difficult. We still need to evaluate and measure impacts but with a willingness to accept that no perfect measure will ever exist.

Mary Baker highlighted the societal impact of brain disorders and the need to understand what causes distress to patients as well as the contextual issues such as changing family structures, stigma, migration, co-morbidities and the availability of drugs online. She stressed the importance of information in shifting attitudes, and challenged whether Europe was adapting to the increasing burden of brain disorders - including whether the risk and benefit needed to be rebalanced to further innovation and patient involvement in trials.

Conclusions

1. People with brain disease need multidisciplinary care in addition to neurological or psychiatric consultations
2. Patient organisations provide great benefit in helping people with brain disease to cope with their illness
3. The effects of brain disorders on the individual and the society are difficult to measure but that does not mean that they are not important. Measuring cost of illness and cost-benefits for interventions for brain disease is highly complex
4. The conventional hierarchy of evidence does a disservice to the evaluation of the value of complex interventions. The value of an intervention to society is not necessarily proportional to the quality of the evidence. Thus the absence of gold standard evidence from large trials or systematic reviews does not mean that an intervention is not valuable
5. Brain diseases such as Parkinson's disease and Alzheimer's disease not only have a devastating effect on individuals but also profound effects on society. Furthermore the changing structure of European populations, especially the increased proportion of elderly citizens, means that brain diseases are becoming more common and their effects on society more intense

Recommendations

1. Healthcare providers should ensure provision of multidisciplinary care to people with brain disease
2. Healthcare providers should foster patient organisations by helping them to set and maintain standards of practice and involving them in planning of services and research
3. Measurement approaches should be designed to fit the purpose for which interventions are intended, rather than insisting on a gold standard of evidence
4. Policy makers should understand that randomised controlled trials for some complex interventions for brain disease are not feasible and be prepared to accept their adoption on the basis of alternative types of evidence. Research needs to adapt to the changing needs of society. In particular clinical trials need to be made more relevant to the real world instead of being focused on a minority of people with brain diseases (i.e. considering also population groups such as children, elderly and patients with co-morbidity)
5. Communication of research and science to society needs to be improved so that European citizens can contribute to designing and monitoring research and make informed decisions when voting about health issues

PLENARY SESSION 3: Europe's Best Brains: Our Strengths



Juan Lerma



André Syrota



Giovanni Frisoni



Peter Andersen

Chair: **Juan Lerma**, Chair of the West Europe Regional Committee of the International Brain Research Organization (IBRO)

Speakers: **André Syrota**, Chairman and CEO of Inserm, Vice-President of Science Europe;

Giovanni Frisoni, Deputy Scientific Director, IRCCS Fatebenefratelli, Brescia - The National Centre for Alzheimer's and Mental Diseases;

Peter Andersen, Senior Vice-President, Lundbeck Research Organisation

André Syrota spoke about the scientific strengths in European brain research, both historically and today particularly in transnational initiatives. Several obstacles still remain, including a fragmentation of effort and the need for easier mobility of scientists within Europe, but he also pointed to encouraging major European approaches in neurosciences such as NeurATRIS, ERA-NET (NEURON) and Joint Programming Initiatives.

André Syrota made particular reference to the Human Brain Project, a decade-long initiative to model the human brain, which was recently announced by the European Commission as a Future and Emerging Technologies flagship project. We need modern mathematics to go from syndromic diagnosis to mechanistic diagnosis and such long-term funding is essential, he said.

Giovanni Frisoni spoke about the impact that infrastructures and repositories can have for European brain research, providing tools for building knowledge in neuroscience through the collection of data/specimens

that can be analysed, store and reused, with results being communicated. The scales of data, such as images, that are now being handled have grown enormously in a bid to help drug development in the neurosciences. We need markers of disease activity that will allow us to track the progression of the disease and to develop trials which last a short period of time in a few patients, he explained. Large datasets also enable the move from using syndromes to using biomarkers in the clinic, he added.

