

35 partners from industry and academia to join European research initiative for the prevention of Alzheimer's dementia

- *The European Prevention of Alzheimer's dementia (EPAD) Initiative is a collaborative research initiative to improve the chance of successfully preventing Alzheimer's dementia and to better understand early aspects of Alzheimer's disease before dementia develops.*
- *The 5 year EPAD programme is part of the Innovative Medicines Initiative, a joint undertaking between the European Union and the European Federation of Pharmaceutical Industries and Associations, EFPIA.*
- *EPAD will establish a European-wide register of 24,000 participants, of which 1,500 will be invited to participate in a trial to test new treatments for prevention of Alzheimer's dementia*

Paris, January 15, 2015 – The members of the EPAD initiative today announced the start of a novel collaboration between academic and private sectors to test innovative treatments for the prevention of Alzheimer's dementia.

Previous attempts to bring new drugs for Alzheimer's disease to the market have been disappointing despite a high level of investment. However, the realisation that Alzheimer's disease is a progressive disorder and that early intervention may be more effective has led to research efforts being focused on prevention. The goal of the initiative is the prevention of dementia in people with evidence of the disease (such as biomarker abnormalities as identified by specific tests), who still may have little or no complaints or clinical symptoms.

"EPAD is part of a global initiative that will make a fundamental difference to the understanding and management of Alzheimer's disease in people with very early or no symptoms at all. This could be a game-changer. It is only possible because of the absolute commitment of academics, industry, policy makers and the public to work hand in hand to defeat this global threat", said Prof Craig Ritchie, EPAD Co-coordinator and Professor of the Psychiatry of Ageing at the University of Edinburgh.

New tools and methods now allow the identification of patients in the early stages of Alzheimer's disease. This creates an opportunity to have new treatment options investigated in clinical studies early on. A difficulty however remains with the large number of patients and study sites needed to confirm a therapeutic effect within a limited span of time. In contrast to several pharmaceutical companies and academic institutions pursuing this in isolation, a joint effort clearly has advantages: the identification and referral of the concerned patients is accelerated and several treatment options can be tested rapidly within one same trial.

Therefore, EPAD aims to develop a platform using existing information from national or regional patient cohorts or register studies, which have already identified potential patients. Through EPAD, the

undertaking of better, adaptive, multi-arm proof of concept studies for early and accurate decisions on the ongoing development of drug candidates or drug combinations is facilitated.

“Preventing the development of dementia in biomarker-positive people would be a fantastic step forward in our fight against Alzheimer’s disease. The EPAD and its novel trial concept will hopefully help speed up the drug discovery progress and bring us closer to this ambitious aim”, said Jean Georges, Executive Director of Alzheimer Europe.

All data collected from the cohort and trial will become publically available for analysis to improve disease models in the pre-dementia phase of Alzheimer’s disease.

“This project has numerous advantages over current approaches. These include the excellent pre-trial characterisation of subjects to inform selection and reduce screen failure, the establishment of the highest possible quality study sites across Europe, the rapid decision making on the likely success of a drug (or combination of drugs) in subsequent confirmatory trials as well as access to a shared placebo group.”, said Serge Van der Geysen, EPAD Coordinator and Director for Neuroscience External Affairs at Janssen Pharmaceutica NV.

“The UK is taking a leading role in the global fight to progress dementia research,” said Prof Ritchie. “The Prime Minister’s Dementia Challenge, the establishment of the Dementia Platform UK and now the leadership of The European Prevention of Alzheimer’s Dementia (EPAD) Project reflect the commitment to develop the best possible environment to undertake the research that will make a difference to the care offered to people with dementia and to eventually prevent its development.”

Led from the University of Edinburgh, the UK’s contribution to EPAD also includes the Universities of Leicester, Cambridge, Oxford and Cardiff.

Professor Simon Lovestone of the University of Oxford and lead for the NIHR Translational Research Collaboration in Dementia, said: “The scale of the problem with dementia is so great we cannot carry on doing things the same way as we are now. The exciting thing about EPAD is that it brings a novel approach to clinical trials, that has a real chance of making serious progress towards prevention. Because of the research networks that have been established in the UK, based in the NHS, I think we will be able to make a substantial contribution to this important public-private consortium”

Professor Sir John Savill, Chief Executive of the Medical Research Council in the UK and the Head of the College of Medicine and Veterinary Medicine and a Vice Principal of the University of Edinburgh, said: “Scotland is in a unique place to lead this European collaboration, and is increasingly recognised as a centre of world-leading expertise in the global fight to combat dementia. This partnership represents an excellent and much-needed opportunity to put preventative strategies at the heart of caring for the increasing numbers of people affected by Alzheimer’s disease.”

Professor Anthony Brookes of the University of Leicester is providing technologies which will enable the project to scan for suitable clinical trial subjects in real time, across many diverse patient collections throughout Europe and beyond. This is based on his team’s Café Variome ‘data discovery’ system, about which he said: “The project will be able to discover the existence and location of potential trial subjects by merely a few button clicks, rather than by email and phone based explorations that could take months to complete. This substantial time saving is essential for drug testing on early stage Alzheimer patients, and we have found a way to achieve this advance without moving any subject data out of any source database.”

