EPAD Deliverable 4.6

EPAD Cohort Protocol with regulatory advice and ethics committee approval

Executive Summary

This deliverable will detail the EPAD Cohort protocol, and report on regulatory advice for the EPAD programme and ethics committee approvals for the Cohort study. The process used to develop each of these deliverables will be explained and the collaborations with other EPAD WPs will be described.

The EPAD Cohort Protocol was driven scientifically by WP1, who articulated the selection criteria, assessments to be undertaken and their frequency (cf. D1.1 and D1.3). WP2 provided a summary statistical analysis plan. Assessments which include; a single cognitive test battery, were delivered by the Cognitive and Clinical SAG, an imaging protocol was developed by the Imaging SAG, genetic sampling and other biomarker assessments were defined by the Genetics and Biomarker SAGs respectively as part of the deliverables from WP1 (cf. D1.3). The Participant and Study Partner Information Sheets and Informed consent forms have been developed with WP8 (cf. D8.1 and D8.2). Each WP contributed to the writing of the EPAD Cohort Protocol though an extensive process of drafting and comments resolution that was managed by WP4. The final deliverable was agreed at an Authors meeting and the final protocol approved by the EPAD ExCom and signed off the Authors as a deliverable in WP4.

The EPAD project Consortium sought CHMP scientific advice on the overall goal of EPAD to inform the design and aid in the execution of a standing Proof of Concept (PoC) platform evaluating innovative treatments aimed at the secondary prevention of Alzheimer Dementia. The feedback was positive and there was no requirement to request clarification of any of the points raised. A summary of the detailed answers to the questions raised is included in this report.

The EPAD LCS protocol has been submitted to & approved by ethics committees in the UK and Spain. It is currently under review in France, Switzerland, Sweden and The Netherlands. A summary of the first wave of submissions is included in this report.

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