Innovative Medicines Initiative

For immediate release

IMI/OUT/2013-02644

PRESS RELEASE

Pharma-Cog and EMIF-AD projects bring Alzheimer's treatments closer to reality

BRUSSELS, 22 May 2013 – The number of people with Alzheimer's disease is increasing, and there are no treatments available that will make a real difference to the relentless course of this disease. IMI's Pharma-Cog and EMIF-AD projects are working towards new drugs and diagnostics that could bring hope for patients and their families.

There are some drugs available for Alzheimer's disease, and while they do help, they only treat the symptoms and don't slow the progression of the disease. Researchers have hunted for the holy grail of a drug that stops Alzheimer's in its tracks and even reverses some of the brain changes. However, many attempts have failed, partly because improvements seen in animals don't always translate into benefits in people. The aim of the most advanced of the two Alzheimer's projects, Pharma-Cog, is to change this.

Pharma-Cog Academic Lead Regis Bordet, Departement de Pharmacologie, CHU de Lille et Université Lille 2, says: "The aim of Pharma-Cog is to propose to the pharmaceutical industry and academic research laboratories new methods for successfully developing new drugs for the treatment of Alzheimer's disease. The outcomes of the Pharma-Cog project should pave the way for delivering new drugs that will improve patients' cognitive and behavioural symptoms and slow the progression of the disease. This should also reduce the economic and social burden of the disease."

The Pharma-Cog researchers are working to develop animal models that more closely mimic Alzheimer's disease in humans. It is hoped that these models may be better at predicting how effective the drug is in humans.

The working hypothesis of Pharma-Cog is that no single physiological, functional or biochemical marker will be sensitive enough to respond to a drug sufficiently to provide the confidence to progress to later clinical phase studies, but that a collection of markers will be necessary. To achieve this, a multidimensional "MATRIX" approach will be implemented throughout the project, by conducting parallel studies in animals, healthy volunteers and selected patient cohorts using the same fully translational endpoints, the same provocation challenges, and the same therapeutic interventions.

Pharma-Cog Project Coordinator Dr Jill C. Richardson, Director, External Alliances and Development, R&D China at GlaxoSmithKline says: "We believe the application of a multidimensional matrix to detect early disease and its response to novel drugs will reduce attrition in Phase III studies, which will speed up the development of crucially needed new treatments for this devastating disease."

Another IMI project working in the Alzheimer's area is EMIF-AD, which started in early 2013 and is part of IMI's wider EMIF (European Medical Information Framework) programme. There have been many different studies on Alzheimer's disease, and there is a huge volume of data available, but little of it is linked together, which makes it hard to use it to draw any useful conclusions. The aim of EMIF-AD is to connect data from a variety of sources such as patient health records, research cohorts, biobanks, registries, epidemiology studies and biomarker research, including drug and disease history, test results, and gene sequencing. The EMIF project has access to around 48 million patient records from 7 different countries, and the EMIF-AD project will be able to benefit from this information.

Academic Lead for EMIF, Professor Simon Lovestone, PhD, MRCPsych, Professor of Old Age Psychiatry and Director of NIHR Biomedical Research Centre for Mental Health at the Maudsley and King's College London, says: "As part of the EMIF-AD project, we plan to analyse millions of patients' records to find links between genes, biomarkers, disease and outcome. By reusing existing data, rather than having to generate new information, we can move forward more quickly."

Because EMIF-AD brings together data from many patients and many sources, the first step will be to reassure the data 'owners' that the data will be used responsibly and appropriately. The next step is to work out how to structure, analyse and harmonise the data, which will be a challenge, but the project has

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brought together some highly skilled researchers from across Europe.

EMIF Project Coordinator Bart Vannieuwenhuyse, Senior Director Health Information Sciences at Janssen Pharmaceutica NV, says: "The EMIF research teams include people from three independent research consortia and a range of different disciplines. We are currently forming work teams and are looking forward to working with academic and industry scientists with such a range of different areas of expertise."

