

# ALZHEIMER'S DEMENTIA EARLY DIAGNOSIS, CHARACTERIZATION, PROGNOSIS AND TREATMENT DECISION VIA A SOFTWARE-AS-MEDICAL DEVICE WITH AN ARTIFICIAL INTELLIGENT AGENT

Petronilla Battista, Raffaello Nemni, Paolo Vitali, Marco Ali, Moreno Zanardo, Christian Salvatore, Graziella Sirabian, Dario Capelli, Luciano Bet, Edward Callus, Enrico Giuseppe Bertoldo, Valentina Fiolo, Brigida Minafra, Giuseppe Scotti, Francesco Sardanelli, Sergio Papa, Isabella Castiglioni

## INTRODUCTION

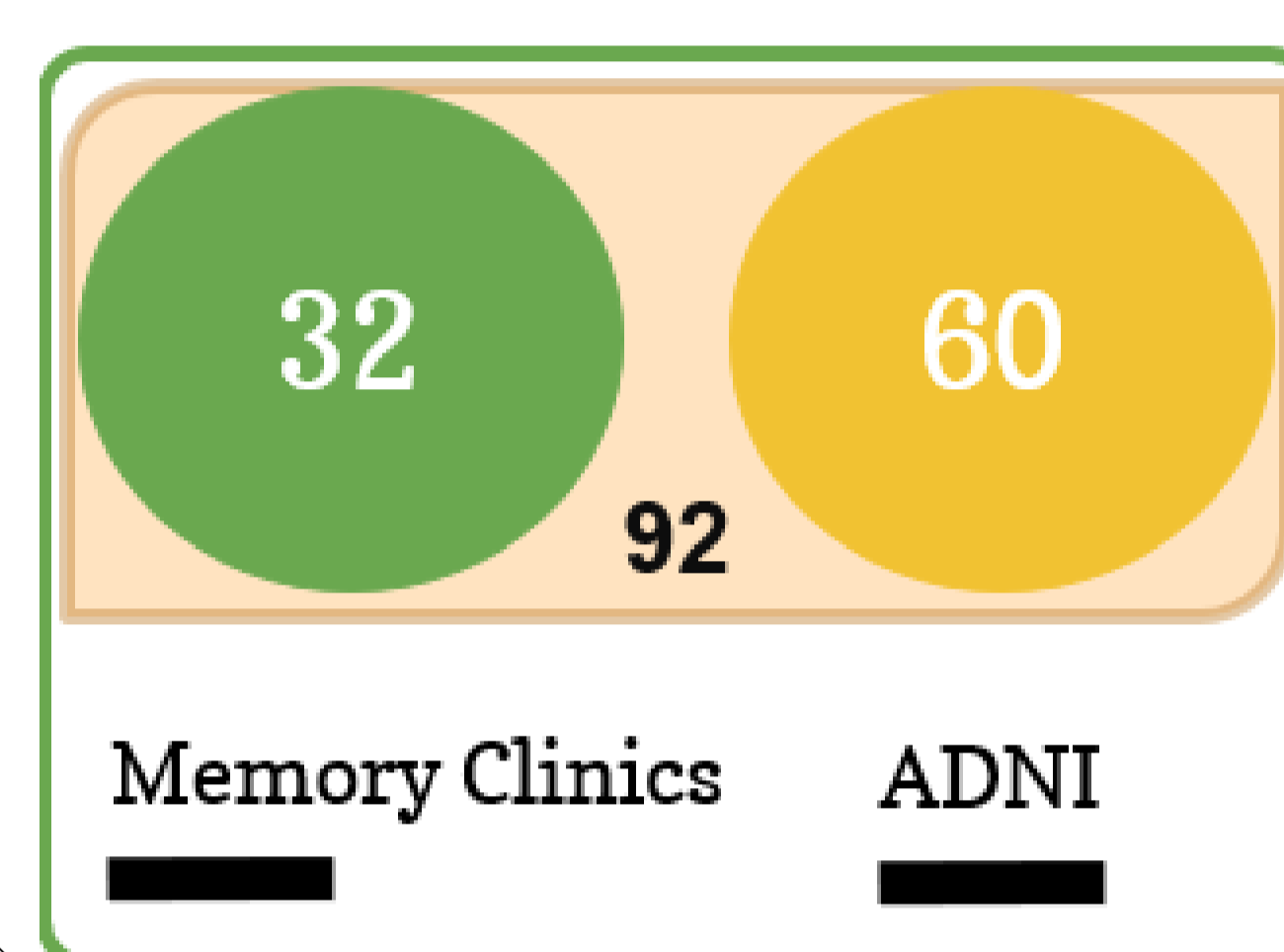
- **TRACE4AD** (DeepTrace Technologies s.r.l, Italy) is a machine learning-based software-as-medical device able to predict the conversion to Alzheimer's disease (AD) dementia of subjects at risk within 24-months exploiting automatic processing of T1-weighted MPRAGE brain MRI study and neuropsychological tests [1] [2].
- TRACE4AD **provides a report** with the predicted **individual risk** of conversion to AD dementia, specific cognitive deficits, and suggestions **supporting neurologists** in diagnosis and characterization, prognosis, and decision-making.

