

Publishable Summary

This deliverable will detail the protocol and associated documents of the AMYPAD Diagnostic and Patient Management Study (DPMS), as well as report on the status of submissions to local ethics committees. The process used to develop this deliverable will be explained and the collaborations with other AMYPAD Work Packages (WPs) will be described.

The AMYPAD DPMS was scientifically driven by WP3, which articulated the details of the study, including the selection criteria, the assessments to be undertaken, and their frequency.

The protocol submitted is the result of a yearlong intense collaboration between academia, industry, Alzheimer's Europe, and the European Medicines Agency that provided detailed advice on objectives and methodology. The most relevant advice was the need to base the primary objective of the study on the impact of amyloid PET imaging on diagnostic thinking.

A substantial challenge for the protocol was represented by the integration of the Diagnostic and Patient Management Study in the clinical routine of the eight centers participating in the project, each of them having different diagnostic approaches and routines. This integration was achieved through these several in person meeting between the leading team and the principal investigators of each center, in order to receive comments and inputs on the objectives and on the methodology of the study.

The Participant Information Sheet and Informed Consent Form has been developed in collaboration with WP6, which provided advice on ethical issues. The study has been registered in the European Clinical Trial Database with the following registration number: 2017-002527- 21. At the moment of this report, the AMYPAD DPMS protocol has been submitted to the local ethical committee in Geneva, Switzerland. A summary of the status of the first-wave submissions in all the other centers is included in this report (see section 2.2)

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