PharmaCog
Prediction of cognitive properties of new drug candidates for neurodegenerative diseases in early clinical development

Project Coordinators
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Alzheimer’s disease

- Alzheimer’s destroys brain cells, causing memory loss and problems with thinking and behavior severe enough to affect work, lifelong hobbies or social life.

- Alzheimer's disease is complex with different types of abnormalities in the brain.
What does this mean for patients and Europe?

• Has no current cure. But treatments for symptoms, combined with the right services and support, can make life better for the patients.

• The number of Alzheimer's patients is increasing rapidly, and along with it, the impact of the disease on society.

• There is an accelerating European effort under way to find better ways to treat the disease, delay its onset, or prevent it from developing.
The Challenges for new drug development in Alzheimer’s disease (1/2)

- The traditional drug discovery process is not efficient

- There are no efficient models that are available which allow scientists to mimic the disease in the laboratory

- There are no sensitive measures available that can be used to determine the effect of a new drug

- Trials in Alzheimer’s disease need to run for 2 years and cost 10’s of millions Euros per study to test new medicines
The Challenges for new drug development in Alzheimer’s disease (2/2)

- The lack of ability to model disease means that:
  - it is difficult for drug developers to predict the best new medicines
  - it is difficult to predict the most effective drug dose exposure
PharmaCog Approach

• Accelerate Alzheimer’s drug development following 3 major steps

  Develop experimental models and clinical models that mimic aspects of the disease and help to predict treatment efficacy

  Develop markers using these models to predict effective dose ranges and treatments efficacy

  Develop Alzheimer’s markers sensitive to the disease progression
How PharmaCog is innovative?
Translation and Harmonisation (1/3)

Experimental Models
- Develop laboratory based models and clinical models that mimics aspects of the disease and help to predict treatment efficacy
- Develop markers using these models to predict effective dose ranges and treatments efficacy
- Develop Alzheimer’s markers sensitive to the disease progression

Clinical Models

Core biomarker set

Blood analysis
Cognitive testing
Brain scans
Brain talk (EEG)
How PharmaCog is innovative?
Translation and Harmonisation (2/3)

**Experimental Models**
- Develop laboratory based models and clinical models that mimics aspects of the disease
- Develop Alzheimer's markers sensitive to the disease progression

**Clinical Models**
- Develop markers using these models to predict effective dose ranges and treatments efficacy
- Brain scans
- Blood analysis
- Brain talk (EEG)
- Cognitive testing

**Core biomarker set**

**Reinforced by:**
- harmonised protocols procedures
- centralised and standardised data analysis
How PharmaCog is innovative?
Translation and Harmonisation (3/3)

- Focus on increasing ability to predict new effective medicines from laboratory studies and clinical models

- Validate the tools necessary to streamline Alzheimer’s disease drug discovery

- All studies conducted are designed to improve our ability to identify successful new medicines as early as possible while stopping progression of those destined to fail
Expected outcomes

Robust and well-characterized experimental / clinical models to predict drug efficacy

A validated translational battery of markers that can be used to support drug dose prediction and clinical efficacy

Relationship between the changes in the biomarkers and the clinical efficacy

An Alzheimer’s biomarker battery to better predict the disease progression and support new medicine development
How PharmaCog will benefit to patients in Europe?

• Improve the availability of models required to make drug discovery easier and accelerate effective medicine to patients

• Set the standard for European drug discovery providing the best protocols for use in Alzheimer’s disease research

• Drive the development of a new generation of leading scientists focussed on improving the drug development process
Examples of added value of the consortium (1/2)

• **EFPIA partners:**
  
  – Experts in Alzheimer’s Disease Drug Discovery
  
  – Provide archived data from experimental and clinical studies using gold standard agents
  
  – Quantitative pharmacology expertise

• **Academic partners**
  
  – Expertise of world leading disease scientists
  
  – Development of new promising models
  
  – European *Alzheimer's Disease Neuroimaging Initiative* leader
Examples of Added value of the consortium (2/2)

- **European Medicine Agency (EMA):**
  - Advise on regulatory matters
  - Information on ongoing or concluded clinical trials in Alzheimer’s

- **Small and Medium Enterprises (SMEs):**
  - Bring new promising biomarkers
  - Help in the constitution of clinical trials authorization dossiers, administrative and Ethics procedures

- **The patients’ Association Alzheimer Europe:**
  - Communication of the project results
  - Lead the work on ethical issues
PharmaCog results/achievements so far

• Analysis of the archived data
• Analysis of new biomarkers in experimental models
• Constitutions of the first clinical trials dossiers
• Purchase of new equipments and start harmonization of protocols
• Constitution of technical, ethical and communication groups
• Post-docs already hired in institutions
PharmaCog Budget and Timing

Financing:
• IMI funding: €9.6 million
• EFPIA contribution: €10.2 million
• Other contributions: €7.9 million
• Total project cost: €27.7 million

Timing:
• Starting date: 1st January 2010
• Duration: 5 years
The PharmaCog Consortium:
Principle Investigators (1/2)

Public Partners

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SMEs

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Patient Groups

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Regulatory Authorities

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## Private Partners

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Further information

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• Soon the PharmaCog section on the Alzheimer Europe website: www.alzheimer-europe.org

www.imi.europa.eu