## AIM

To test **TRACE4AD** in the **clinical setting** in its ability, at baseline, to:

- predict** amnesic Mild Cognitive Impairment (MCI) conversion to AD dementia **within 24-months**;
- characterize **cognitive** deficits;
- support** neurologists' decision-making.

## SUBJECTS



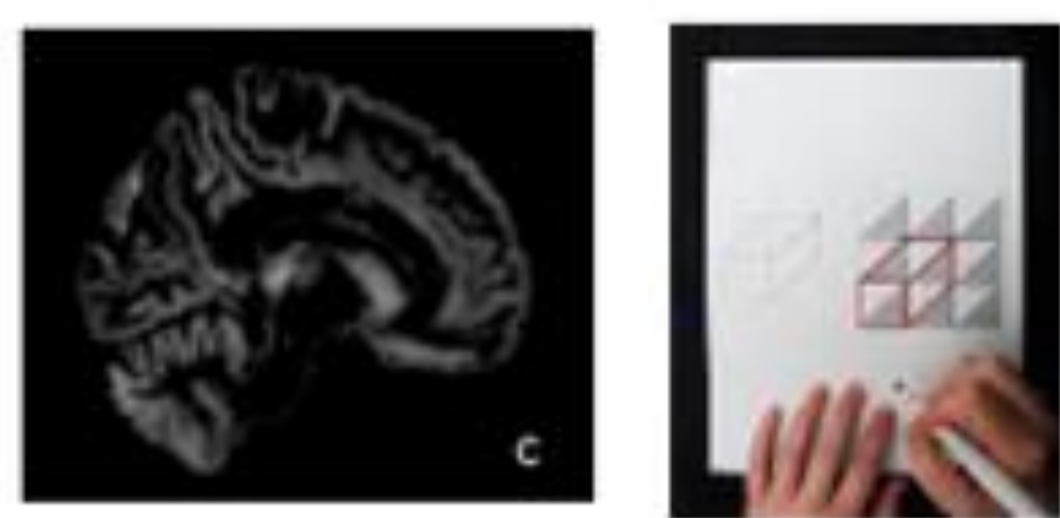
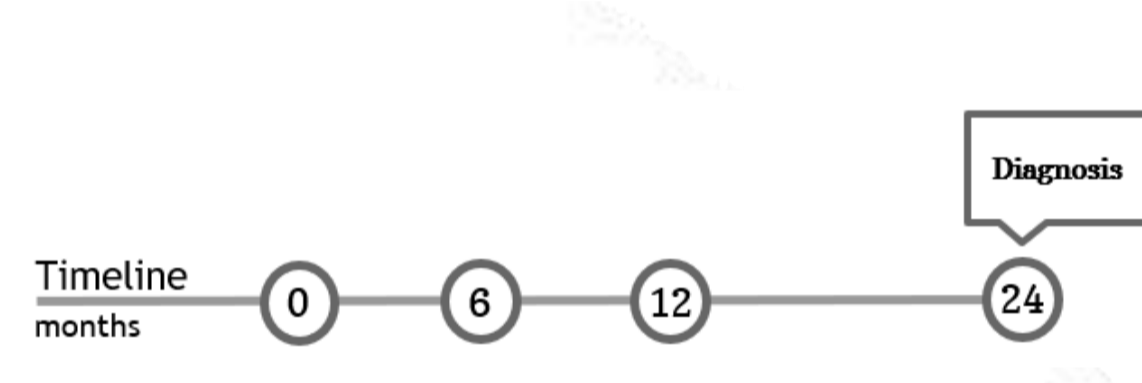
- Patients were recruited from 2 Italian centers
- Demographic's:  
Mean age  $73.12 \pm 7.6$ ,  
46% female

## REFERENCE STANDARD

- the neurologist-s **clinical diagnosis** at 24-months
- the **neuropsychological assessment** at the baseline
- the **agreement** with the neuro exam and intervention decision time and type defined by neurologists at the baseline.

