Towards InTBIR: an International Initiative for TBI Research

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The role of the European Commission in research

Shaping and implementing research policies
- Proposes and implements research policies such as the European Research Area, the Europe 2020 strategy and the Innovation Union

Funding research and innovation
- Manages the 7th Framework Programme for Research & Technological Development (FP7)
- FP7 supports research done by a wide range of participants
- Aims at strengthening the science and technology base, increasing the competitiveness of industry and improving lives of citizens
Total FP7 budget: € 54,582 billion

*of which Health €6.1 billion
Together is better!
Cooperation across borders and barriers

**Between countries:**

*Multinational consortia*, with at least 3 partners from 27 EU Member States or Associated Countries

researchers from **any country in the world** can participate provided their contribution is essential

**Between different types of organizations:**

*Public & private sector:* universities, research centres, large companies, SMEs, etc

**Between disciplines:**

*Multidisciplinary*, translational research
What do we want:

• to improve the health of European citizens
• to increase competitiveness of European health-related industries and businesses
• to addressing global health issues
• to supporting the aims of Europe 2020: the ‘Innovation Union’ via:
  ➢ Collaborative research: FP7 projects
  ➢ International cooperation activities: Programme-Level Cooperation with non-EU countries
  ➢ Coordinating national research programmes
FP7 Health - brain research

What did we do?

- ~100 collaborative projects on the brain and its diseases
- > €520 million invested so far
- €50 million = total FP7 funding going to traumatic brain and spinal cord injury to date
- €9 million = FP7 Health funding going to traumatic brain and spinal cord injury to date

⇒ Underfunded = priority area for future actions
Successive FP6 (NeuroNE) and FP7 projects (PLASTICISE) allowed:


• Showing that Anti-Nogo-A antibodies applied in vivo after spinal cord or brain trauma in rats leads to outgrowth and regeneration of injured nerve fibres and to a high degree of functional recovery (Freund et al, Nature Medicine, 2006).

• Launching a Phase I trial to test the anti-Nogo-A antibodies in spinal cord-injured patients.

• Showing that compensatory plasticity is still possible in the adult brain and spinal cord (Gosh et al., Nature Neuroscience, 2010).

• Showing that the use of chondroitinase to activate plasticity dramatically enhance the effects of rehabilitation (Garcia-Alias et al., Nature Neuroscience 12,1145, 2009).
Why international cooperation in health research?

- Health is a priority for industrialised, emerging economies and low income countries
- “Rich world” diseases (cancer, diabetes...) also affect developing countries and vice versa (AIDS, TB...)
- Diseases do not respect borders
- Treatments and cures are universal
What can we do together: Programme Level Cooperation

What is it?
Bilateral or multilateral agreements with one or more public or private funding bodies

How does it work?
- Discussion at high level to define areas of common interest
- Workshop(s) to identify priority topics within the areas
- Issuing of calls in FP and in the cooperating country(ies)
- Independent evaluation, selection and funding of proposal(s)
- Close cooperation of the funded projects
- Sharing of results
International K.O. Mouse Consortium (IKMC)
Mutate all protein-coding genes in the mouse
NIH, EU Commission, Genome Canada
Total investment: $100 million, EC: €13 million
www.knockoutmouse.org

International Cancer Genomics Consortium (ICGC)
To obtain a comprehensive description of genomic, transcriptomic and epigenomic changes in 50 different tumour types
NIH, EU Commission, and 11 other countries (DE, UK, AU, Canada, CHN, India, etc)
Total investment > $250 million; EC: €21 million
www.icgc.org
**Programme Level Co-operation - In preparation -**

**International Human Epigenome Consortium (IHEC)**

Co-ordinate the production of reference maps (at least 1000 epigenomes) of human epigenomes for key cellular states relevant to health and diseases
NIH, EU Commission, CIHR (Canada), 10 other countries
Total investment foreseen >$100 million
www.ihec-epigenomes.org

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**Proposed International Initiative on Traumatic Brain Injury**

Promote clinical research, CER and data collection in TBI

NIH, EU Commission, CIHR (Canada), open to all interested funding bodies
Total investment foreseen >$80 million, EC foreseen for 2013: €30 million

10/24/2011
Why the focus on TBI?

"Unfortunately, there's no cure – there's not even a race for a cure."
Why the focus on TBI?

Huge unmet medical need:

- **>1.2 million new patients/yr in the EU**
  (TBI incidence: 235 per 100 000 per year)
- **>2.5 million** suffering from long term consequences of TBI
- **>75,000 deaths/yr**, the majority from road traffic accidents
  (15 TBI-associated deaths per 100 000 population per year)
- **> 100,000 handicapped/yr** (moderate and severe disability combined). TBI is the leading cause of disability in people under 40 years of age
- **75% of the victims are children and young adults**

Causes of TBI world-wide

**Significant economic burden and healthcare costs:**

€8809: Average cost per TBI patient in the EU27 in 2010

€33 billion: Total cost of TBI injuries in the EU27 in 2010

<table>
<thead>
<tr>
<th>Number of subjects (million)</th>
<th>Cost per patient (€PPP 2010)</th>
<th>Total costs (million €PPP 2010)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Direct healthcare costs</td>
<td>Direct non-medical costs</td>
</tr>
<tr>
<td>Traumatic brain injury</td>
<td>3.7</td>
<td>2697</td>
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</tbody>
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Why the focus on TBI?

Unmet need for effective therapies:

• Limited progress in TBI treatment seen in the past 20 years: out of 33 phase III clinical trials, only 10 provided significant results.

• Successful clinical trials did not significantly improve TBI care because:
  - treatments are effective on very specific TBIs, but applicability to the full TBI spectrum is limited
  - choice of treatment depends on availability of infrastructures and habit

• Clinical research that has advanced the field of TBI and should be encouraged:
  - Evidence-based clinical guidelines
  - Observational studies
  - Meta-analysis of individual patient data

need for a global effort towards better standardisation and comparative effectiveness research (CER)
The International Initiative for Traumatic Brain Injury Research

Open to all interested funding agencies

Objectives?
- Promote clinical research, CER and data collection in TBI
- Use CER to identify the most effective available treatments and interventions for the different types of TBI;
- Improve diagnostic classification of TBI;
- Establish a comprehensive TBI patient database and make it available – within the remits of personal data protection issues – to the scientific community for further data analysis.

Expected outcome?
- Better diagnosis and therapies leading to improved clinical outcomes for TBI patients!
November 2009 - March 2010

- First contacts between EC and NINDS to look for possible cooperation on TBI. A common theme of interest is found in clinical trials and CER in TBI.

June 2010, February 2011:

Joint EC/NIH workshops are organised in Las Vegas and Washington DC

Conclusions:

- urgent need for identification and standardisation of effective treatments in TBI
- best achieved through large prospective clinical studies coupled to CER
- need for a global effort to optimise resources: funding agencies worldwide to join forces into an International Initiative for Traumatic Brain Injury Research (InTBIR)

October 2011

- Expected launch of InTBIR
InTBIR: Goals over the next two days:

To agree upon:

- The short- and long-term goals of InTBIR
- The implementation of InTBIR:
  - timing and content of calls
  - the governance of InTBIR
- The skeleton of a document summarising goals, policies and working modalities of InTBIR

To discuss key scientific questions:

- Key aspects of TBI research such as:
  - adequacy of diagnostic criteria and outcome scales;
  - data collection and sharing;
  - strategies to apply CER to the TBI field.
- A common working methodology for data collection (what data to collect, how, where to store them), prospective observational clinical trials and CER analysis.
Thank you for your attention!

Questions?

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