

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 2020.

Recruitment activity within the PNHS had stopped during the last quarter. This was due to the closure of sites and cessation of research visits as a result of the global COVID-19 crisis. During this time sites were able to focus on other study related activities such as the backlog of data entry, quantification and preparation of documents needed for the global amendment.

By June 2020 some AMYPAD PNHS sites had slowly started to resume recruitment. These sites are carefully taking into account local and national measures concerning safety and distancing and it is expected that all sites will follow suit by September 2020. It is important to note however, that despite the reopening of sites progress will be slow and this will lead to a deficit in the total recruitment figures by September 2021 when AMYPAD PNHS is expected to finish. However, recruitment projections with an additional 6month no cost extension show that the original recruitment targets (prior to COVID-19) can be achieved.

To conclude, the past quarter has seen little progress within the PNHS in terms of recruitment due to the COVID-19 crisis with 579 participants consented of which 414 underwent a PET scan. From June 2020, 9/17 sites have begun to resume recruitment activity with all sites expected to restart by the end of Q3 2020. Moving forward, 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 and undergo the training required for the collection of additional data and for the use of the eCRF database designed for the non-EPAD PCs. The additional data collection planned for the PNHS is a reduced number of variables including: RBANS, CDR and MMSE.

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