

## 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 July - September 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 for the PNHS. Previously a separate Collaboration Agreement have been established for the first non-EPAD cohort EMIF-AD Twin study to govern data sharing and use, as well as potential IP issues. Separate agreements are under discussion with other cohorts such as ALFA+ and GAP. Further to these discussions, work has also started on harmonising the data coming in from the non-EPAD cohorts and creating a database for this information to be stored.

Over the past period, (July to September 2019), 3 Wave-2 sites (and 2 Participant Identification Centres) have gained Ethical Committee (EC) approval with the approval for a further 2 sites expected mid-October 2019. All these sites along with the 5 Wave-2 French sites that gained approval in June 2019 are expected to be active within Q4 of 2019.

During the last quarter, the project has passed the milestone of 200 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 Q4 2019. In addition, during this period the study has seen no adverse safety events and the external safety review charter has been finalized with the first external review of adverse events scheduled to take place in October 2019. To conclude, the past quarter has seen good progress in the PNHS, with the approval of 8/12 Wave-2 sites and the increased recruitment rate, achieving 290 participants at the end of September, exceeding the expected figures for the month. 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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