BIOCLINICA®
MOLECULAR MARKER LABORATORY

EXPERT BIOMARKER SERVICES
For Alzheimer's Disease Research

Alzheimer's Disease (AD), a fatal neurodegenerative disorder characterized by progressive cognitive impairment and memory loss, is the major cause of dementia. The two main neuropathological hallmarks of AD are extracellular amyloid plaques, and neurofibrillary tangles (NTFs), primarily composed of the protein tau.

A biomarker is a characteristic that can be objectively measured and evaluated as an indicator of a normal or pathological process, or as a measure of response to therapy. Application of cerebrospinal fluid-based (CSF) and blood-based biomarkers in clinical research has revolutionized the understanding of AD. Especially, detection of Aβ and tau in CSF has led to crucial advancements in disease detection at its earliest stage *(Fig 1)*.

In general, biomarkers have proven extremely useful throughout the different steps of AD clinical trials: patient inclusion and enrichment, and evaluation of target engagement and clinical efficacy of therapeutic drugs. Changes in CSF and blood-based biomarkers reflect different pathological processes in AD.

Fluid-based biomarkers can facilitate development of new AD therapies by allowing:

- Enrichment and stratification of patients
- Evaluation of target engagement
- Measurement of disease progression
- Clinical efficacy and safety assessment of therapeutic drugs

Biomarkers of AD Pathological Cascade

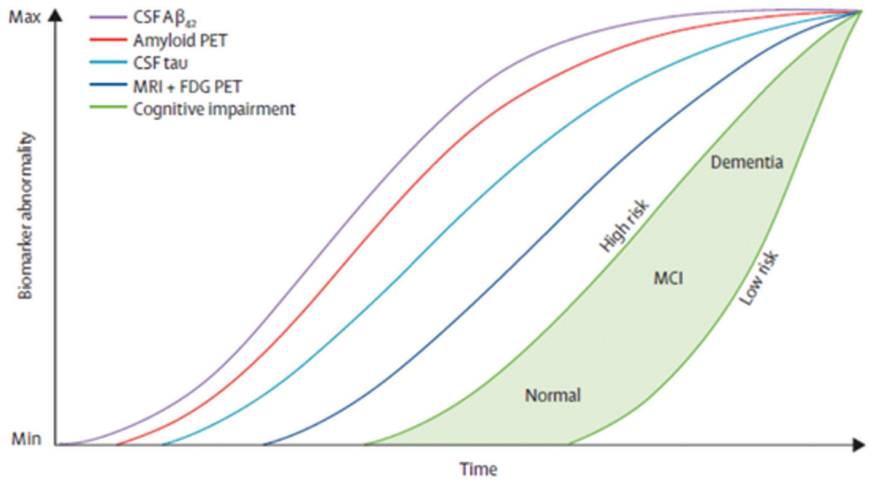

Figure 1 *- CSF biomarkers, along with imaging techniques, are key tools for the early detection of AD. CSF $A\beta_{1-42}$ and tau can be detected prior to clinical symptom onset, usually several years in advance (Jack RC Jr et al., 2013).*

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INFORMED DECISION-MAKING.
QUALITY DATA.
IMPROVED OUTCOMES.

Bioclinica AD biochemical marker capabilities:

- Fit-for-Purpose Validation
- Expertise in Sample Handling
- Centralized analysis to minimize assay variability
- Controlled storage of biological samples
- Established partnership with internationally recognized KOL
- AD specific Proficiency Testing Program

Population Enrichment

The core diagnosis-biomarkers, $A\beta_{1-42}$, tau and p-tau[181] have proven decisive for discriminating AD- from non AD dementias, ensuring the inclusion of only correctly diagnosed patients in clinical trials. In addition, recent clinical studies have showed that blood-based biomarkers appear to be relevant for predicting and assessing AD.

The use of biomarkers in your AD investigational therapy trial will provide critical insight to a better patient characterization, refined selection criteria and patient stratification.

Target Engagement

Ensuring if a drug selectively interacts with its intended protein target is critical for any clinical trial. CSF and blood-based biomarkers represent a simple, scalable and less costly mean to ensure appropriate therapeutic target engagement.

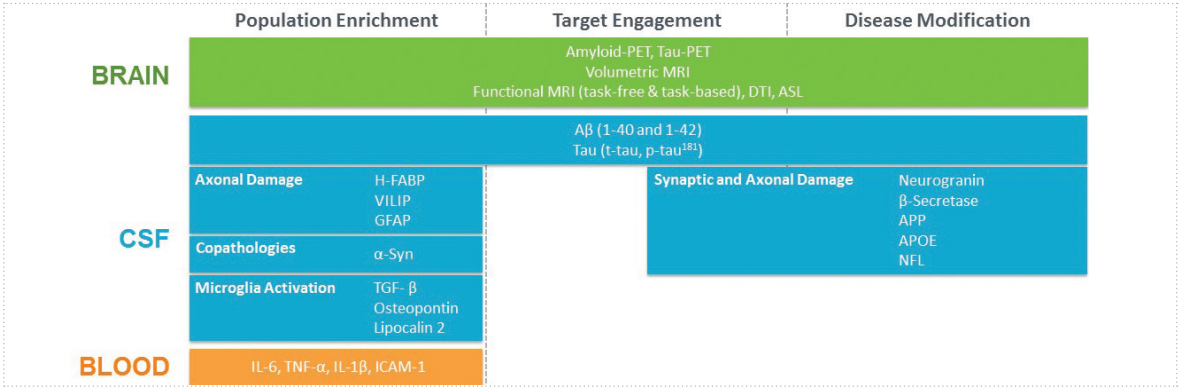
Bioclinica Lab helps you identifying clinical biomarkers that can faithfully report drug-targets interaction in your clinical trial.

Disease Modification

AD biomarkers are used to measure disease progression, and clinical efficacy and toxicity of treatments. Changes in AD markers in CSF reflect brain-related pathological changes and could prove valuable for assessing the biochemical effects of drugs in clinical trials.

Spanning all phases of drug development, Bioclinica's biomarker experts will work with you to design and conduct stringent biomarker analysis to provide key insights into the development of your drug.

Bioclinica AD Biomarkers



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