## METHODS

Structural MRI  
T1 weighted  
1.5 Tesla



65 scores/subscores from 7 neuropsychological tests

GM  
1 segmented VOI x Voxel-based features

Feature extraction: kPLS / PCA  
Feature selection: FDR

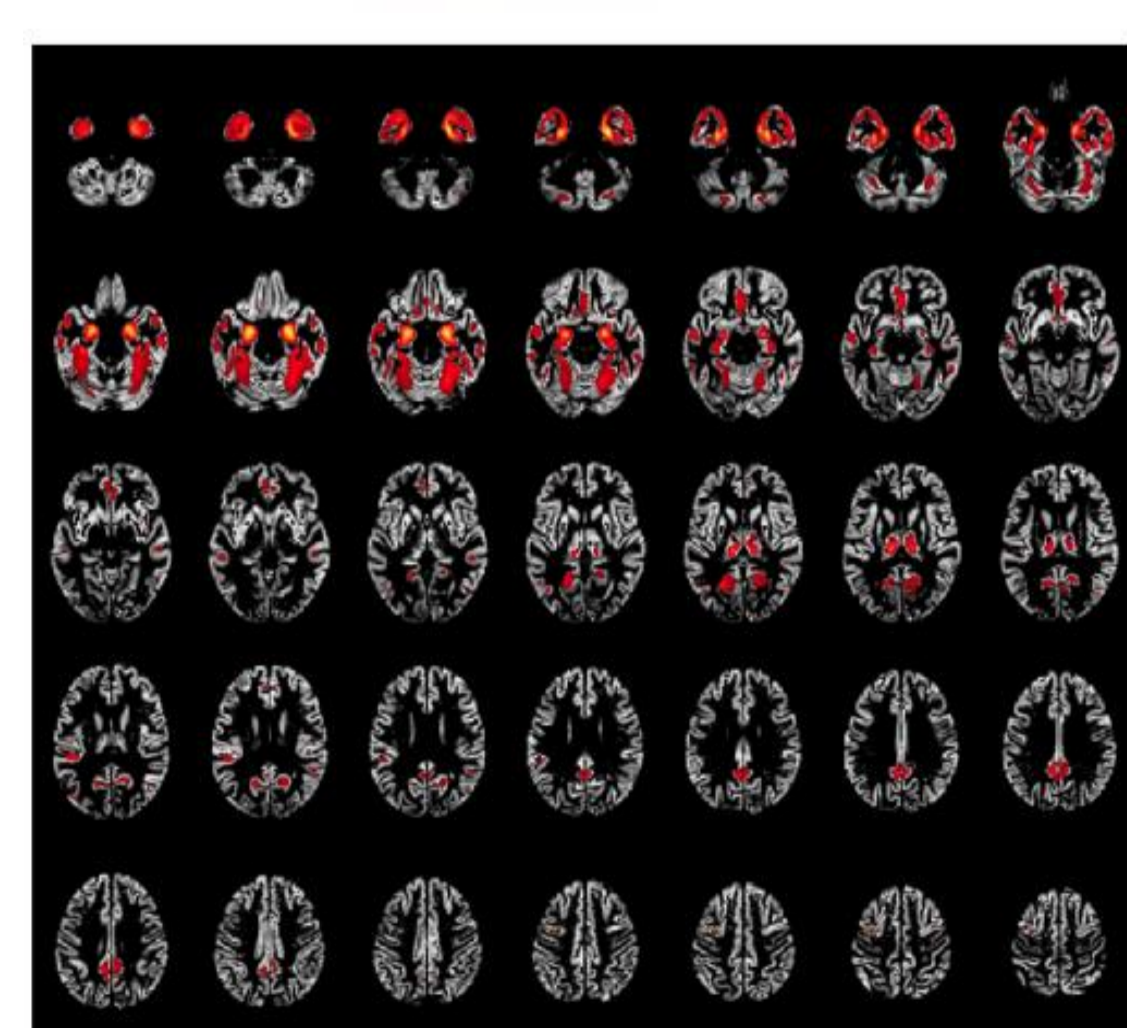
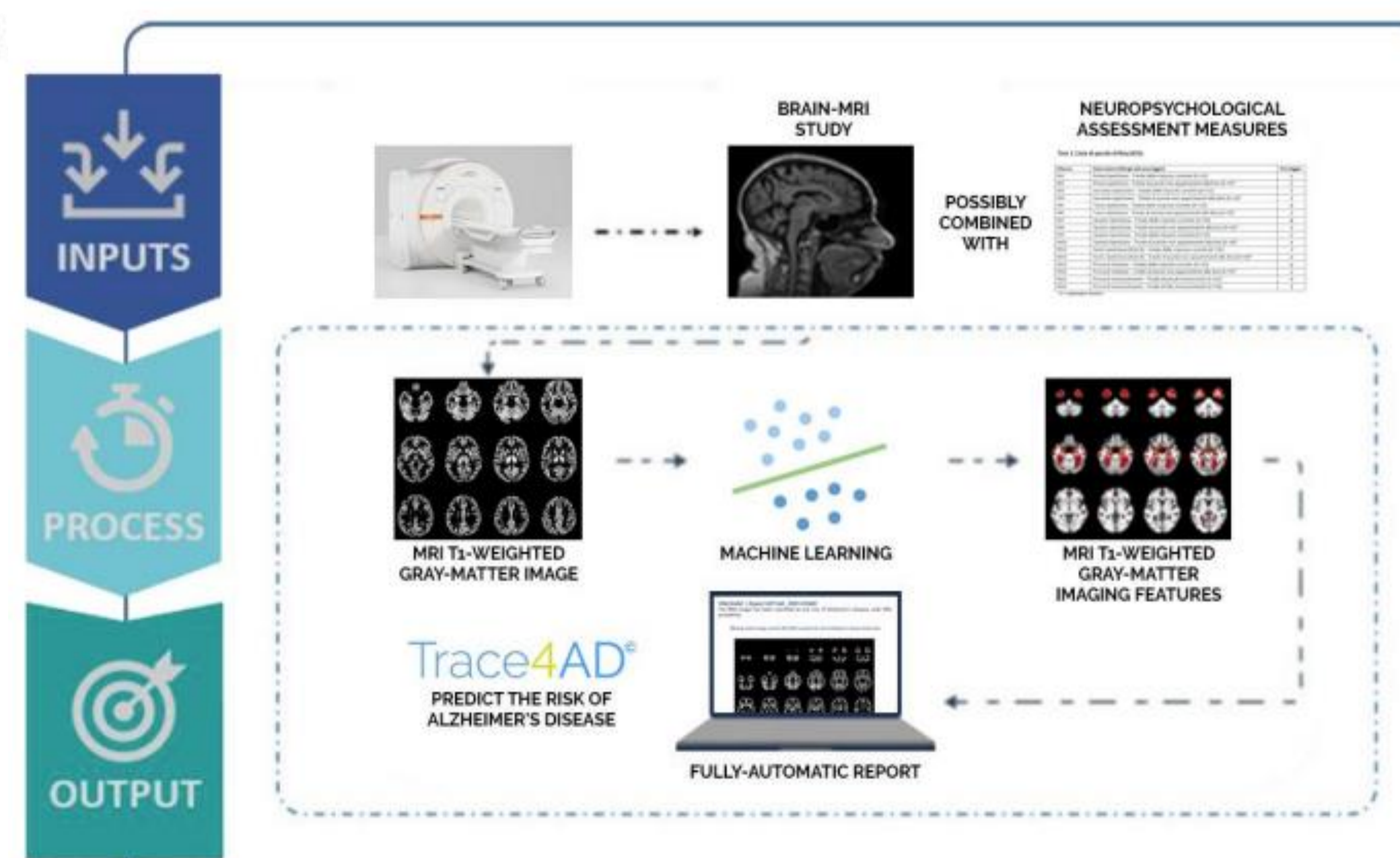
TRACE4AD extracted the **gray matter map** from MPRAGE and used it (combined with **cognitive measures**) to make inferences.

