AMYPAD Deliverable 5.2

Report on the preliminary Scientific Advice from regulatory bodies

Publishable Summary

On behalf of the AMYPAD Consortium and more specifically within WP5, a Scientific Advice (SA) with the European Medicines Agency (EMA) was initiated on the 5th of October 2018 by SYNAPSE. This SA covered both amyloid PET tracers used in AMYPAD, namely Vizamyl ([18F]flutemetamol) and Neuraceq ([18F]florbetaben). The SA was sought in relation to the use of quantitative amyloid PET for subject selection, monitoring disease progression, and treatment outcome in proof-of-concept clinical trials of Alzheimer's disease.

The SAWP met on the 11-14th of February 2019, and the advice was given in written form, which was received by the AMYPAD Consortium on the 4th of March 2019. In this deliverable, the overall strategy for the SA is outlined, the AMYPAD questions and positions are described, and a summary of the advice is given. The complete feedback from EMA is annexed to this document.

The Process for obtaining future HTA advice was also considered at the same time as well as revisiting the initial advice given by NICE in 2016. This ensures that the Regulatory Strategy of AMYPAD is refined and future interactions with regulators are aligned with both previous advices and current analytical plans within the project.

Finally, AMYPAD's WP3, WP4 and WP5 have discussed specific analyses that could help address the suggestions of this scientific advice and the previous HTA advice. The report also contains information on the current plans for such analyses and where AMYPAD might disagree with EMA regarding the presence or absence of evidence on the value of amyloid PET for particular applications.

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