AMYPAD Deliverable 4.4

Mid-term Recruitment Report

Quarterly report V2

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 April - June 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. This report has also taken into account the feedback from the previous quarterly report and now includes additional sections regarding safety reporting and discussing the amyloid positivity balance in the study.

Furthermore, this report also provides an update on the current status and plans for the inclusion of non-EPAD cohorts as parent cohorts for the PNHS. Separate Collaboration Agreements have been established for the first two non-EPAD cohorts (EMIF-AD Twin study and ALFA+) to govern data sharing and use, as well as potential IP issues. Separate agreements are under discussion with other cohorts.

Over the past period, (April to June 2019), 2 extra Wave-1 sites have become active now a total of 5 Wave-1 sites are recruiting, with the only Wave-1 remaining sites being KI and UKK. In addition, the first non-EPAD cohort has started recruitment at the VUmc, namely the EMIF-AD Twin cohort.

In this period, the project has reached the milestone of 100 consented participants and expectation is that the recruitment rate continues to increase with the approvals and activation of Wave-2 sites, reaching approximately 500 subjects enrolled by the end of the year. In addition, during this period the study has seen 4 adverse events, one of which has been considered serious and possibly related to the study product. Further details of these adverse events are found in section I of this report. The pharmacovigilance processes established within PNHS have been followed according to the regulations and all participants have fully recovered from their events. Finally, the independent safety board has been identified and the first review of safety events is scheduled to take place before October 2019, when follow-up scans might start.

To conclude, the past quarter has seen good progress in the PNHS, with the activation of 5/7 Wave-1 sites and the increased recruitment rate, achieving 136 participants before the summer, exceeding the expected figures for June. Moving forward, the focus is on establishing the remaining non-EPAD cohorts, activating the outstanding Wave-1 and 2 sites and improving recruitment strategies across centres.

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