



# **InTBIR – 5 years on:** *"Great Expectations"*

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# ***EU Support for Research & Innovation***

- EU support for R&I through Framework Programmes.  
eg: FP7 (2007-2013), Horizon 2020 (2014-2020)
- Distinct from national programmes of EU Member States
- Horizon 2020 budget: €77 billion/7 years (€5.5 b for neuro)
- Three priorities:
  1. "***excellent science***" ie European Research Council (ERC) and Marie Skłodowska-Curie Action (eg research fellowships)
  2. "***industrial leadership***"
  3. "***societal challenges***", including "***Health, Demographic Change and Wellbeing***" => mainly large-scale collaborative research.

# HORIZON 2020

*"Open Science, Open Innovation,  
Open to the World"*

# EU brain research

Addressing the continuum from knowledge to delivery



- FP7: €3.1 billion
- H2020 to date: €2.4 billion



- Coordinating national research activities
- Strategic research agenda
- Transnational calls



- Speeding up the development of innovative medicines
- Open collaboration in public-private consortia



- Joining forces to address common global goals
- Implementation & comparative effectiveness research

Human Brain Project

- Harness modern ICT to understand the brain
- € 1 billion / 10 years





## EC contribution to InTBIR

- **CREACTIVE** - Collaborative REsearch on ACute Traumatic brain Injury in intensiVe care medicine in Europe.  
Led by Mario Negri Institute, with 10 partners in 7 countries.  
EU contribution: € 5.44 million (Oct. 2013-Sept. 2018)
- **CENTER-TBI** - Collaborative European NeuroTrauma Effectiveness Research in TBI.  
Led by Antwerp University Hospital, with some 37 partners from 19 countries, incl. Australia, China, New Zealand, USA.  
EU contribution: €30 million (Oct. 2013-March 2020)



## ***"Working together to improve outcomes and lessen the global burden of TBI by 2020"***

### **Mission statement:**

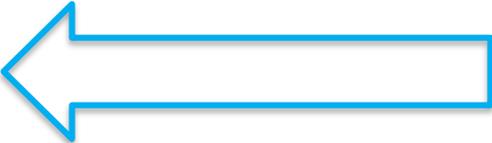
*"InTBIR is a cooperative effort (EU, US, Canada)... to coordinate and leverage clinical research activities on TBI research.*

*InTBIR's goal is to improve health care and lessen the global burden of TBI by 2020 through the discovery of causal relationships between treatments and clinically meaningful outcomes."*

by developing common approaches to pool resources and results

## ***InTBIR***

### **Objectives:**

- *Use Observational Data and Comparative Effectiveness Research (CER) to Identify Best Practices and Improve Quality of Care in TBI*
- *Collect and Share TBI Patient Data* 
- *Translation*
  - Living Guidelines for Global TBI
  - Towards improved Injury Classification and Patient Stratification

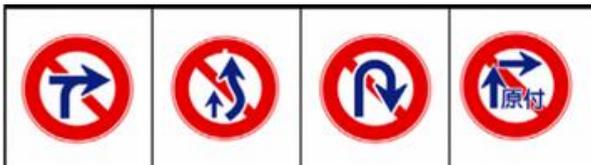
## *InTBIR*

### Lessons learnt

➤ Sharing patient level clinical data

=> more complex than anticipated

For data sharing - informed consent management,  
compliance to data protection law, platforms, etc.



## Current challenges

- Demonstrate interoperability and functionality of the ***data sharing platform***
- Pilots and a broad approach implementing ***data analysis across InTBIR studies***
- Supporting activities:
  - Finalisation of ***informed consent management guide***
  - Implementing InTBIR ***publication policy***
  - Development of ***data sharing policy***
  - Development of data integration strategies, like the ***CER-question approach***, enabling data analysis across studies

## Demonstrated strengths

- *Well established global collaboration*
- *Experience with regulatory qualification procedures*
- *Comprehensive clinical data and results from several InTBIR studies becoming available*
- *Initiated pioneering clinical guideline development to help bring innovation to the patients.*
  
- **InTBIR - a potential model for other global initiatives.**

## Recommendations

- Strengthen and improve infrastructure
- Demonstrate capabilities and expertise by delivering pilots and fully implementing data sharing strategy
- Consider widening scope by integrating other countries / institutions and/or related disease and research areas (eg epilepsy) to increase *critical mass and scope*.

*"Open Innovation, Open Science, Open to the World"*

- From 2018, EC will fund a platform to explore further opportunities for intra-European and international cooperation:

**"Coordinating European brain research and developing global initiatives "**

(Horizon 2020 Health work programme 2018-19 published 27 Oct. 2017)



European  
Commission

# Thank you



## Sharing of patient level clinical data is complex

### Ethical requirement

The ***informed consent*** has to cover the intended data analysis and the handling of data / potential cross border transfer.

### Legal requirements

**Data privacy law** has to be respected and data management accepted by local authorities – e.g. patient level data stay always ***personal data***.

### Methodical challenges

***A data sharing platform***, has to be established ensuring compliance with applicable data privacy law in all regions / countries.

***Data analysis across different clinical studies*** addressing the planned and novel objectives.

# Addressing the barriers to data sharing

## Ethical requirement

- ***informed consent management guide*** under development

## Legal requirements

- Cross border transfer of patient level data probably not possible in many cases, e.g. European projects/clinical studies
- **Federated data base approach** as feasible practical solution
- **Data sharing platform** building on data centres in the US, Canada and Europe agreed upon and under development

# Addressing the barriers to data sharing

## Methodological

- Pilots to demonstrate proof-of-concept/functionality of data sharing platform planned.
- Data analysis across InTBIR studies – most challenging task
  - Limited availability of common clinical endpoints across studies
  - However, first pilot projects have been initiated
  - Innovative strategies, such as CER-question approach could enable data sharing on a broader level.



Based in its strengths has a significant potential to contribute to achieving the objectives of the ***Open Innovation, Open Science, Open to the World*** strategy.

Building on the lessons learned, established infra-structure and results InTBIR researchers have clear advantage to be successful either in upcoming calls for proposals addressing open topics or becoming a crucial partner in existing or upcoming initiatives sharing InTBIR objectives ***CER, data sharing, guideline development, global collaboration, etc.***

Being a reference point for ***clinical guideline development*** – the implementation of innovative approaches like Living Systematic Reviews for TBI and beyond.