# IHI Call Days | Call 9

## DEDICATE

*Dynamic Evaluation and Digital Inference of Cognitive Ageing through Technology in Europe*

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Link to the IHI brokerage platform:

- Proposal sharing tool: DEDICATE
- Participant profile

# Challenges and objectives

- **Alzheimer's Disease and related dementias (ADRD)** are characterised by a **slow cognitive decline** with an **unpredictable longitudinal trajectory,** starting decades before symptoms and diagnosis may emerge.

- Someone's **trajectory of early cognitive decline is unique** to each individual and there is currently no effective tool to capture such a trendline at pre-symptomatic stages of diseases:
  - Current in-clinic evaluations are costly, infrequent, and heavily reliant on subjective reports.
  - Traditional cognitive tests are not challenging enough for cognitively 'normal' populations and are therefore limited by practice and learning effects that prevent the detection of subtle decline over time in asymptomatic patients.

- We **aim** to identify and validate **first-in-class longitudinal biomarkers** of the **earliest pre-symptomatic stages of ADRD,** through **user-adaptive deep phenotyping digital tools** and consumer technologies **in an ecological real-life setting.**

- With **Europe's ageing population**, there is an **urgent need** for accessible, objective, and continuous **cognitive health assessments** to enhance early detection, disease monitoring and preventive intervention in ADRD:
  - 52 million persons are at the pre-symptomatic stages somewhere on the AD continuum in Europe[1]
  - '*You cannot treat what you cannot measure'* - Drug development aiming to prevent ADRD requires the capacity to measure cognitive decline in pre-symptomatic individuals.

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1. Gustavsson A et al. Global estimates on the number of persons across the Alzheimer's disease continuum. Alzheimer's & Dementia. 2023, 19:658-670.
ADRD, Alzheimer's disease and related dementias.

