AMYPAD Deliverable 3.8

All approvals package

Publishable Summary

The AMYPAD DPMS study aims at exploring the impact of amyloid PET imaging on diagnostic thinking in the workup of patients with SCD-plus (subjective cognitive decline associated with features that increase the likelihood of preclinical Alzheimer's disease [AD]), mild cognitive impairment (MCI), or dementia where AD is in the differential diagnosis.

The population target for this study is 900 patients, to be recruited in 8 sites across Europe. The first step was then to ensure the approval of the AMPYAD DPMS protocol in the different sites in order to start recruiting patients and achieve the objective.

This document describes the various submissions of the protocol to the ethics committee or/and national competent authorities, in order to obtain the initial approval of the AMYPAD Diagnostic and Patient Management Study (DPMS) in each site.

It includes the detailed process of the protocol submissions until initial approval is granted by the relevant authorities in each participating country. Additionally, a summary of site activations for screening and enrolment in the AMYPAD clinical trial is presented. For some sites, only the ethics committee approval was necessary o get initial approval, while for others, regulatory authorities were also included in the process. Both approval pathways are described when applicable.

As initially planned, 8 sites received the approval for AMYPAD DPMS and are now active and running, from Geneva being the first site to start in January 2018 to Stockholm being activated in September 2019.

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