

Publishable Summary

This quarterly report provides information on the project progress within the AMYPAD Prognostic and Natural History Study (WP4), with a focus on the period between September - December 2019. The report is fully data-driven and highlights the submission process of obtaining approvals (ethical and regulatory) for the study protocol in all sites, site activation, subject recruitment, and tracer utilisation efficiency status.

Furthermore, this report also provides an update on the current status and plans for the inclusion of non-EPAD cohorts as parent cohorts (PCs) for the PNHS. In addition to the previous Collaboration Agreement with the first non-EPAD cohort EMIF-AD Twin study, there are two more data sharing agreements (DTA) established and finalised with the ALFA+ and FACEHBI cohorts based at BBRC and Fundació ACE respectively. Indeed, the recruitment of ALFA+ participants into AMYPAD began in December 2019. In November 2019 a data harmonisation working group was established following a face to face meeting in Barcelona where the Sponsor attended in addition to work package leads and experts in Neuropsychology from VUmc and BBRC.

Over the past period, (September – December 2019) 5 Wave-2 sites had Site Initiation Visit (SIV) becoming fully active in AMYPAD PNHS. These sites are: Montpellier, Tayside, Paris la Pitié, UZ Leuven and Paris Nord. The remaining 7 sites are scheduled to have their SIV in January 2020 with the exception of Fundacio ACE which is planned for 7th February 2020. At the end of December 2019, there were 10 active sites in AMYPAD PNHS.

By the end of the last quarter, the PNHS has consented a total of 384 participants (compared to 290 at the end of Q3) and the expectation is that the recruitment rate continues to increase with the activation of Wave-2 sites. During this period the study has seen two new mild adverse safety events and the external safety review charter has been finalized with the first external review of adverse events performed in November 2019.

To conclude, the past quarter has seen good progress in the PNHS, with the activation of 5/11 Wave-2 sites and the increased recruitment rate, achieving >400 participants in early January 2020. Moving forward, the focus is on establishing the remaining non-EPAD cohorts, working on data harmonisation strategies, activating the outstanding Wave-1 and 2 sites and improving recruitment across centres.

AMYPAD Deliverable 4.9

Mid-term recruitment report

Quarterly report V4 (Month 39)

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