# Strategic roadmap for an early diagnosis of Alzheimer's disease based on biomarkers

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**The diagnosis of Alzheimer's disease can be improved by the use of biological measures. Biomarkers of functional impairment, neuronal loss, and protein deposition that can be assessed by neuroimaging (ie, MRI and PET) or CSF analysis are increasingly being used to diagnose Alzheimer's disease in research studies and specialist clinical settings. However, the validation of the clinical usefulness of these biomarkers is incomplete, and that is hampering reimbursement for these tests by health insurance providers, their widespread clinical implementation, and improvements in quality of health care. We have developed a strategic five-phase roadmap to foster the clinical validation of biomarkers in Alzheimer's disease, adapted from the approach for cancer biomarkers. Sufficient evidence of analytical validity (phase 1 of a structured framework adapted from oncology) is available for all biomarkers, but their clinical validity (phases 2 and 3) and clinical utility (phases 4 and 5) are incomplete. To complete these phases, research priorities include the standardisation of the readout of these assays and thresholds for normality, the evaluation of their performance in detecting early disease, the development of diagnostic algorithms comprising combinations of biomarkers, and the development of clinical guidelines for the use of biomarkers in qualified memory clinics.**

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