AMYPAD Deliverable 3.1

Report on feedback from EMA on design of diagnostic study

Publishable Summary

This deliverable reports the various phases of the procedure that was activated by the Applicant in order to receive scientific advice from the European Medicines Agency (EMA) and the HTA authorities (NICE and TLV) on the design, endpoints and outcome measures of the AMYPAD diagnostic study.

The procedure started with a preliminary conference call that took place in August and gave the Applicant the opportunity to pre-discuss the content of the briefing package and the seven main questions to be submitted for advice.

The second step was a face to face meeting that took place on the 26th of October. The meeting was very effective in providing the applicant with a set of advice, which is being implemented into the AMYPAD diagnostic study. The changes to align with the expectations of the CHMP and the national reimbursement authorities will hopefully increase the potential value of the real world evidence that will be generated from five years observation of the impact of amyloid PET imaging on diagnostic thinking, patient management and use of medical resources in 900 patients.

This document also describes the feedback provided by the European Medicines Agency and how the design has been updated to match regulatory expectations.

The input of the EMA on the design and outcomes of the AMYPAD diagnostic study will ensure the results will have an impact on the placement of amyloid PET in the diagnostic pathway of patients evaluated for Alzheimer's disease, facilitating the change in healthcare practices.

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