## PRELIMINARY RESULTS

**TRACE4AD accurately predicted conversion/non-conversion to AD dementia in**

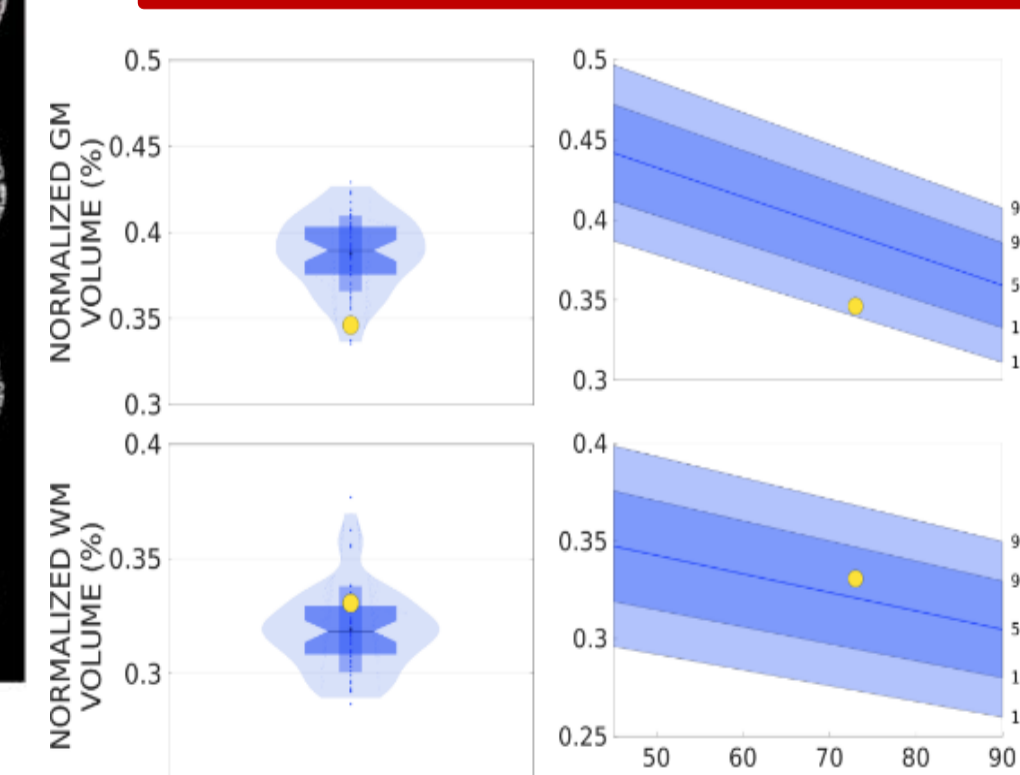
- 93.3% of patients based on the MRI study alone
- 96.6% based on MRI and cognitive measures.

- Cognitive deficits characterized by TRACE4AD were found in agreement with the neuropsychologists assessment for all patients except 1 who presented with major depression.



### TRACE4AD | Report DTT-AD\_PCDI004.01MNP

The T1-weighted MRI data and neuropsychological assessment have been classified by TRACE4AD as high risk for Alzheimer's disease dementia within 24 months. In addition to the typical memory impairment, significant difficulties in visuo-constructive functions are detected.



