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# Academia and industry join forces in largest European initiative to investigate the value of β-amyloid brain scans as a diagnostic and therapeutic marker for Alzheimer's disease

- *The Amyloid imaging to prevent Alzheimer's disease (AMYPAD) Initiative is a collaborative research initiative aiming to improve the understanding, diagnosis and management of Alzheimer's disease through the utilisation of β-amyloid PET imaging.*
- *The 5 year AMYPAD 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.*
- *AMYPAD will apply β-amyloid PET imaging to an unprecedented number of patients who are suspected to be in the early stages of Alzheimer's disease to determine its clinical added value in diagnosis and patient monitoring and to develop data to establish its prognostic value in therapeutic clinical trials*

**London, October 5, 2016** – The members of the AMYPAD initiative today announced the start of a novel research initiative between academic and private research partners to investigate the value of β-amyloid using positron emission tomography (PET) imaging as a diagnostic and therapeutic marker for Alzheimer's dementia.

Beta-amyloid (β-amyloid) deposition in the brain is one of the neuropathological hallmarks on the path towards development of Alzheimer's disease (AD). The recent advent of commercially available β-amyloid PET tracers has opened up new potential for the visualisation of brain β-amyloid *in vivo*. It may improve an early diagnosis of AD, and, when recognised in a pre-symptomatic population, even provide an opportunity for secondary prevention of AD. However, the full value of this relatively novel technology and its optimal position in the diagnostic workup of patients is not yet fully understood.

"The AMYPAD Consortium brings together a world-class team of highly synergistic partners from across Europe to form a pan- European network including the most active PET sites. This will ensure effective access to patients and also maximise exposure to technical knowledge and disease modelling. This is a game-changing step in establishing the value of β-amyloid PET imaging in clinical practice", said Prof Frederik Barkhof, AMYPAD Project Coordinator and Professor of Neuroradiology at VU University Medical Center, Amsterdam and at University College London.

Understanding the value of imaging of β-amyloid using PET provides a unique opportunity to achieve 3 major goals: **1)** improve the diagnostic workup of people suspected to have AD and their management; **2)** understand the natural history of AD in the pre-symptomatic stage; **3)** select people for treatment trials aiming at preventing AD by ensuring a more homogeneous and appropriate enrolment. Through

engagement with regulators, the AMYPAD consortium will maximize the value of its findings for pharmaceutical companies, healthcare providers, and patients.

AMYPAD will determine in a real-life clinical setting for whom diagnostic β-amyloid imaging is appropriate, when this is best performed and how the resulting information is influencing diagnostic certainty, patient management and ultimately decision trees and cost-effectiveness of dementia care.

"The development of β-amyloid imaging has been a tremendous research success which allows a more accurate diagnosis of Alzheimer's disease and a better selection of research participants for ongoing clinical trials. The AMYPAD project will provide much-needed information on the best place of this new technology in everyday clinical practice. Thanks to projects like these, we hope to get closer to our aim of ensuring a timely and accurate diagnosis for all patients.", said Jean Georges, Executive Director of Alzheimer Europe.

AMYPAD will address the above goals in close collaboration with IMI project EPAD (the European prevention of Alzheimer's dementia project www.ep-ad.org), a major global initiative to create a novel environment for testing new treatments for the prevention of Alzheimer's dementia.

"AMYPAD will apply amyloid PET on an unprecedented scale to patients who are suspected to be in the early stages of AD and generate the knowledge to fully integrate PET β-amyloid markers into current clinical practice in a cost-efficient way, by demonstrating its diagnostic, prognostic and therapeutic value from a multi-stakeholder perspective.", said Dr Gill Farrar, AMYPAD Project leader and Scientific Director at GE Healthcare Life Sciences.

**About Alzheimer's disease and dementia**

Alzheimer's disease is a progressive degenerative disease which causes loss of neurons in the brain. The symptoms may eventually 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 AMYPAD**

AMYPAD aims at studying the onset, dynamics, and clinical relevance of brain β-amyloid in the spectrum from normal aging, through subjective cognitive decline towards mild cognitive impairment and ultimately dementia to due to Alzheimer's Disease (AD), studying the value of β-amyloid imaging as a diagnostic and therapeutic marker for AD.

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

We propose to use β-amyloid-PET in a very large number of subjects recruited from population studies, as well as memory clinics cohorts. Collectively, they will span the range from completely normal aging to asymptomatic β-amyloid deposition and early AD. In close collaboration with EPAD (www.ep-ad.org), the cohorts will be followed with careful longitudinal monitoring and MRI to determine (surrogate) outcomes of cognitive decline and neurodegeneration.

AMYPAD is mainly sponsored by the European Union's Horizon 2020 research and innovation programme and the European pharmaceutical industry (via EFPIA) under the auspices of the Innovative Medicines Initiative 2 Joint Undertaking.

The AMYPAD programme has budget of €27.3M distributed across a total of 15 partners from the private and academic sectors:

- VU University Medical Center Amsterdam
- Barcelonabeta Brain Research Center
- Karolinska Institutet
- Centre Hospitalier Universitaire de Toulouse
- Alzheimer Europe
- University Hospital of Cologne
- Janssen Pharmaceutica NV, part of the Janssen Pharmaceutical Companies of Johnson & Johnson
- Radboud University Medical Centre
- The University of Edinburgh
- Université de Genève
- IXICO Technologies Limited
- University College London
- Synapse Research Management Partners
- GE Healthcare Life Sciences
- Piramal Imaging

For more information, contact info@amypad.eu, check out www.amypad.eu or follow us on Twitter @IMI_AMYPAD

**About the AMYPAD Study**

AMYPAD is a European project to establish the true value of amyloid PET in a diagnostic and prognostic setting (www.amypad.eu). This 5-year long project is a collaboration between industry and academic partners funded by the IMI-2 program. Throughout Europe AMYPAD will recruit 900 memory clinic patients and 3100 preclinical or prodromal AD subjects from natural history cohorts. Up to 50% of subjects will undergo dynamic scanning and have repeat imaging, for a total of 6000 amyloid PET scans.

In close collaboration with EPAD (www.ep-ad.org), the cohorts will be followed with careful longitudinal monitoring and MRI to determine (surrogate) outcomes of cognitive decline and neurodegeneration.

**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

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**Disclaimer**

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

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