



# Remote Assessment of Disease And Relapse - Alzheimer's Disease

Measuring functional decline using digital devices

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# Functional decline in Alzheimer's disease

- Key diagnostic criterion
- Major challenge for patients, carers, and society
- Required for approval of new AD medications
- Traditional methods to measure function / ADL are insufficient
- UNMET NEED: The ability to accurately track and measure **functional decline** in AD cohorts to shorten clinical development and generate payer-relevant evidence of real world impact of therapeutic interventions

1. In the past 4 weeks, did {S} **usually** manage to find his/her personal belongings at home?

→ **If yes**, which best describes how he/she usually performed:

- 3 ☐ without supervision or help
- 2 ☐ with supervision
- 1 ☐ with physical help

2. In the past 4 weeks, did {S} select his/her first set of clothes for the day?

→ **If yes**, which best describes his/her **usual** performance:

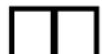
- 3 ☐ without supervision or help
- 2 ☐ with supervision
- 1 ☐ with physical help

3. Regarding physically getting dressed, which best describes his/her **usual** performance in the past 4 weeks: (check one)

- 4 ☐ dressed completely without supervision or physical help
- 3 ☐ dressed completely with supervision, but without help
- 2 ☐ needed physical help only for buttons, clasps, or shoelaces
- 1 ☐ needed some help even if clothes needed no fastening or buttoning
- 0 ☐ someone else dressed him/her

Standard pen-paper tests  
of ADL are inaccurate:

ADCS - ACTIVITIES OF DAILY  
LIVING (ADL) INVENTORY



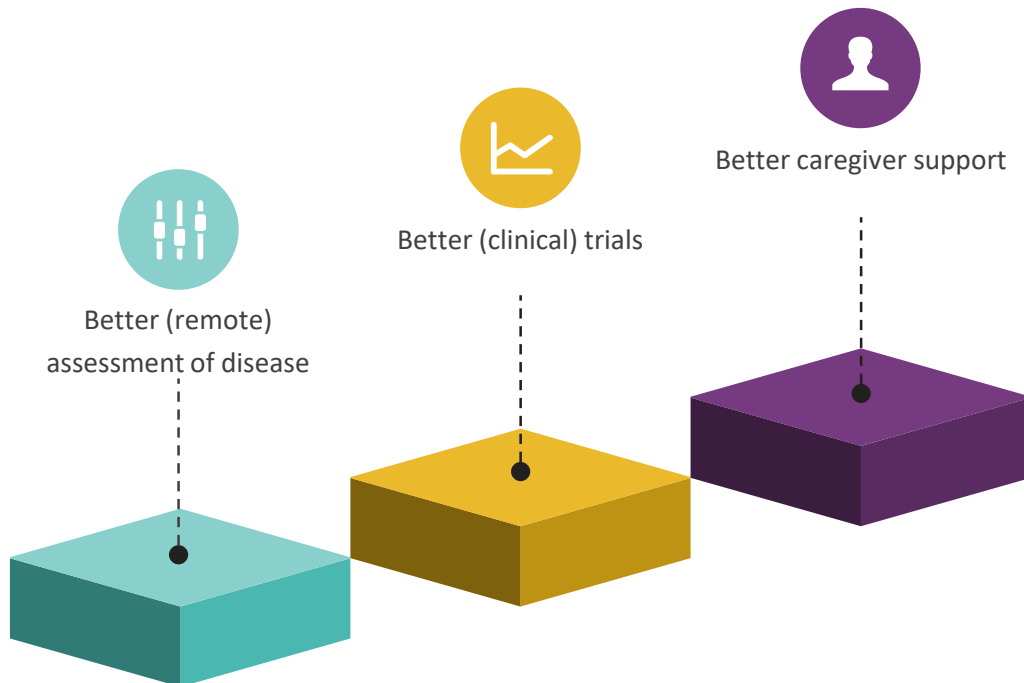
## Wearables and other digital biomarkers - Opportunities

