



Innovative Medicines Initiative

# PharmaCog

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



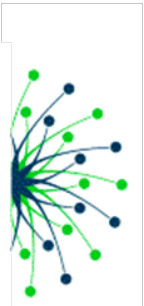
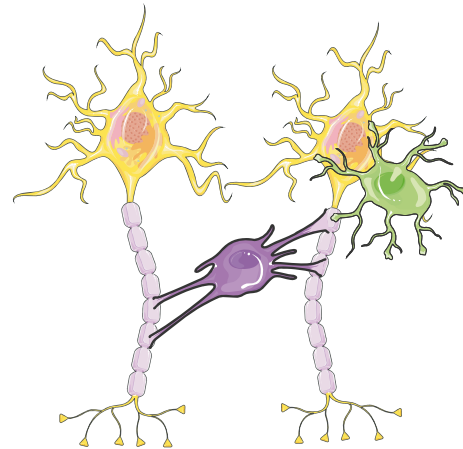
Project Coordinators  
Dr Elaine A Irving, GlaxoSmithKline R&D  
Prof Olivier Blin, University of Marseille



# Alzheimer's disease



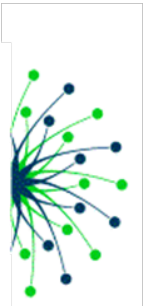
- Alzheimer's destroys brain cells, causing memory loss and problems with thinking and behavior severe enough to affect work, lifelong hobbies or social life.
- Alzheimer's disease is complex with different types of abnormalities in the brain



# 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.

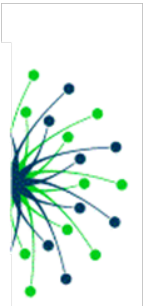


# The Challenges for new drug development in Alzheimer's disease (1/2)

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- 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
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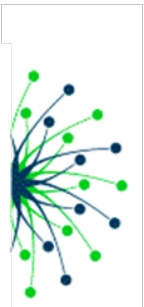


# The Challenges for new drug development in Alzheimer's disease (2/2)

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- 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

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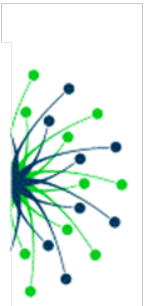


- Accelerate Alzheimer's drug development following 3 major steps

**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



Clinical Models

Develop laboratory based models and clinical models that mimics aspects of the disease and help to predict treatment efficacy

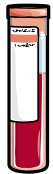
Develop markers using these models to predict effective dose ranges and treatments efficacy

Develop Alzheimer's markers sensitive to the disease progression



Brain scans

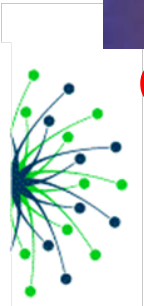
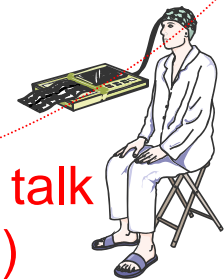
Blood analysis



Cognitive testing

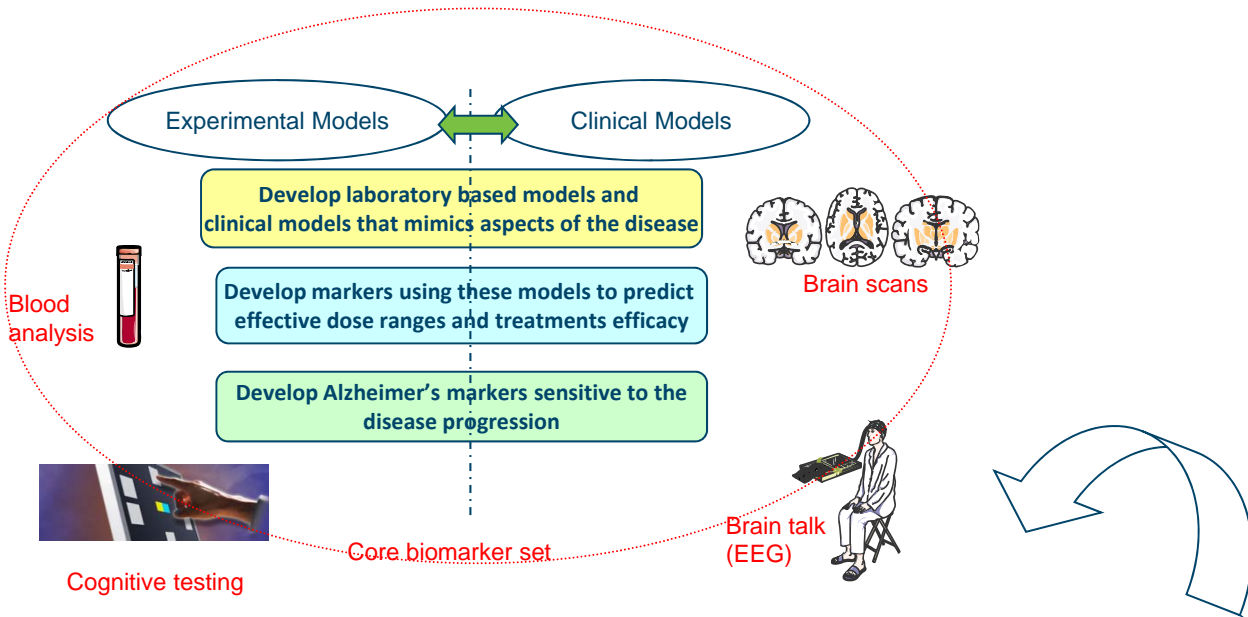
Core biomarker set

Brain talk (EEG)



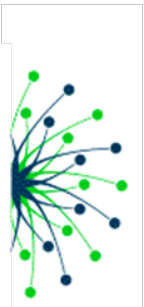
# How PharmaCog is innovative?

