

# BRAIN DISORDERS: THE NEED FOR IMPROVED TREATMENT

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European Parliament Interest Group on Mental  
Health, Well-being and Brain Disorders

*Brussels, 2<sup>nd</sup> June 2015*

Prof. David Nutt  
Frédéric Destrebecq



# Agenda

- The European Brain Council
  - Presentation
  - Achievements
  - Publications
  - Advocacy
- The CINP White Paper
  - Main issues
  - Proposed actions
  - Stakeholders' response

# Acting as the common platform for the « brain space »

- Uniting patient, scientific, medical and industry perspectives around a common vision
- From which brain space can speak with one voice
- Recognized by EU and other institutions as such



# Bringing together patients, scientists, clinicians and industries since 2002

- Promoting brain research in Europe and improve the quality of life of those affected by brain diseases
- Supporting basic and clinical research in Neuroscience
- Fostering dialogue bw. Science & Society

# EBC Board Members

- **EFNA** – European Federation of Neurological Associations
- **GAMIAN Europe** – Global Alliance for Mental Illness Advocacy Networks
- **EAN** – European Academy of Neurology
- **EANS** – European Association of Neurosurgical Societies
- **ECNP** – European College of Neuropsychopharmacology
- **EPA** – European Psychiatric Association
- **FENS** – Federation of European Neuroscience Societies
- Industry partners



# EBC Associate & Observers

- **B4B** – Brains 4 Brain
- **Euro-CNS** – European Confederation of Neuropathological Societies
- **EUFAMI** – European Federation of Associations of Families of People with Mental Illness
- **ESO** – European Stroke Organisation
- **FEPS** – Federation of European Physiological Societies
- **ESN** – Federation of the European Societies of Neuropsychology
- **ILAE-CEA** – International League Against Epilepsy - EU
- **National Action Groups and Brain Councils**