Giovanni Frisoni also outlined the supportive role of facilities such as neuGRID, an online brain analysis environment that offers access to large image datasets and algorithms for the extraction of biomarkers, and open access and research network initiatives in Europe.

Peter Andersen spoke about the European life sciences business model, and identified a problem that the progress we see in basic science as not translated to medical innovation quickly enough. The innovation ecosystem is not working that well - it requires industry to have a high contribution margin and to pick up

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basic research and convert to something useful for the end user, according to Peter Andersen. He stressed the importance of ensuring equilibrium between the 'push', or new medical innovation and the 'pull', or willingness to pay. He suggested more medicines-adapted pathways to patients (conditional approval for use with patients

who are expected to benefit) in order to reduce regulatory hurdles. And he welcomed the success of the Innovative Medicines Initiative, which is bringing stakeholders around the table and which he hopes will continue in Horizon 2020.

Conclusions

1. Europe has a great research community of neuroscientists, good research infrastructures with a clear potential to lead world neuroscience research and innovation
2. Neuroscience research as research in general has flourished in the southern European countries during the last years). The current cuts in research budgets in these countries jeopardize this positive development and put at risk the future leadership of Europe in innovation
3. Transnational collaborations and large consortia can be effective at a European level. However, EC policies tend to be copied and reproduced by local governments and the EC should not forget that great discoveries arose from small laboratories working under a bottom-up, curiosity-driven approach

Recommendations

1. Consider the possibility of excluding national funds dedicated to R&D in the calculation of national deficits
2. The Human Brain Project (HBP) is regarded as an opportunity for technological development. This is expected to have important outcomes. However, the HBP should be funded complementary to and not instead of other neuroscience initiatives at European level
3. Awareness among policy makers about brain disorders needs to increase at both European and local levels and the stigma around brain diseases needs to be addressed at a European level
4. Policies of prioritisation and public investment in basic and clinical research should reflect the size of burden of the individual diseases, measured as total costs i.e., both direct health care costs and follow-on costs outside the health care system e.g., sickness leave early retirement and absenteeism
5. Foster public private partnerships (PPP) for Horizon 2020
6. In order to reward the development of new innovative drugs for brain diseases the introduction of the EU Patent should be expedited, ensuring a high level of protection. In addition, the pricing and reimbursement system should be reviewed for possibilities of permitting payers and originators to better manage uncertainty and regulations should allow for as much flexibility as possible
7. Basic research of excellence should be continued to be supported at EU level and local governments should not to reduce the budget of fundamental science

OPENING SESSION: 28 May 2013



Bairbre Nic,Aongusa



Kathleen Lynch



Isabel de la Mata



Fabien Calvo

Chair: **Bairbre Nic,Aongusa** Assistant Secretary General, Department of Health, Ireland

Speakers: **Kathleen Lynch**, Minister of State with responsibility for Disability, Equality mental health and older people, Department of Health, Ireland;

Isabel de la Mata, Principal Adviser for Public Health, Directorate General for Health and Consumer Protection, European Commission;

Fabien Calvo, Deputy General Director INCa and Director of the Cancer Institute of the French National Alliance for Life and Health

Kathleen Lynch spoke about the burden of brain disease in Ireland and also the stigma, which is not reserved only for people living with mental illness, but also family, friends and people supporting them. She spoke about how mental health can become an everyday issue through community engagement, health promotion and early intervention, and how the health system also needs to move from an over-reliance on in-treatment and develop an attitude where we believe people can truly recover, in their own homes and communities.

Isabel de la Mata brought a perspective from DG Sanco. She also stressed the need for replacing institutional with community-based approaches and spoke about the new Joint Action on Mental Health and Well-Being in this context.

Fabien Calvo, delivered a keynote address on the lessons to be learned from the French strategy and investment into fighting cancer, and how this could inspire a pan-European strategy for addressing brain-related health issues.