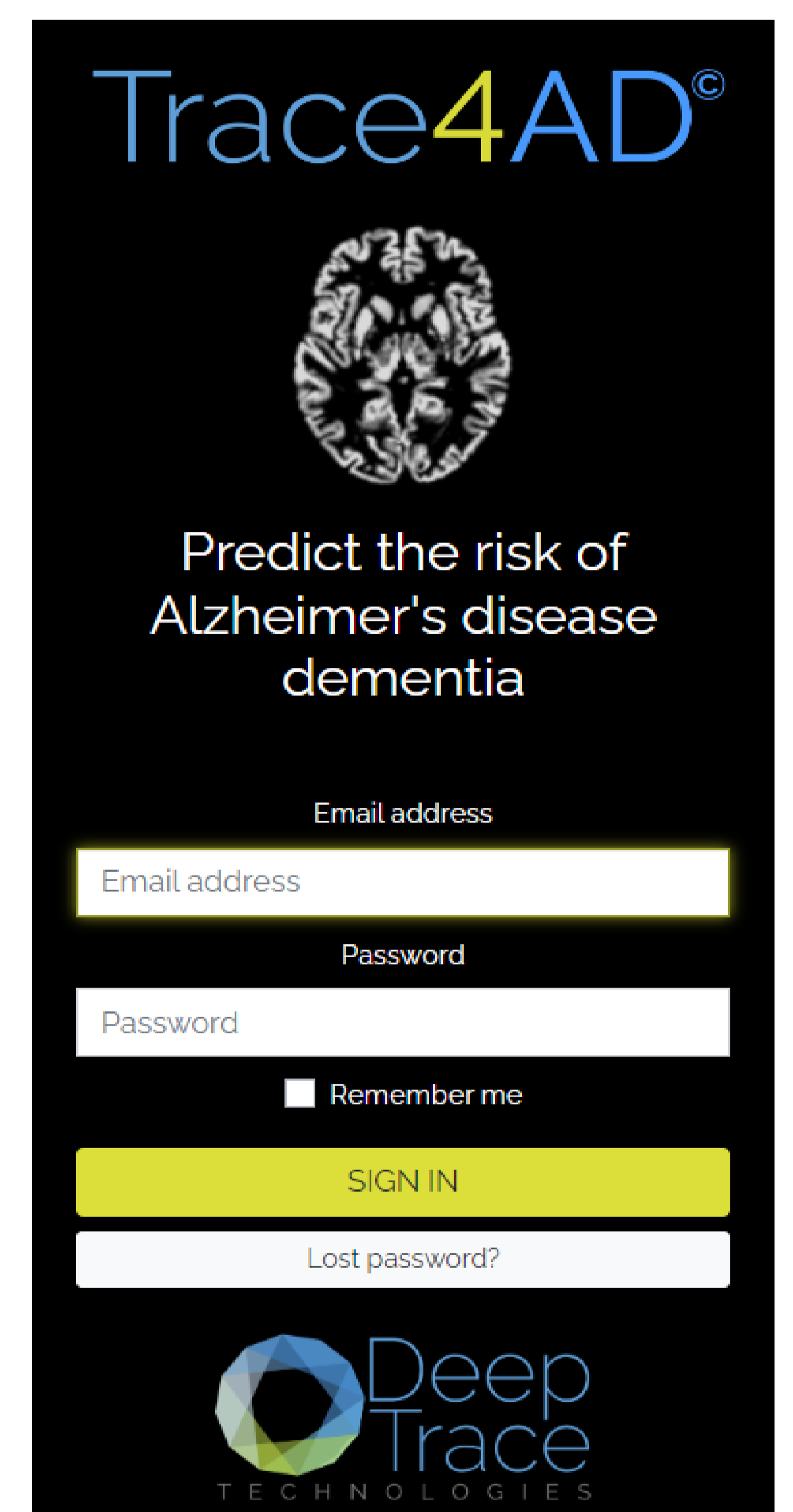
- Disagreement between the neurologist's prediction and the tool at baseline was in only 2 patients, defined with no risk and high risk of dementia conversion, respectively. A follow-up visit was scheduled for those patients.

## SUMMARY

- AI can be used to **support** neurologists in characterizing the diagnosis, prognosis, decision, and timing of intervention. TRACE4AD requires training for its use in clinical practice.

### CONCLUSION:

TRACE4AD is promising, safe, and effective in supporting neurologists in the clinical practice of MCI across different centers.



- TRACE4AD supported prompt neurologists' decision in 88.2% patients at baseline: 6 patients with cognitive complaints, defined with normal cognition by the tool, had no interventions; 9 patients with subtle cognitive deficits, recommended for treatment by the tool, had a tailored intervention.

### References:

- [1] Salvatore, C., Cerasa, A., & Castiglioni, I. (2018). MRI characterizes the progressive course of AD and predicts conversion to Alzheimer's dementia 24 months before probable diagnosis. *Frontiers in aging neuroscience*, 10, 135.
- [2] Battista, P., Salvatore, C., Berlingeri, M., Cerasa, A., & Castiglioni, I. (2020). Artificial intelligence and neuropsychological measures: The case of Alzheimer's disease. *Neuroscience & Biobehavioral Reviews*, 114, 211-228.
- [3] Jack C R, Bernstein M A, Fox N C, Thompson P, Alexander G, Harvey D, et al. (2008) The Alzheimer's disease neuroimaging initiative (ADNI): MRI methods. *J. Magn. Reson. Imaging* 2008:27, 685-691

SCAN ME

