

Mid-term recruitment report Quarterly report V5 (Month 42)

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 first quarter of 2020. The report shows the fast increase in the recruitment of patients in all eight active sites as expected.

With all sites running since Q4 2019, the recruitment rate has been stable and allowed to be on target with the expectations of reaching 900 patients in June 2020.

As of March 11th, 2020, 751 patients have been included and 503 scans performed. However, at this moment, the worldwide coronavirus pandemic has forced the study to stop recruiting patients for an unknown duration.

At the moment the study includes 203 SCDs, 335 MCIs and 213 Dementia patients. The tracer balance between VizamyI and Neuraceq has been improving to reach 49.3% and 50.7% respectively

The recruitment will be able to resume once the situation has stabilized, with an expected delay to reach the 900 patients.

For this reason, an end of study in September 2021 may not allow the future new patients to complete the last visits planned in the protocol before the end of the study. In this frame, a focus on the V1 (3 months) will be made, as this visit represents the primary endpoint of the study. A protocol amendment is planned to make the subsequent visits optional.

We however must consider that COVID-19, apart from impacting recruitment, may also impact scanning in the future. Indeed, since there will be many regular clinical practice patients waiting for scans, research scans may be delayed until clinical ones are cleared.

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