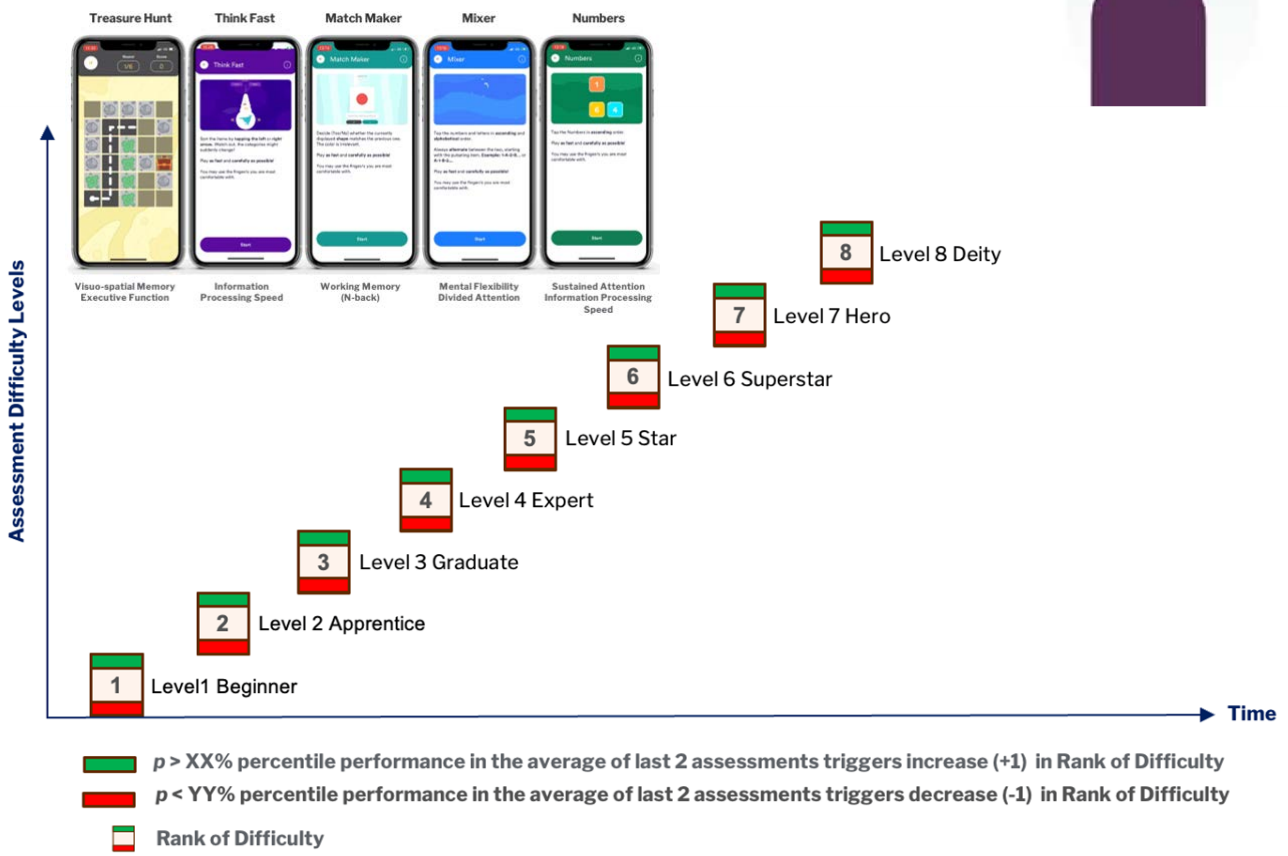
# Our Approach

## A European-Wide Brain Health Study

- **Objective:**
  - Build a European-wide 2-year large-scale prospective study to evaluate a **user-adaptive deep phenotyping tool** for self-monitoring of cognitive health to validate **predictive biomarkers of pathological decline** in a diverse ageing population at risk of ADRD.

- **Our Solution:** Indivi-Cognition
  - **User-adaptive & gamified** smartphone BYOD assessments of all functional domains of cognition
  - **Dynamic Difficulty Adjustment systems** enabling to:
    - Saturate learning/practice effects
    - Sensitise the capacity to detect decline in cognitively unimpaired individuals
    - Enhance engagement

- **High-Level Study Design:**
  - **Population**: >50 y-o, cognitively unimpaired (Stage 0-2*)
  - **Sample size**: N=25,000 with an estimated MCI conversion rate of 2% per year through stratified cohort enrichment in AD risk factors, subjective cognitive complaints and blood-based biomarker positivity
  - **Duration**: 2 years with weekly remote assessments




*Jack CR et al. Revised criteria for diagnosis and staging of Alzheimer's disease: Alzheimer's Association Workgroup. Alzheimers Dement. 2024, 20:5143-5169.

ADRD, Alzheimer's disease and related dementias; BYOD, bring your own device; MCI, mild cognitive impairment.

# Is our project suitable for IHI?

- **A public-private collaboration** is essential for our proposal as it brings together the strengths of both sectors:
  - **Public institutions**, such as academic hospitals and memory clinics, patient advocacy groups, and health technology assessment researchers providing clinical expertise, patient access, and validation in real-world settings
  - **Private industry** contributing with technological innovation, resources for large-scale clinical study implementation, and pathways to value demonstration.

- The proposed **first-of-its-kind DEDICATE European-wide Brain Health Study** demands a substantial multi-stakeholder multi-year funding which may only materialise in a **pre-competitive framework** such as those IHI may support.

- An IHI-funded **partnership** model would accelerate pragmatic development and **ensure our technology solution is clinically sound, widely applicable, and readily suited for seamless integration** into healthcare systems.



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# Outcomes and Impact

- The main outcome of our project is the validation of first-in-class **longitudinal biomarkers of the earliest pre-symptomatic stages of ADRD**:
  - Using deep phenotyping tools and consumer technologies,
  - Reflective of cognitive functioning in an ecological real-life setting
  - Predicting the risk of conversion to prodromal symptomatic AD (mild cognitive impairment)
- Our proposal will allow **seamless translation from research to healthcare integration** by combining real-world evidence validation, multi-stakeholder collaboration, and interoperability, to create a scalable, trusted BYOD technology solution for cognitive health monitoring in ageing populations.
- Our project empowers **patient-centric research** by providing accessible, continuous cognitive self-monitoring
  - enabling earlier detection of decline and intervention for potential prevention of disease, as well as
  - improving healthcare and quality of life through proactive, personalised care.
- This novel approach aiming at detecting hidden signature trajectories of cognitive decline in apparently healthy individuals with or without amyloid biomarkers will **strengthen Europe's leadership in brain health and ageing innovation**, extending its reach and transformative impact while addressing a major societal and economical challenge of our time.



ADRD, Alzheimer's Disease and related dementias; BYOD, bring your own device.

# Expertise and resources

## We have:

- A proven track record in science, technology, drug development and digital biomarkers.
- A robust digital health technology and data analytics with experience in translating research into clinically validated solutions.
- Experience in complex large-scale decentralised trials involving academic and industry partners.

## We are looking for:

**Academic Hospitals & Memory Clinics**:

- Clinical research expertise.
- In-depth knowledge of neurodegenerative disorders.
- Access at scale to the trial target patient populations.

**Patient Advocacy Groups**:

- Guide patient-centric design for long-term adherence and support adoption.

**Health Economics and Outcomes Researchers**:

- Assessment of cost-effectiveness.
- Pathway to impact definition.
- Enhancement of case for adoption and reimbursement.

**Bio-Pharmaceutical Industry Partners**:

- Regulatory experience to advance acceptance and adoption of novel endpoints in ADRD.
- Feasibility of implementation in drug development trials.

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