

## AMYPAD Deliverable 3.4

### Mid-term Recruitment Report

#### Quarterly report V2

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### Publishable Summary

This quarterly report aims at providing detailed information on the progress of the AMYPAD Diagnostic and Patient Management study with a specific focus on the progress achieved during the second quarter of 2019. The report shows the increase in the recruitment of patients in the active sites as well as the work made to include more sites in the study.

During this review, the Sponsor demonstrates that the strong progress made in the first quarter 2019 are now allowing to proceed with a stable recruitment rate allowing to complete recruitment within timelines. Moreover, efforts are still made in order to activate two to three additional sites.

On a total of 900 expected patients, we currently have 379 randomized and 205 being already scanned. With a recruitment rate over 45 patients per months in average since start of 2019, the Last Patient In (LPI) can be expected before June 2020, our target.

In addition, the activation of a new site in Lausanne in June (CHUV), and a final approval expected this summer in Sweden, we expect to see our recruitment rate increase to reach our goal earlier.

A safety process has been put in place and is now working, and we have, since the start of the study, faced 5 AEs, with only one possibly related to the injection of the tracer.

In this first part of the study, the tracer batch utilization has been slightly below the target of 3,5, which was expected at sites starting with a limited number of patients and is expected to get closer to the target as the recruitment moves forward.

In the meantime, a results analysis plan has been put in place and the first work on data has started, together with a dissemination plan being drafted.

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**Acknowledgement:** This project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 115952. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.