AMYPAD Deliverable 4.2

EPAD/AMYPAD Protocol with regulatory approval

Publishable Summary

This document is comprised of a short description of one of the clinical studies under AMYPAD, the Prognostic and Natural History Study (PNHS), as well as its package for submission to ethical review, composed of the Clinical Trial Protocol, the Patient Information Sheet and the Informed Consent Form.

The PNHS is a longitudinal study which comes to, in collaboration with the European Prevention of Alzheimer's Dementia Longitudinal Cohort Study (LCS), improve the understanding of the natural history of the disease and identify the window of opportunity for secondary prevention. All participants in the PNHS are invited from the LCS and the two studies will happen in parallel, with many interdependencies and optimal alignment of study visits. Once a LCS participant enters the PNHS, it will undergo at least one Positron Emission Tomography scan to understand the level of amyloid load in the brain. This information will then complement the comprehensive list of assessments gathered during the LCS, further characterizing the cohort and improving understanding of the early stages of the disease, as well as the selection for Proof of Concept (PoC) studies.

Due to the complex relationship between the two clinical trials, several meetings were held in order to develop a clinical trial protocol that can be easily implemented while providing valuable additional information to the joint goals of AMYPAD and EPAD. In this document, the study design is outlined and the motivation behind the decisions reflected in the protocol is presented. At the end of the document, the submission package is annexed, together with the latest plan for ethical submission in each participating center.

For more information: info@amypad.org

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