## Translation and Harmonisation (2/3)



### Reinforced by:

- harmonised protocols procedures
- centralised and standardised data analysis





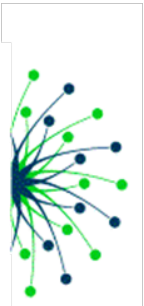
# How PharmaCog is innovative?

## Translation and Harmonisation (3/3)

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- 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

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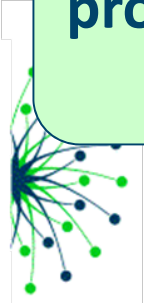


**Robust and well-characterized experimental / clinical models to predict drug efficacy**

**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**

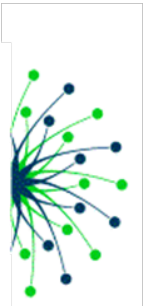


# How PharmaCog will benefit to patients in Europe?

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- 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)

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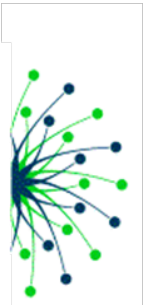


- **EFPIA partners:**

- 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

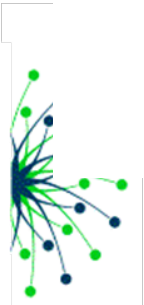


# Examples of Added value of the consortium (2/2)

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- **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
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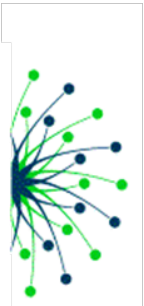


# PharmaCog results/ achievements so far

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- 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

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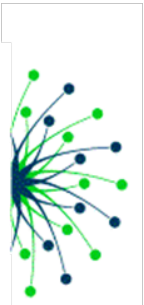


## Financing:

- 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 :

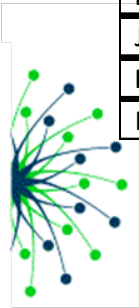
## Principle Investigators (1/2)



### Public Partners

<b>Prof Olivier Blin</b>	<b>University of Marseille</b>
Dr David Bartréz-Faz	IDIBAPS, University of Barcelona
<b>Prof Regis Bordet</b>	<b>University Lille</b>
Prof Ulrich Hegerl	University of Leipzig
Dr M-T Herrero Ezquerro	University of Murcia
<b>Prof Jens Wiltfang</b>	<b>University of Duisberg-Essen</b>
<b>Dr Fabienne Aujard</b>	<b>Centre Natuional de la Recherche Scientifique (CNRS)</b>
Dr Pierre Payoux	Institut National pour la Santé et la Recherche Médicale (INSERM)
<b>Prof Marina Bentivoglio</b>	<b>University of Verona</b>
<b>Prof Giovanni Frisoni</b>	<b>Fatebenefratelli, Istituto di ricovero e Cura a Carattere Scientifico (IRCCS-FBF), Brescia</b>
<b>Prof Claudio Babiloni</b>	<b>University of Foggia</b>
<b>Dr Gianluigi Forloni</b>	<b>Mario Negri Institute, Milan</b>

<b>SMEs</b>	
Dr Nathalie Compagnone	Innovative Concepts in Drug Development
Dr Philippe Verwaerde	AlzProtect
Dr Severine Patel	Qualissima
Dr Pasquale Beurdeley	ExonHit
Dr Jean de Barry	Innovative Health Diagnostics
<b>Patient Groups</b>	
Jean Georges	Alzheimer Europe
<b>Regulatory Authorities</b>	
Dr Karl Broich	European Medicines Agency





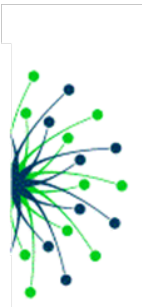
# The PharmaCog Consortium : Principle Investigators (2/2)

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## Private Partners

Dr Elaine Irving	GlaxoSmithKline R&D Ltd
Dr Hans-Göran Hårdemark	AstraZeneca R&D
Dr Bernd Sommer	Boehringer Ingelheim International GmbH
Dr Georges Imbert	Novartis Pharma AG
Dr Esther Shenker	Institut de Recherche Servier
Dr Yves Lamberty	UCB Pharma SA
Dr Dirk Beher	Merck Serono
Dr John Atack	Janssen Pharmaceuticals
Dr Susanne Ostrowitzki	Hoffman-La Roche
Dr Jan Egebjerg	Lundbeck



# Further information

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- Contact Person:

Elaine.A.Irving [AT] gsk.com

Olivier.Blin [AT] ap-hm.fr

Alexandra.Auffret [AT] ap-hm.fr



- Soon the PharmaCog section on the Alzheimer Europe website : [www.alzheimer-europe.org](http://www.alzheimer-europe.org)

[www.imi.europa.eu](http://www.imi.europa.eu)

