

EPAD Deliverable 4.7

Master Protocol complete for Trial

Platform

Executive Summary

This deliverable provides the master protocol for the EPAD Proof of Concept (PoC) trial. The EPAD POC trial will test numerous interventions whose aim is to prevent the onset of Alzheimer's dementia.

In the EPAD PoC trial we will be testing several interventions at the same time – this is called a platform trial. The aim for each intervention will be to prove that it affects the disease process it is targeting and also either improves or slows deterioration in cognitive performance relative to research participants receiving placebo. If these targets are met then the intervention will go onto further testing in a much larger population of people. This future testing is a requirement before getting a license for the drug to treat people with Alzheimer's disease before they develop dementia.

The EPAD PoC trial uses what is called an 'adaptive' approach. This means that the Independent Data Monitoring Committee (IDMC) looks at the data every 3 months to assess whether the intervention is so effective it could go into later testing sooner OR it shows very little chance of having even a small effect then further development of the intervention may be stopped. This approach means that decisions may be made earlier on which interventions are likely to work, in turn speeding up development as well as stopping the development of interventions with little chance of success thereby avoiding failures in the more advanced phases of drug development.

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