

News Release

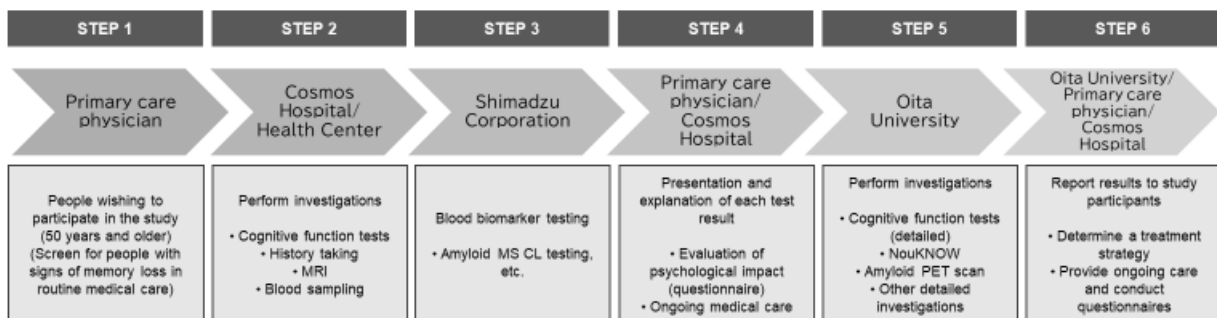
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To Develop Japan's First Blood Biomarker-Based Diagnostic Workflow for Dementia Shimadzu, Eisai, Oita University, and Usuki City Medical Association Commence Joint Research

Shimadzu Corporation (Shimadzu), Eisai Co., Ltd. (Eisai), Oita University, and Usuki City Medical Association hereby announce the commencement of a cohort study using Usuki City as a demonstration site. This joint study will attempt to develop Japan's first diagnostic workflow for mild cognitive impairment (MCI) and Alzheimer's disease (AD) that uses blood biomarkers. In accordance with "Guidelines for Proper Use of Cerebrospinal Fluid and Blood Biomarkers in Dementia"*1, this study aims to demonstrate the utility of blood biomarkers and improve the early diagnosis of Alzheimer's disease within a coordinated system of medical care that encompasses primary care physicians and specialists who are members of dementia-related medical societies.

In cases of Alzheimer's disease, which is said to account for more than 60 % of dementia cases, amyloid beta (A β , a protein thought to cause AD) starts aggregating in the brain around 20 years before AD onset. Positron emission tomography (amyloid PET) and cerebrospinal fluid (CSF) testing are used to estimate the degree of A β accumulation in the brain, but only a limited number of facilities are capable of performing these investigations and the high cost of testing and physical stress involved due to the invasiveness of these investigations also pose a challenge. The increased use of blood biomarkers is expected to reduce the burden on patients.

■ Study Schema



Note: In STEP 1, around 200 people wishing to participate in the study are recruited, and in STEP 2, specialists select 100 people based on medical history (interview) and cognitive function tests.

Usuki City Medical Association will recruit applicants (50 years and older) who wish to participate in the study. Primary care physicians affiliated with Usuki City Medical Association will perform simple cognitive function tests on applicants and select around 200 people with suspected MCI or mild dementia. Specialists affiliated with Usuki City Medical Association Cosmos Hospital (Cosmos Hospital) will then take an in-depth medical history and perform more detailed cognitive function tests

before making a final selection of 100 subjects with MCI or mild dementia who are suspected of having Alzheimer's disease. Shimadzu will be responsible for analyzing and evaluating blood biomarker data obtained using Shimadzu's Amyloid MS CL system for measuring amyloid peptides in blood (Amyloid MS CL)*². Primary care physicians affiliated with Usuki City Medical Association and specialists affiliated with Cosmos Hospital will present and explain test results to participants, evaluate the psychological impact of these results, and provide ongoing medical care as needed. At the Department of Neurology, Faculty of Medicine, Oita University, detailed cognitive function tests will be performed, a self-assessed measurement of brain health will be performed using the "NouKNOW"*³ tool developed by Eisai, A β accumulation will be checked by amyloid PET, and the utility of blood biomarkers will be verified. Eisai will use its expertise in dementia research to propose ideas and assist with study planning and provide advice on methods of analyzing and reviewing test results and psychological impact. All four parties will combine findings from evaluating the clinical performance of blood biomarkers and the psychological effects of disclosing test results to ascertain the acceptability of blood biomarkers under actual clinical conditions.

With this joint research, the four parties aim to establish a new diagnostic workflow for Alzheimer's disease that is based on blood biomarkers and includes primary care physicians. Through this work, the four parties are committed to building an ecosystem that improves the early detection of Alzheimer's disease and to developing social infrastructure that allows those concerned and their families to live in peace and security.

*1 Japanese Ministry of Health, Labour and Welfare Grants for Scientific Research, Study Group, March 31, 2021
https://www.neurology-jp.org/guidelinem/pdf/dementia_biomarker.pdf

*2 Amyloid MS CL is a product that measures amyloid peptides (the main component of amyloid plaques, which are a characteristic feature of Alzheimer's disease) in the blood and provides biomarker data related to amyloid beta levels. In June 2021, Amyloid MS CL was the first product to measure amyloid peptides with a mass spectrometric technique to be approved for use as a medical device in Japan.

*3 "NouKNOW" (non-medical equipment) is a tool developed by Eisai for the self-assessment of brain health (brain performance). "NouKNOW" was developed based on an algorithm created by Cogstate Ltd. (Headquarters: Australia) for which Eisai holds the exclusive rights for development and commercialization worldwide. "NouKNOW" uses common playing cards displayed on a PC or similar device to test brain response time, attention, visual learning, and memory. "NouKNOW" are registered trademarks of Eisai.

Please visit the website for further details <https://nouknow.jp/>

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