

Publishable Summary

The AMYPAD project encompasses two studies: 1) the Diagnostic and Patient Management Study (DPMS) which aims at assessing the impact of β -amyloid PET imaging on the clinical management of individuals in the spectrum from subjective cognitive decline (SCD) towards mild cognitive impairment (MCI) and in dementia of unclear etiology; and 2) the Prognostic and Natural History Study (PNHS) that will be conducted to contribute to the European Prevention of Alzheimer's Dementia (EPAD) Longitudinal Cohort Study (LCS) to improve Alzheimer's Disease modelling by introducing β -amyloid PET as additional imaging biomarker.

In the two studies, a total of three different acquisition protocols are envisaged: A standard imaging protocol will be implemented in all sites and two advanced protocols will add on the standard one and be implemented in a sub-set of sites. The two advanced protocols are the "coffee-break" dynamic acquisition protocol and PET/MRI acquisition protocol. An operation guide will be prepared for each acquisition protocol and will contain detailed tracer and specific instructions for each site on image acquisition and data transfer and will stress the importance of maintaining acquisition protocol consistency throughout the whole length of the study. In addition to the Site Operation Guide (SOG), a site-specific document will be provided outlining scanner specific reconstruction parameters. The aim of this document is to outline the general Site Operation Guide as per deliverable D2.3 of the AMYPAD Description of Action (DoA).

This document should be regarded as definitive SOG for the standard protocol in both the DPMS and PNHS (similar but separate SOGs will be prepared for each study and each tracer). Similar versions of the SOG for the advanced protocols will be created in the near future and will not have an impact on the scheduled date for the first patient in for those protocols. Please note that this deliverable consists of the actual site operations manual and, therefore, the language is directed for the sites to have clear and concise instructions on how to proceed.

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