

ALZEVIT: Online recruitment of APOE ε4/ε4 carriers without severe cognitive impairment to evaluate preventive approaches for Alzheimer



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ALZEVIT study will establish a nationwide, decentralized digital framework to enable large-scale APOE genotyping screening in adults aged 45 and older, supporting future precision-prevention strategies and the development of trial-ready cohorts for next-generation Alzheimer’s interventions.

DESIGN & METHODS

APOEε4 is the strongest common genetic risk factor. Homozygous ε4/ε4 individuals carry the highest lifetime risk and earlier onset of disease, accounting for approximately 15–20% of ADcases.

Recent evidence suggests that APOEε4 contributes to 56.9% of neuropathologically confirmed AD burden. APOEε4/ε4 carriers exhibit near-complete lifetime penetrance on amyloid pathology and earlier disease onset. However, disease onset varies widely across individuals, indicating the influence of additional biological and environmental modifiers. To enable preventive interventions before clinical or biological symptom onset, large-scale APOE screening and structured registries of ε4 carriers are urgently needed.

ALZEVIT addresses this need by implementing a nationwide digital recruitment strategy focused on cognitively unimpaired ε4/ε4 individuals in France.

The study is based on the APO-Easy® qPCR genotyping kit, a CE-IVDR and FDA-approved, rapid and extraction-free multiplex assay capable of determining APOE genotypes in less than two hours from saliva-derived DNA, supporting scalable population-level screening.

Phase A
Online registry

1. Online Screening and Inclusion (online cognitive testing)

2. DNA Kit Dispatch

3. Sample Collection at home and Return

4. Central Laboratory Analysis

1. Online registration
• Study overview
• Informed consent form

2. Oral self-sampling kit

3. Prepaid kit return from participant to Firalis

4. Genotype analysis at the FIRALIS laboratory

Phase B
Deep phenotyping

1. Eligibility and Scheduling (memory center assessments (20%) or online assessment (80%) (teleconsultation).

2. Clinical and Biomarker Assessments (modifiable risk and resilience factors in APOE genotype carriers)

3. Registry Integration

Amoneta Diagnostics

APO-Easy® Genotyping Kit

EU-IVDR 2017/746

CE 0459

FDA APPROVED

DEN240032

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M12

M18

M24

Phase A will enrol ~50,000 adults aged ≥45 years via online recruitment, remote informed consent, and home saliva sampling kits, establishing a secure GDPR-compliant registry and generating Personalized Risk & Trajectory Profiles across APOE genotypes.

Phase B will develop a trial-ready cohort of ~2,350 participants enriched for ε4 carriers, combining hybrid clinical and teleconsultation assessments with deep phenotyping across cognitive, clinical, imaging, biomarker, multi-omics, and environmental (micropollutant) domains to **identify determinants of disease onset and characterize genotype-specific trajectories, while enabling scalable, low-cost APOE screening to accelerate future preventive and disease-targeting trials.**

- **Prevention & public health impact:** ALZEVIT targets early AD detection through APOE ε4/ε4 screening.
- **Nationwide digital APOE screening:** Enabling large-scale & equitable access across France.
- **Advancing personalized medicine:** ALZEVIT will improve risk stratification and enable earlier, more effective clinical intervention.
- **Innovative, scalable diagnostic solution:** Development of rapid, low-cost, multiplex APOE genotyping test, suitable for large-scale population screening.
- **Trial-ready ε4/ε4 cohort:** Accelerating preventive Alzheimer’s research and future DTT evaluation.

CONCLUSION

ALZEVIT represents a nationwide precision-prevention initiative designed to identify APOE ε4/ε4 individuals through digital, large-scale genotyping.

By combining population screening with deep phenotyping and multi-omics analyses, the study seeks to improve understanding of factors influencing Alzheimer’s disease onset and to establish a trial-ready cohort for future preventive interventions.

The program may provide a scalable framework for integrating genetic risk assessment into routine AD prevention strategies.

New CM2R/Memory Centers or collaborators are welcome to join us!

Contact us: clinical@firalis.com

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Explore the ALZEVIT website

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