# EBC contributed to increased funding in Brain Research

- Mapping of cost & burden of major brain diseases

Paper published in 2005 and 2010

- Consensus for Brain Research

Paper published in 2006 and 2011

# Early Publications

- The Burden of Brain Diseases in Europe

*Olesen J and Leonardi M. Eur J Neurol 2003, 10:471-7*

- Cost of Brain Disorders in Europe

*Andlin-Sobocki P, Jonsson B et al. Eur J Neurol 2005, 12 Suppl 1:1-27*

- Size and Burden of Mental Disorders in Europe

*Wittchen, H-U et al. Eur. Neuropsychopharmacol 2005, 15(4):355-490*

- Research Allocation for Brain Research in Europe

*Sobocki P et al. Eur J Neurosci 2006, 24:1-24*

- Consensus Document on European Brain Research

*Olesen J, Baker MG et al. J Neurol Neurosurg Psychiatry 2006, 77*

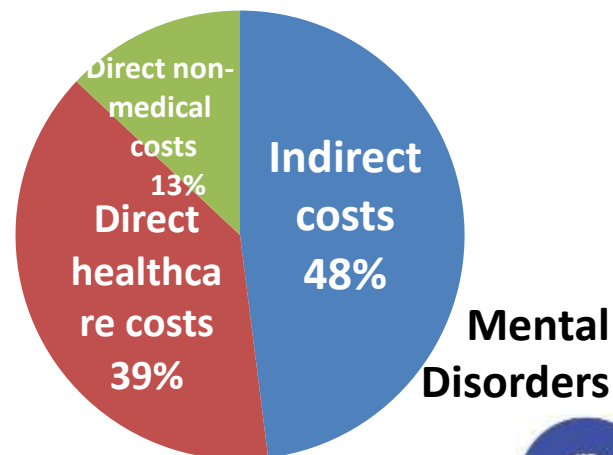
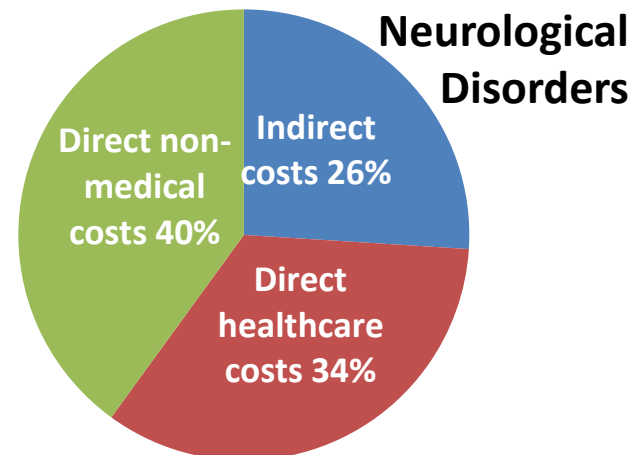
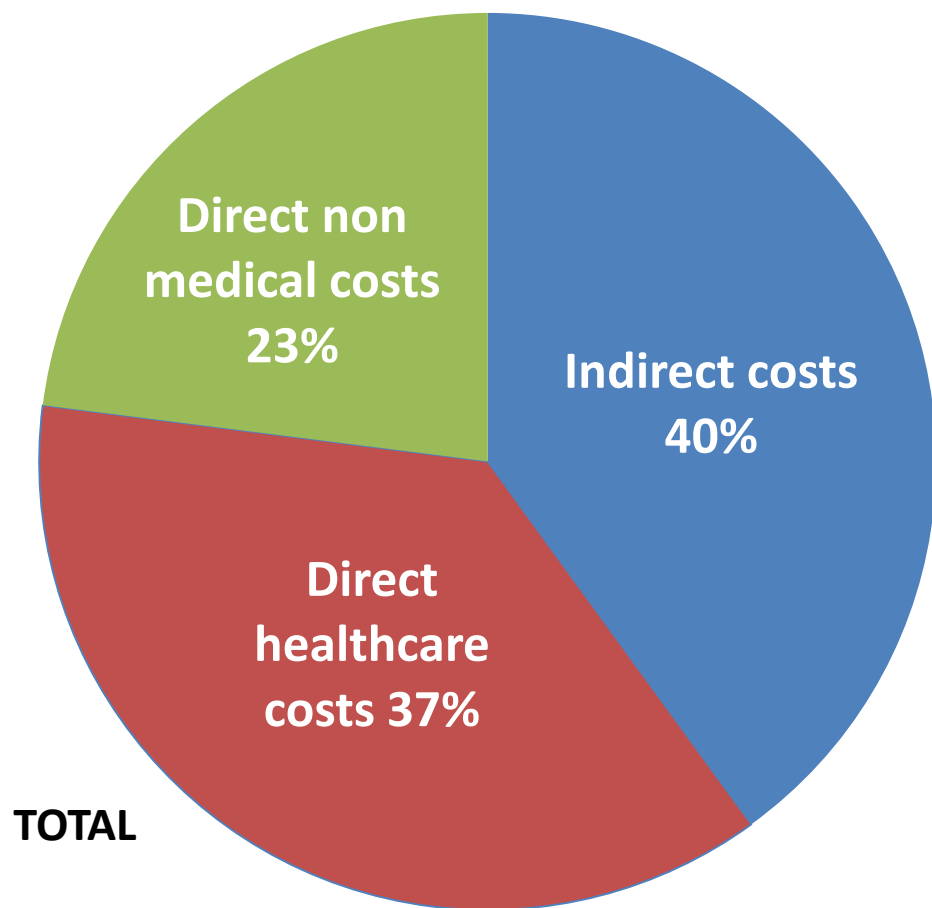