He said that molecular genetic platforms, networks of clinical research teams, dedicated cancer research programmes, forbidding smoking in public areas and screening for breast and colorectal cancers were among measures that had significantly improved the fight against cancer. More incorporation of patients into clinical trials was important and also innovation should be shared, said Dr Calvo, who described how an interactive registry had been set up to locate clinical research teams. And one of the main lessons to take home was not to have too many goals, he noted.

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PLENARY SESSION 4: The Innovative Brain: New Policy Approaches



Richard Bergström



Richard Johnson



Jackie Hunter



Martin Härter



Adriana Maggi

Chair: **Richard Bergström**, Director, European Federation of Pharmaceutical Industries and Associations (EFPIA)

Speakers: **Richard Johnson**, Chairman, OECD/BIAC Science & Technology Committee; member, National Academy of Sciences Board on Life Sciences;

Jackie Hunter, CBE, CEO of OI Pharma Partners Ltd;

Martin Härter, Professor, University Medical Centre-Eppendorf, Hamburg;

Adriana Maggi, Director, Centre of Excellence on Neurodegenerative Diseases, University of Milan

Opening the session, Richard Bergström said there was a need to reduce friction between stakeholders in brain research and that there was a lack of trust and co-ordination, that things slip between the cracks. He cited the example of antibiotics, where people knew more than a decade in advance that there would be a problem, and asked what policy conclusions could we take from this. He said the complexity of the brain was both frustrating and exciting, and that we need to make some changes about the way we work together and the way things are set up.

Richard Johnson spoke about investing in innovative brain research and the new opportunities for generating and using knowledge. We need to reorient our policies to support traversing the scale and complexity of the brain, he said. The United States approach is developing next-generation tools for brain research to ask the right questions, and aligning initiatives with innovative policies could have profound implications not just for the brain but across societies and economies, he noted. In particular if we could delay the onset of Alzheimer's

disease by 10 to 15 years it would be a "game-changer", according to Richard Johnson, who urged moves to thinking globally and acting locally, where collaboration can bring together national plans, identify gaps and learn. He also sees a huge leadership role for Europe with new types of shared databases.

Jackie Hunter addressed the need to re-engage industry in brain research and innovation. She pointed out problems with the Central Nervous System (CNS) therapy pipeline and cited several steps that could better support industry engagement in neuroscience. They include more basic neuroscience research to improve mechanistic understanding, more standardised animal models of disease, more exploratory translational studies, more cost-effective clinical trials and more clarity around regulation and reimbursement endpoints. She added that there are real opportunities in the open innovation model - companies and academia are talking about it and it needs to be joined up to change the paradigm for neuroscience research.

Martin Härter spoke about translating new knowledge into policy decisions for healthcare, using the instance of Psychenet, an initiative in Hamburg to promote mental health. Psychenet takes a regional approach and encompasses several sub-projects that include five disease-specific areas to improve awareness about mental health and address stigma, promote prevention and early detection and develop integrated and innovative structures of care. We need far more interdisciplinary research to understand how to transfer the results of complex and evidence-based mental health interventions into practice, according to Martin Härter.

Adriana Maggi spoke about coordinating approaches to research across Europe, and in particular the Joint Programming in Neurodegenerative Diseases (JPND) initiative. JPND is a global initiative bringing countries together to come up with ideas and align on common strategic goals. Led by the EU countries, JPND is working towards implementing its plan by alignment of national resources and initiatives and by focusing on linkage, harmonisation and data sharing with high potential for international cooperation. The goals are defragmentation and to enable the development of new treatments and preventive strategies.

Conclusions

Policy proposals intended to address unmet needs and harness significant understanding must target several policy domains:

1. European healthcare and societal opportunities and challenges
2. Technical and scientific opportunities and challenges
3. Regulatory and healthcare delivery challenges to provide effective, efficient and sustainable healthcare to citizens and patients

The time is right to utilise the trust built on previous incentives like IMI, JPND, psychenet-Hamburg project, which have brought all the stakeholders together to focus on neuroscience and healthcare research related to brain disorders. There are also opportunities to learn from other therapeutic areas such as cancer and initiatives going on in the USA.