About Alzheimer's disease and dementia

Alzheimer's disease is a progressive degenerative disease which causes loss of neurons in the brain. The symptoms eventually and inevitably manifest as Alzheimer's dementia which impacts cognition, function and behaviour, becomes progressively worse over time and cannot be reversed. There are 7.7 million new cases of dementia globally each year, suggesting one new case every four seconds. There were an estimated 44.4 million people with dementia in 2013 and this number is estimated to increase to 135.5 million by 2050.¹ Currently approved treatments may temporarily stabilise or slow the worsening of symptoms, but do not alter the course of the disease. Attempts to bring new drugs to market for the treatment and prevention of Alzheimer's dementia have been disappointing despite massive commercial, public and academic investment of time and resources.

About EPAD

The EPAD project is part of a global effort in the fight against Alzheimer's disease, which also includes initiatives such as the Global Alzheimer Platform. The EPAD Project is a major European initiative to create a novel environment for testing numerous interventions targeted at the prevention of Alzheimer's dementia defined as a delay in the onset of clinical symptoms among people with preclinical evidence for AD pathology (i.e. preclinical AD as per NIA-AA and similar definitions) and a delay in the onset of clinical dementia among people with such evidence who already show some clinical symptoms (ie MCI due to AD or prodromal AD and similar definitions).

EPAD is mainly sponsored by the European Commission and the European pharmaceutical industry (via EFPIA) under the auspices of the Innovative Medicines Initiative Joint Undertaking (IMI JU). The EPAD programme has an initial budget of €64M distributed across a total of 35 partners from the private and academic sectors:

- Janssen Pharmaceutica NV, Belgium
- University of Edinburgh, United Kingdom
- University of Oxford, United Kingdom
- Barcelonabeta Brain research Centre, Spain
- Synapse Research Management Partners SL, Spain
- Karolinska Institutet, Center For Alzheimer Disease Research, Sweden
- Stichting VU-VUmc, Netherlands
- University of Cambridge, United Kingdom
- Medical Research Council Biostatistics Unit, United Kingdom
- Berry Consultants LLP, United Kingdom
- Hôpital de la Salpêtrière, France
- Institut national de la santé et de la recherche médicale, France
- University of Leicester, United Kingdom
- IXICO Technologies Ltd, United Kingdom
- Araclon Biotech, S.L., Spain
- Fraunhofer, Germany
- Eisai, United States
- Sanofi-Aventis Recherche & Développement, France
- Novartis Pharma AG, Switzerland
- Boehringer Ingelheim International GmbH,

¹ Alzheimer's Disease International (<http://www.alz.co.uk/research/statistics>)

- Université de Genève, Switzerland
- Stichting Katholieke Universiteit, Netherlands
- Cardiff University, United Kingdom
- Centre Hospitalier Universitaire de Toulouse, France
- Quintiles, LTD, United Kingdom
- Alzheimer Europe, Luxembourg
- Erasmus Universitair Medisch Centrum Rotterdam, Netherlands
- Germany
- Ely Lilly and Company Ltd, United Kingdom
- Lundbeck A/S, Denmark
- Takeda Development Centre Europe Ltd, United Kingdom
- AC Immune SA, Switzerland
- Biogen Idec Inc., United States
- Amgen NV, Belgium
- Pfizer Limited, United Kingdom
- UCB Biopharma SPRL, Belgium

The project is divided into eight Work Packages with four Scientific Advisory Groups. The trial will be delivered through approximately 30 study sites within six country/regional areas.

While the EPAD platform will be designed to help testing both pharmacological and non-pharmacological interventions, initially the focus will be on testing drugs and drug combinations to ensure a greater chance of success for clinical trials. The EPAD programme will initially run for five years.

For more information, contact info@ep-ad.org or check out www.ep-ad.org

About the EPAD Platform/Register

EPAD aims to develop a platform using existing information. The EPAD platform will draw European participants, whose records are already part of existing national/regional cohort or register studies, into an EPAD register of approximately 24,000 people. From this group, 6,000 people will be asked to join a pan-European EPAD Cohort for consistent, longitudinal follow-up, and approximately 1,500 of them will eventually be invited to enter the EPAD Proof of Concept Trial. This approach aims to ensure EPAD has access to an at-risk population showing biomarker evidence of Alzheimer's disease prior to the development of dementia.

About the Innovative Medicines Initiative

The Innovative Medicines Initiative (IMI) is Europe's largest public-private initiative aiming to speed up the development of better and safer medicines for patients. IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe. IMI is a joint undertaking between the European Union and the European Federation of Pharmaceutical Industries and Associations, EFPIA.

More information can be found at www.imi.europa.eu

Acknowledgement

The research leading to these results has received support in the UK from the National Institute of Health Research Dementia Translational Research Collaboration, and from the Innovative Medicines Initiative Joint Undertaking under grant agreement n° 115736, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013) and EFPIA companies' in kind contribution.



Disclaimer

This communication reflects the views of the EPAD Consortium and neither IMI nor the European Union and EFPIA are liable for any use that may be made of the information contained herein.

CONTACTS:

Dr. Serge Van der Geyten
EPAD Coordinator
Director, Neuroscience External Affairs
Janssen Pharmaceutica NV
+32 14 60 85 51 (direct)
+32 474 55 83 99 (mobile)
svdgeyte@its.jnj.com

Prof. Craig Ritchie
EPAD lead
Professor of the Psychiatry of Ageing
University of Edinburgh
c/o Anna Borthwick
University of Edinburgh Press & PR Office
+44-131-650 22 46
anna.borthwick@ed.ac.uk and
press.office@ed.ac.uk