# 2010: Total cost of Brain Disorders in Europe amounted to € 798 billion

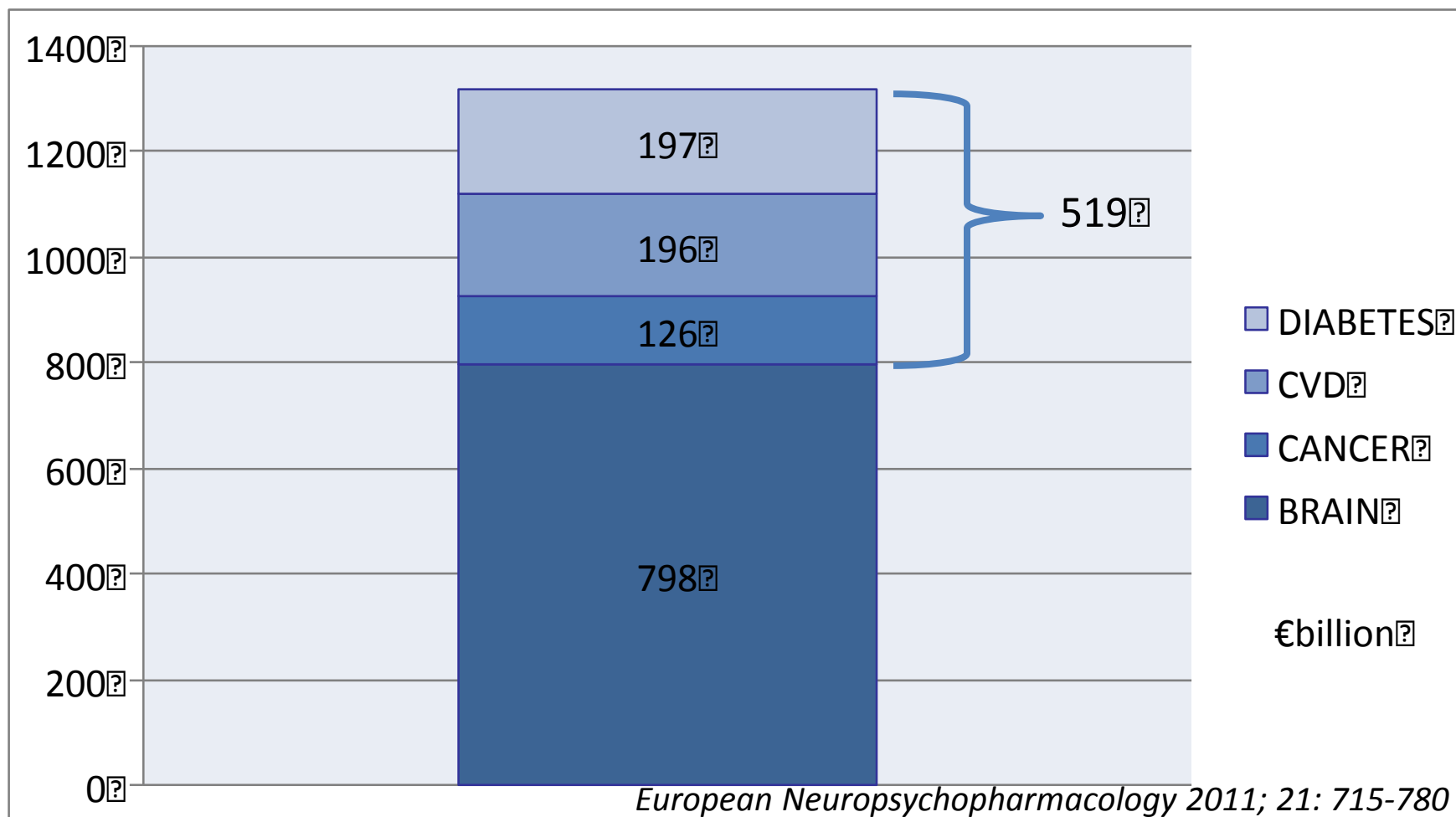
- Cost Document released in 2011
- Continuation of first study (2004): + € 386 billion
- More than **1/3** of Europe's population affected

*European Neuropsychopharmacology 2011; 21: 715-780*

# Cost of Brain Disorders in Europe – 2010



# Cost of Brain Disorders in Europe – 2010



# Consensus Document – 2011

- Collection of 45 research themes updated from 2006
- Used for selection of topics in first calls of FP7
- Revision reflecting changes in research priorities and advances
- Multi-authored, multi-national:
  - 200 European scientists and patients organizations
  - proposals for future research programmes
  - needs and achievements of research in Europe