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Recommendations

1. True patient engagement in R&D and healthcare policy
 - Support the education and empowerment of patients
 - Involve patient groups in policy setting, prioritisation, assessment and implementation of evidence-based healthcare
2. Attract investment to neuroscience and – healthcare research related brain disorders in Europe
 - As well as maintaining excellent ERC-type funded science base, promote and incentivise future pan-European research, infrastructure and collaboration. This should be across the full spectrum of neuroscience and healthcare research to enable critical mass to be applied to big challenges in this area
 - Continue funding, via Innovative Medicines Initiative(IMI) 2 and other mechanisms, collaboration from both within and across sectors to harness the new science and drive its translation for economic and health benefits
3. Have the courage to use brain disorders as a paradigm to capitalise on new science and accelerate the translation from population based medicine to personalised based medicine
 - Ensure freedom to operate so that large data sets, such as anonymised healthcare data, patient registries, can be created, curated and used for research purposes to aid disease understanding and biomarker development
 - Incentivise innovative approaches to clinical development including novel trial methodologies, novel end points, biomarkers and diagnostics
 - Promote new ways of implementing healthcare solutions
 - Look at new ways of incentivising prevention and wellness

PLENARY SESSION 5: The Inclusive Brain: Changing Paradigms



Ingrid Klingmann



Angela Coulter



Luca Pani



Pedro Montellano

Chair: **Ingrid Klingmann**, Chair, European Forum for Good Clinical practice (EFCGP)

Speakers: **Angela Coulter**, Senior Research Scientist, University of Oxford, Director of Global Initiatives, Informed Medical Decisions Foundation, Boston;

Luca Pani, Director General, Italian Medicines Agency (AIFA);

Pedro Montellano, President, Global Alliance of Mental Illness Advocacy Networks (GAMIAN) Europe

Angela Coulter spoke about the need to engage patients in health research as participants rather than as subjects. Patients have an important role to play in improving research quality and relevance and can be involved in helping to design studies, particularly research questions, outcome measures, advising on ethics and recruitment and communication. Informed consent needs to be translated into forms the patients can use and better strategies are needed relating to the role of families in informed consent, according to Angela Coulter. We also need to address waste in the process of research and improve communication of research results for patients and the public, she noted.

Luca Pani gave a regulatory view in the quest for new medicines in brain disorders. The research and development of a new drug for brain disorders still constitutes a very risky, long and costly investment, noted Luca Pani, and countries are facing high-cost therapies but also limited financial resources.

He outlined several policy recommendations, including that personalised medicine should be an integral part of the R&D process, that regulators, industry, academy, HTA bodies healthcare assistants and patients should collaborate to identify sustainable approaches to the development of new drugs, that the individuality of brain disorders must be accounted for in clinical trials and that stigma and prejudice towards brain disorders should be addressed.

Pedro Montellano spoke about changing paradigms on patient involvement in brain health. Patients are now seen as key opinion leaders and must be seen as equal partners in future decision making in developing new health policies, in research for new treatments and in managing their own treatment, according to Mr Montellano. Clinicians and patients are not on opposite sides, but in different positions on the same side, he said. He also highlighted the need to strengthen the role of patient organisations for brain disorders to play a stronger role at all levels to minimise the effects of those serious disorders.

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Recommendations:

- 1.** Systematically enlarge the capacity of patients who are knowledgeable in new treatment development for brain disorders
- 2.** Develop mechanisms (e.g. guidelines, legal requirements, consensus process, etc.) to enable patient involvement in academic and commercial research processes, ethics committees, competent authorities, data review boards
- 3.** We must reposition treating physicians at the center of drug development programs to provide direct feedback on the effects of drugs to R&D, (the individuality of brain disorders must be recognized and accounted for in clinical trials)
- 4.** It is necessary to promote the collaboration between regulators, industry, academy, HTA bodies, healthcare assistants and patients in order to identify sustainable approach to the development of new drugs
- 5.** Encourage and support research on assessing brain disorder patients' capacity to give informed consent
- 6.** Enforce the duty of ALL researchers to make the results of ALL clinical trials available to the public
- 7.** Enable a PATIENT-led campaign to raise public awareness of the devastating effect of brain disorders and the need for more and better treatment in an attempt to raise more intellectual and financial support
- 8.** Highlight the need of a healthy life-style to increase brain functionality over time
- 9.** Strengthen the role of patient organisations in brain disorder indications to play a stronger role in all recommendations mentioned before

