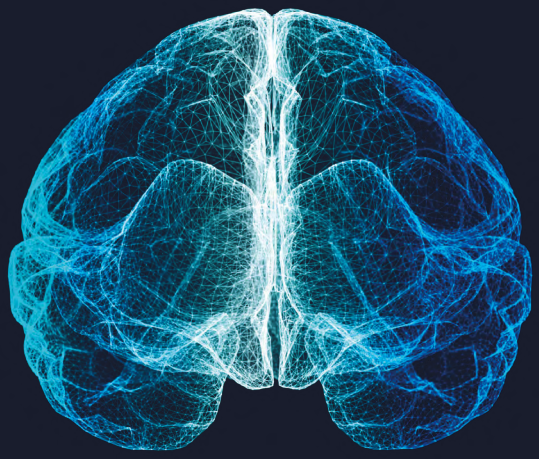


QYSCORE + QYPREDICT

Enhancing MRI accuracy with AI to improve clinical outcomes

The Challenge:
Alzheimer's Disease Trials Are Complex, Costly, and Uncertain

- Despite decades of research, developing DMTs for Alzheimer's disease remains a high-risk endeavor with major clinical and operational challenges.
- Limited and variable clinical response: Many therapies in have shown limited clinical patient benefits, partly due to high placebo responses[i] and the heterogenous clinical progression in early-stage patients (MCI, prodromal AD).[ii]
- Excessive screen failure rates: DMT trials in AD have high screen failure rates ranging from 46% for studies of Mild AD to 78% for MCI/prodromal AD, drastically increasing costs and timelines.
- Escalating patient-screening costs: In AD, trials incur higher costs per patient than many other therapeutic areas, with patient-screening costs comprising 50–70% of total per-patient expenses for AD trials,[iii] placing enormous financial pressure on trial sponsors and CROs.

QYNAPSE

Supporting Clinical Trial Success:
Precision Imaging with QyScore® by Qynapse

At Qynapse, we believe that by more accurately identifying and monitoring structural, functional and molecular changes in the brain, we can enhance the quality of patient candidates for clinical trials and better characterize treatment effects and safety profiles with greater sensitivity and specificity.

QyScore® (for healthcare) is an FDA-cleared and CE-marked platform that enables automatic labeling, visualization, and volumetric quantification of segmentable brain structures and lesions from MRI images.

In addition, QyScore® (for clinical studies) combines advanced functional, diffusion and PET neuroimaging capabilities and AI to deliver validated biomarkers that improve trial efficiency and data quality. These imaging insights can improve patient selection and monitoring in clinical trials, as well as support diagnostic confirmation, and management in routine clinical practice in AD and across various CNS disorders.

- QyScore® has been validated across various CNS diseases and MRI acquisitions, demonstrating strong concordance with the state-of-the-art “Gold Standard” from expert neuroradiologist[iv,v] and with low intra-rater and MRI manufacturer variability.[vi]
- QyScore®’s fully automated PET pipeline is validated for use with 11C-PiB-PET and 18F-PET radiotracers including Florbetapir, Forbetaben, Flutemetamol and NAV4694, showing strong SUVr correlations with expert-validated reference sets.[vii]
- In head-to-head comparisons, QyScore® outperformed ANTs, FreeSurfer, and FSL in segmenting key brain regions, including whole brain white matter and grey matter, amygdala, brainstem, lateral ventricles, and putamen. Accepted to AAIC 2025.

Proven Clinical Trial Experience

Qynapse is actively supporting leading pharma sponsors, CROs, and research consortia in de-risking and accelerating Alzheimer’s trials, with recent positive results

- QyScore® detected widespread reduction in atrophy, associated with Blarcamesine treatment, in a large Phase 2b/3 Alzheimer’s disease clinical trial.[viii]
- SACHA, QyScore®’s cutting edge hippocampal and amygdalar segmentation algorithm, detected 45% reduced hippocampal atrophy associated with Donepezil therapy in prodromal AD. [x]

QyScore® is just the start.

QYPREDICT

Predictive Enrichment for Smarter Alzheimer's Trials

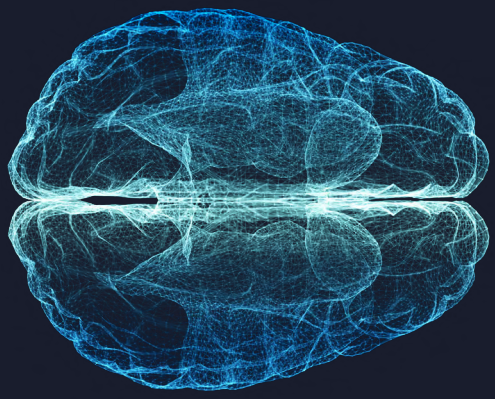
Available for research use only

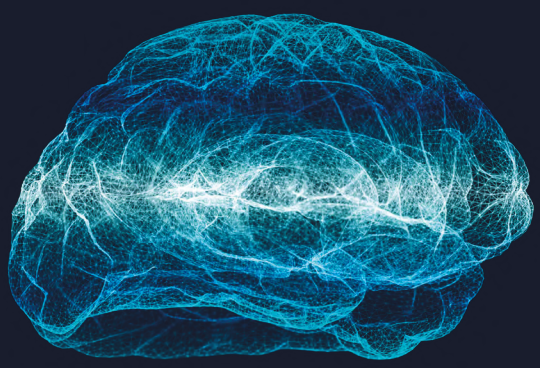
QyPredict® goes beyond diagnosis and monitoring, offering an AI-powered prediction tool that can forecast likely individual clinical disease progression using standard MRI, demographic and clinical data. Utilizing robust algorithms based on a large training dataset of over 2700 brain MRI images, QyPredict® aims to transform clinical trials and patient care.