*European Journal of Neuroscience, Vol. 33, pp. 768–818, 2011*

# EBC advocates for better funding of brain research



	FP5 (pre EBC)	Total in FP6	FP7 2007 - 2013
<b>Brain</b>	115m	431m	3b *
<b>Cancer</b>	235m	914m	2.2b
<b>Cardiovascular</b>	54m	232m	737m

\* Updated: June 2015

# National Brain Councils & Action Groups 2011-2015

- 30 NBCs and NAGs developed
- Pushing for research at local level
- Providing vital grass roots knowledge to the EBC
- Enabling progress at country level
- First Session of NBCs Academy: 17<sup>th</sup> June 2015



# Awareness Raising & Advocacy



**1st European Day of the Brain.  
Ageing, Stroke, and Alzheimer's Disease  
- Finding Innovative Solutions**



**Year  
of the Brain  
in Europe**

# YotB served as pan-European campaign to change the way we perceive our brain

- A programme to raise awareness, educate and challenge current perceptions
  - 200 organisations have pledged their support
- Main themes:
  - Education
  - Awareness
  - Research
  - Ethics
  - Extensive brain ambassadors campaign





# INNOVATIVE PARTNERSHIPS TO ACCELERATE CNS DRUG DISCOVERY FOR IMPROVED PATIENT CARE

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# CNS disorders are the understated health challenge of the 21st Century

- One third of people will develop brain disorders
- Revenues from CNS drugs are predicted to decrease, prompting investors to withdraw their support
- CNS disease research area is seen as the most unpredictable and costly, with a high rate of failure
- Hence, dilemma for investors in an area with high unmet need and potential for development, but with high risks

# We need to revisit the Value Chain for brain disorders

- The societal impact of brain disorders is growing  
Stigma - Demographic changes - Economic Impact
- Non accessibility of treatment  
High cost of treatment - Long waiting time  
– reimbursement & approval
- Brain research lacks input and innovation  
Brain research is underfunded – Industry withdraws from the area

# Topic #1

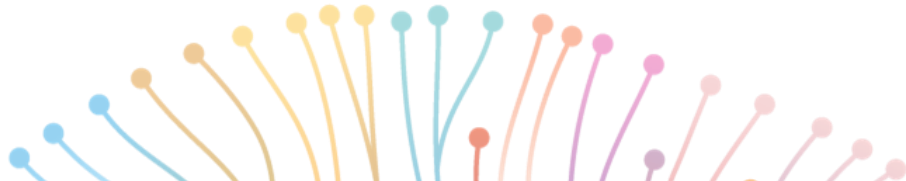
## Connecting Science & Regulation



# A better understanding of brain function is needed

Issues with:

- Higher complexity in CNS
- Few biomarkers & little molecular definition of illnesses
- No clearly defined endpoints
- Poorer understanding than for other conditions

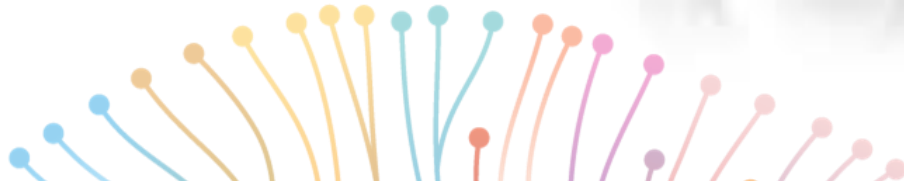


# Proposed solution through

- Collaborative & open approach in drug development
- Improved dialogue re-running of clinical trials
- Sustained communication – unhindered by robust conflict of interest policies
- Refined regulatory processes against scientific advances
- Attracting investment in basic and clinical research

## Topic #2

# Benefit-Risk – Effective research & Implementation into clinical practice



# Clinical trials & real-life practice are disconnected

- Narrow criteria for recruitment
  - Oversight on co-medication, adherence or adverse effects
- 
- How to ensure real-life effectiveness?
  - How to develop new valid clinical trials designs?



