

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 January - March 2020. 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 utilization 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. Since the last report, two more Data Sharing Agreements (DTAs) have been finalised for the FPACK and UCL cohorts based at UZ Leuven and UC Louvain respectively. In addition to this, FACEHBI and FPACK began recruitment into the PNHS during the last quarter. There are currently 4 non-EPAD cohorts active in AMYPAD PNHS: EMIF AD, ALFA+, FPACK and FACEHBI

Over the past period, (January – March 2020) all 17 Sites within AMYPAD PNHS have been activated with the remaining 7 Sites having their SIV during the last quarter. This achievement saw the recruitment numbers increasing greatly until the Study was placed on hold due to the Covid-19 crisis where Sites stopped recruitment entirely. Despite these challenges, the PNHS had consented a total of 567 participants (compared to 384 at the end of December 2019).

In terms of safety reporting, the last quarter has seen two new mild adverse safety events and the first external safety review for 2020 has been finalized in January with the second review scheduled for the end of March.

To conclude, the past quarter has seen good progress in the PNHS, with the activation of all 17 planned Sites and passing the 500 milestone with the number of consented participants by mid-February. Covid-19 crisis in combination with the early closure of EPAD LCS will impact recruitment and planned Study conduct as AMYPAD PNHS will be on hold until further notice and with no recruitment planned in the coming quarter. Instead, Sites will focus on submission of the Global amendment to Ethics Committees and Regulatory Authorities in order to allow for the continued recruitment and follow-up of former EPAD LCS participants post EPAD closure (which took place on the 13th of March).

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