ROUNDTABLE SESSION: Taking action for brain research and healthcare in Europe

The key objective of the conference was to encourage EU Member States and associated countries to focus on brain research and healthcare and to develop, or refine, national strategies with a particular emphasis on the patient as well as research, healthcare and European competitiveness. The final session put the focus on defining what needs to be done in order to progress brain research and improve healthcare across Europe in a strategic and effective way.

The session opened with a short report from first Month of the Brain conference European brain research: successes and new challenges, which highlighted the need for integration in neuroscience research and agreed with many of the challenges raised at the Dublin conference.

Enda Connolly, CEO of the Health Research Board, invited presentations by each of the chairs on the recommendations arising from the plenary sessions (included in this report in lists after each session summary), and chaired a panel discussion and audience question-and-answer session.

Key points that arose during the discussion included:

- Smarter approaches to funding, such as alignment of strategies are needed as well as an increase in funding for neuroscience research in Europe
- The brain needs to be viewed in its physical and social environment, as part of a bigger picture, and basic and clinical scientists need to work together in neuroscience
- Clinical studies are usually performed and drugs validated in a small percentage of the population, excluding children, elderly, patients with co-morbidity. This needs to be changed. Neurosciences probably need patient involvement more than any other indication

- More research is needed around multi-disciplinary team healthcare processes
- Stigmatisation should be addressed - the brain should be considered just as a part of the body – and brain-related issues no different to having a problem with the liver. Today one can talk openly about cancer in countries, where it used to be stigmatized. We should learn from this example
- Delivering through small-to-medium enterprises (SMEs) will be a huge part of the brain-health agenda, with particular opportunities in biomarkers and also care, including new applications for monitoring and services
- Social media and health applications could offer a way to collect data and communicate information about brain health and disorders, though the issue needs to be addressed of how to help consumers identifying relevant, evidence-based information
- Scientists need to engage in public debate about neuroscience and brain health

Bairbre Nic Aongusa, Assistant Secretary General, Department of Health, Ireland, thanked delegates for what she termed a 'stimulating and informative conference' and said that we should not stop here, every one of us can contribute to moving forward. The Department undertook to bring the report to the attention of the Lithuanian presidency (i.e. the next Presidency) to consider the possible next steps, in partnership with the EU Commission, towards addressing the conference recommended policy principles and objectives.

Ruxandra Draghia-Akli, Director of the Health Directorate at DG Research and Innovation (DG RTD), European Commission, rounded off the conference by calling upon stakeholders to work together to improve brain research and innovation in Europe and around the globe.

CONFERENCE COMMITTEE

The Conference Committee consisted of:

- **Marcelis Boereboom** and **Jacqueline Hoogendam**,
Ministry of Health, Welfare and Sport, The Netherlands
- **Magda Chlebus**,
European Federation of Pharmaceutical
Industries and Associations
- **Audrey Craven**,
European Federation of Neurological Associations
- **Marlies Dorloechter**,
Deutsche Gesellschaft für Luft- und Raumfahrt
- **Orla Hardiman**,
Trinity College Dublin and Beaumont Hospital
- **Mogens Horder**,
University of Southern Denmark
- **Cyril Höschl**,
Prague Psychiatric Centre
- **David Nutt**,
Imperial College London
- **Enda Connolly**,
Health Research Board, Ireland, Chair
- **Philippe Cupers**,
European Commission, Chair
- **Sigrid Weiland**,
European Commission
- **Patricia Clarke** and **Gillian Markey**,
Health Research Board, Ireland

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