# Innovative clinical trials w. clear & relevant endpoints should be developed

- Faster access to market
- Lower cost
- Maintained quality standards
- Predictable drug development process



# Proposed solution through

- Involving patients in trial design
  - *Recruitment & access to directories*
  - *Outcome measurement – “Real world targets”*
  - *Better understanding of drug’s performance*
- Including functional outcomes
  - *Patient-centered data collection – via e- or m-Health*
- Easing difficulties related to studies on primates

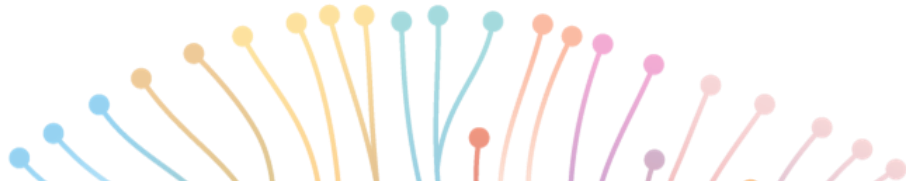
## Topic #3

# Knowledge Transfer & Protection of Innovation



# Proposed solution through

- Creation of “co-operative research centres”
- Platform to organize exchange of knowledge
- Shift of culture and incentives to Academia necessary



## Topic #4

Need for modern 21<sup>st</sup> century perspective on new tools to assess treatment effects



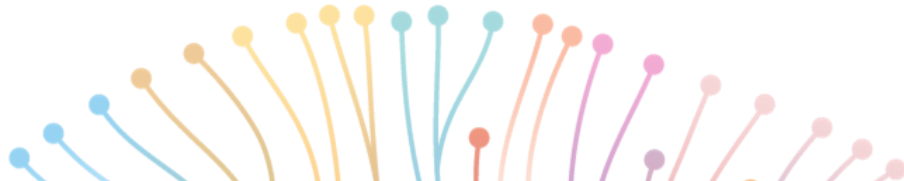
# Current challenges

- Decisions by regulators currently based on tools & scales
  - *Developed in 1970s-80s*
  - *Never updated from latest diseases insights*
  - *Hence no longer scientifically valid...*
- Developing new assessment tool
  - *No agreed biomarkers*
  - *Lack of standardised nomenclature*



# Proposed solution through

- Alternative diagnostic tools, eg. cognitive markers
  - *Cheap to develop*
  - *Valid & robust*
  - *Large database essential to develop & test*
  - *Provides for “Quality of Life” measurement*