Alzheimer's disease can be present for 10 to 20 years before the symptoms emerge (known as the prodromal period), but it's hard to predict who will develop this devastating disease. By delving into the EMIF-AD data, researchers hope to find biomarkers for early onset disease to identify the people who are at risk. These patients could then be invited to join clinical trials to see if it's possible to prevent, or at least slow, the onset of the disease. Once these potential drugs have reached the market, the same markers could be used for early diagnosis and treatment, picking the patients who are most likely to benefit.

Dementias, including Alzheimer's disease, are hard to classify, but the success of their treatment can be completely dependent on an accurate diagnosis. In late 2013, IMI will be launching a project to rethink the classification of neurodegenerative diseases, including Alzheimer's disease and Parkinson's disease. This should lead to data, tools and recommendations that can be used by the biomedical community to develop new treatments and diagnostic tests.

Being able to treat the causes of Alzheimer's disease, rather than just improving the symptoms, will make a huge difference to the lives of patients and their families, as well as helping cut social and healthcare costs.

Pharma-Cog's Jill Richardson adds: "These projects highlight the importance of the partnership between academia and pharma in focusing translational medicine activities towards the common goal of increasing the efficiency of early clinical development."

IMI Executive Director Michel Goldman said: "As Europe's population is ageing, it is essential that we speed up the search for new, more effective treatments for Alzheimer's disease. By bringing together all the stakeholders involved in drug research and development, IMI is well placed to contribute to this effort."

This work is part of the Innovative Medicines Initiative (IMI), a collaboration between the European Union and the Pharmaceutical industry. By supporting the exchange of knowledge and expertise among companies and between public and private partners, IMI is generating achievements and taking on research challenges that are too great for any individual company or organisation to tackle alone. The ultimate goal of IMI is to speed up the development of safer and more effective medicines for patients.

More information:

- Pharma-Cog project factsheet: http://www.imi.europa.eu/content/pharma-cogPharmaCog
  Pharma-Cog project website: http://www.alzheimer-europe.org/EN/Research/PharmaCog
- EMIF project factsheet: http://www.imi.europa.eu/content/emif

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About the Pharma-Cog project

The Pharma-Cog project aims to develop and validate new tools to test candidate drugs for the treatment of symptoms and disease in a faster and more sensitive way. By bringing together databases of previously conducted clinical trials and combining the results from blood tests, brain scans and behavioural tests, the scientists will develop a 'signature' that gives more accurate information on the progression of the disease and the effect of candidate drugs than current methods do. The scientists will conduct parallel studies in laboratory models, healthy volunteers and patients in order to better predict good new drugs as early as possible. This will enable them, for instance, to find out how memory loss in Alzheimer's disease can be simulated in healthy volunteers, for example with sleep deprivation or drugs that temporarily affect the memory, in order to test the effect of candidate medicines early in the drug development process.

About the EMIF project

The EMIF programme aims to develop a common information framework (EMIF Platform) of patient-level data that will link up and facilitate access to diverse medical and research data sources, opening up new avenues of research for scientists. To provide a focus and guidance for the development of the framework, the project will focus initially on questions relating to obesity and Alzheimer's disease, via two dedicated research projects.

- EMIF-AD identifying the mechanisms that make some people more susceptible to dementias (such as Alzheimer's disease) than others;
- EMIF Metabolic determining which individuals with obesity are most likely to develop complications such as diabetes.

Obesity and dementia are two of the greatest healthcare challenges of our time; EMIF's work will pave the way for new diagnostic tools and treatments to help patients with these conditions.

About IMI

The Innovative Medicines Initiative (IMI) is the world's largest public-private partnership in health care. IMI is improving the environment for Pharmaceutical innovation in Europe by engaging and supporting networks of industrial and academic experts in collaborative research projects. The European Union contributes €1 billion to the IMI research programme, which is matched by in kind contributions worth at least another €1 billion from the member companies of the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The Innovative Medicines Initiative currently supports 40 projects, many of which are already producing impressive results. The projects are all working to address the biggest challenges in drug development, to accelerate the development of safer and more effective treatments for patients.

More info: www.imi.europa.eu

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