In a study utilizing data from the Alzheimer's Disease Neuroimaging Initiative, OASIS, and NACC, QyPredict® successfully modeled the future cognitive decline of patients with MCI (defined as either CDR-SB or MMSE changes at 24 months).[iv] This change has the potential to enrich trial recruitment and reduce sample sizes in Alzheimer's Disease by up to 59%.[ix] Over a 12-month assessment period, decliners predicted by QyPredict® demonstrated a 5.8 times greater decline on the CDR-SB compared to those predicted to remain stable.[ix]

Driving Value Across the Clinical Trial Development Lifecycle

- **Pre-screening optimisation**: Reduce unnecessary PET scans and cognitive testing by excluding clearly ineligible patients early.
- **Stratification and enrichment**: Select patients more likely to decline during the trial, significantly improving statistical power to detect a positive treatment effect.
- **Eligibility confirmation**: Confirmation of structural atrophy aligned with diagnosis and required pathological confirmation with amyloid, tau and FDG-PET
- **Efficacy evaluation**: Demonstrate structural, functional and molecular brain response to therapeutic intervention across secondary and exploratory endpoints.
- **Safety monitoring**: Quantify imaging abnormalities associated with immunotherapies and other interventions (e.g., Microbleeds, WMH burden).
- **Global scalability**: QyScore® is site-agnostic, rapidly deployable across global trials, and supports harmonised data acquisition.





QYNAPSE

Let’s transform the future of Alzheimer’s trials one scan at a time.

To Learn more about Qynapseor schedule a pilot, contact us at

info@qynapse.com | www.qynapse.com

QyPredict® is not yet approved or cleared by regulatory authorities

QyScore® (for healthcare) is a medical device software FDA-cleared – (class II) and CE-marked – (class IIa):.

Indications for Use in the U.S. (FDA): QyScore® is intended for automatic labeling, visualization and volumetric quantification of segmentable brain structures and lesions from a set of MR images. Volumetric data may be compared to reference percentile data. QyScore® is not intended for use in clinical scenarios that require evaluation of the number of the white matter hyperintensities.

Indications for Use in Europe (CE): QyScore® is an advanced processing and visualization software for automatic labeling and volumetric quantification of segmented central nervous system structures for patients older than 18 years of age. The software is intended to be used by medical personnel or neuroimaging trained personnel to support diagnosis of central nervous system diseases.

About Qynapse: Qynapse is a medical technology company commercializing an AI-powered and proprietary neuroimaging software platform, creating the potential for earlier clinical precision on the frontlines of CNS disease.

i - https://pmc.ncbi.nlm.nih.gov/articles/PMC3321732/

ii - https://www.mayoclinic.org/diseases-conditions/alzheimers-disease/in-depth/alzheimers-stages/art-20048448

iii - https://schaeffer.usc.edu/research/key-barriers-for-clinical-trials-for-alzheimers-disease/

iv - Gordon, E., et al. (2023). QyPredict prognostic model enriches selection for faster decliners in mild cognitive impairment. Alzheimer’s & Dementia, 19, e081768.

v - Tran, P., et al. (2022). Automatic segmentation of white matter hyperintensities: validation and comparison with state-of-the-art methods on both Multiple Sclerosis and elderly subjects. NeuroImage: Clinical, 33, 102940.

vi - Cavedo, E., et al. (2022). Validation of an automatic tool for the rapid measurement of brain atrophy and white matter hyperintensity: QyScore®. European Radiology, 32(5), 2949-2961.

vii - Navitsky M et al. 2018; Rowe CC et al. 2017; Battle MR et al. 2018; Rowe CC et al. 2016

viii - Macfarlane, S., et al. (2025). Blarcamesine for the treatment of Early Alzheimer’s Disease: Results from the ANAVEX2-73-AD-004 Phase IIB/III trial. The Journal of Prevention of Alzheimer’s Disease, 12(1), 100016.

ix - Villa, L., et al. (2024). Qypredict®: A promising prognostic tool for anti-amyloid therapy patient prioritization. Alzheimer’s & Dementia, 20, e092232.

x - Dubois, B., et al. “Hippocampus Study Group”. (2015). Donepezil decreases annual rate of hippocampal atrophy in suspected prodromal Alzheimer’s disease. Alzheimer’s & Dementia, 11(9), 1041-1049.

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