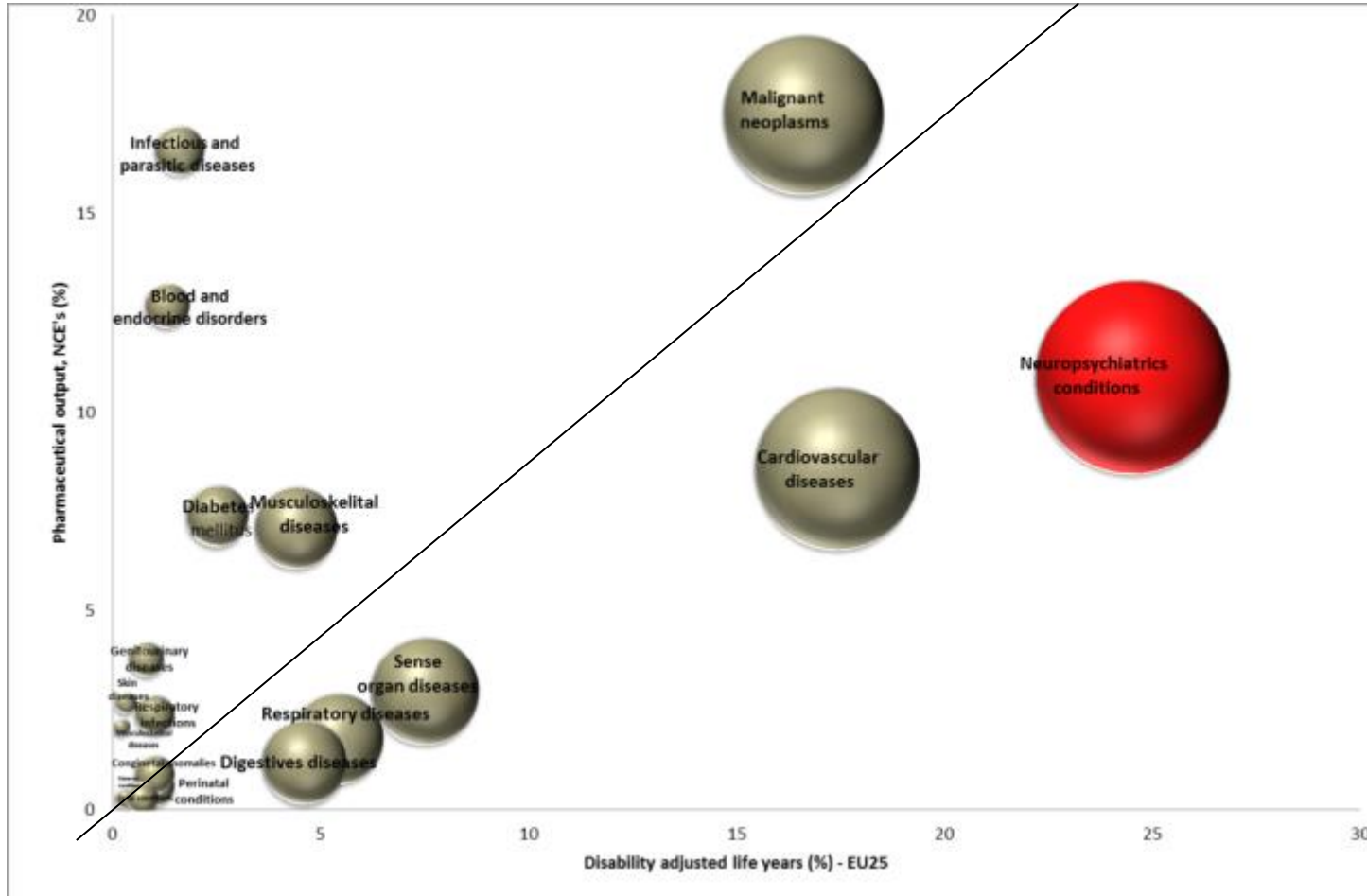
## Topic #5

# Incentivising investment in brain research





# Investment in CNS considerably lower than in other fields



# Low investment can be explained

- Stigma & under-recognition + Complexity

= No prioritising by governments or companies

- In spite of economic impact (mainly indirect)
- Need to raise profile of huge unmet needs in CNS

& demonstrate cost saving effect

# Strong need for

- Stronger Patient Advocacy
- Joint investment strategy
- Awareness raising re.a.o. Cost/Burden & Stigma

# Proposed Actions

- Public awareness & patient involvement in
  - Trial design
  - Definition of endpoints
  - Large-scale patient registries
- Linking science & regulation – eg.adaptive trial design
- Update IP Laws to facilitate repurposing &combination therapy
- Leadership on nomenclature, biomarkers & diagnostic tools
- Reproduction and confirmation of preclinical data

# Capturing the cost of non-treatment

- EBC-run project – Project outline being defined

- Milestones

Concept note

May 2015

Internal Roundtable

19<sup>th</sup> June 2015

Position Paper

Public Roundtable

December 2015

Project & Dissemination

- Duration      Jan.2015 – Dec.2016

# EBC is committed



**#Move4YrBrain**

How do you intend to contribute?



**WE WANT YOU!**



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**Thank you for your attention !!!**