- Objective
- Quantitative
- Repeated
- Unobtrusive, passive, hassle-free

## Wearables and other digital biomarkers - Opportunities

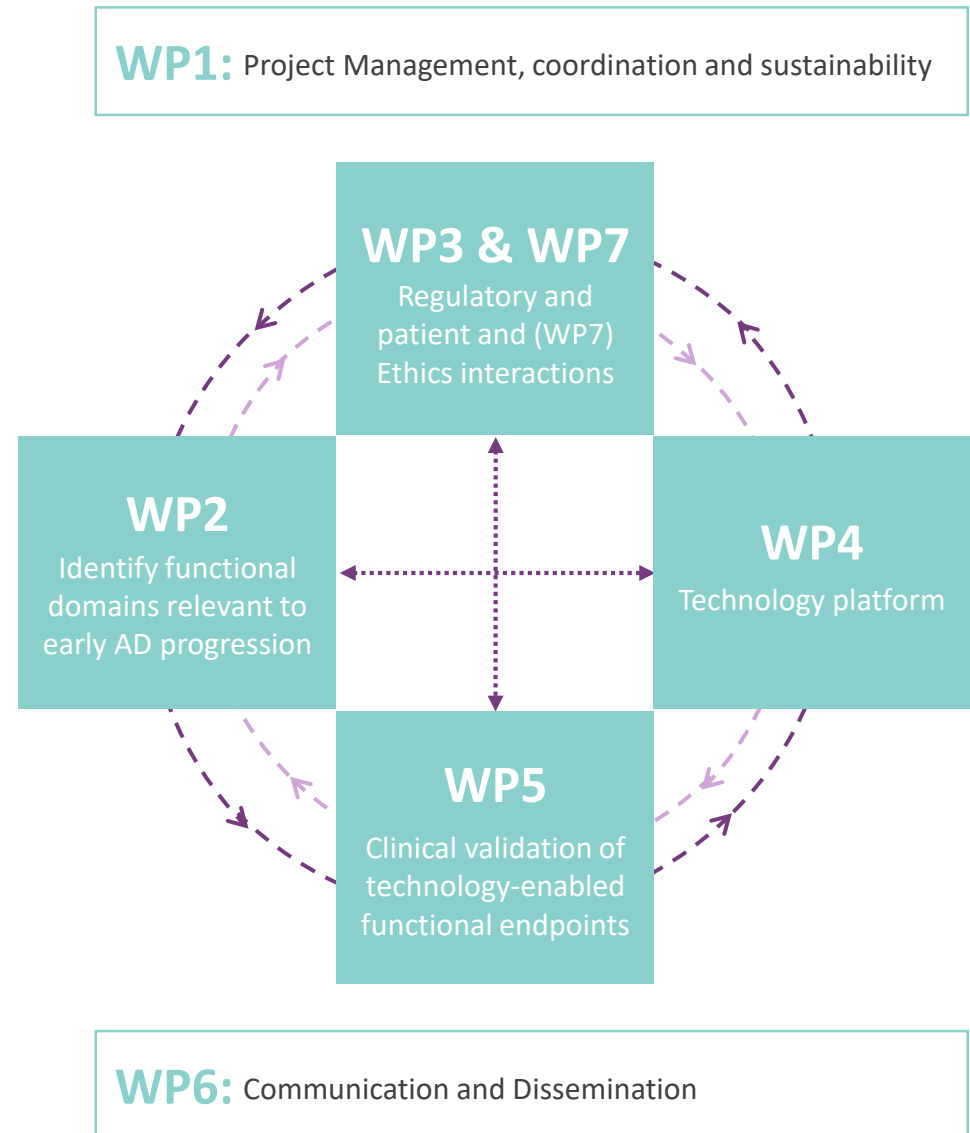
- Objective
- Quantitative
- Repeated
- Unobtrusive, passive, hassle-free
- Data capacity and big-data analysis
- Increased cloud storage capacity and improved analytical techniques offer the potential to harness measures for research and clinical care

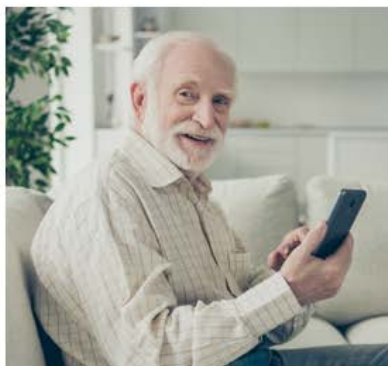
Main goal: The development and validation of technology-enabled, quantitative and sensitive measures of functional decline in people across the AD spectrum



# Work package structure

RADAR-AD is divided into 7 integrated work packages, each with defined tasks and objectives





Patient

Better care



Data



Analysis software

Assessment/  
PredictionParser to output  
that is visually  
attractive for  
clinician/researcher



## The RADAR-AD Consortium

Name	Country	Type
King's College London	United Kingdom	Public
Lygature	The Netherlands	NFP NGO
VU University Medical Centre	The Netherlands	Public
The Hyve	The Netherlands	Private
University of Oxford	United Kingdom	Public
Karolinska Institutet	Sweden	Public
College ter Beoordeling van Geneesmiddelen	The Netherlands	Regulator
Fraunhofer Institute for Algorithms and Scientific Computing	Germany	Public
Alzheimer Europe	Luxemburg	Patient Organization
Janssen Pharmaceutica NV	Belgium	EFPIA
Takeda Development Centre Europe Ltd	United Kingdom	EFPIA
Novartis Pharma AG	Switzerland	EFPIA
Eli Lilly	United Kingdom	EFPIA
Software AG	Germany	EFPIA
Centre for Research and Technology Hellas	Greece	Public
Altoida AG	Switzerland	Private

# Input of people with AD is essential at each step of the project



## Define functional domains

What are functional changes that are important to people and their families ?



## Device selection

Would people use devices? How (often) would they use them in daily life?  
What would make it easier to use them?



## Identify barriers and facilitators for successful implementation

What needs to be considered for remote monitoring in the 'real world'?



## Clinical study

How do we minimize the burden for study participants? How do we ensure compliance and minimize drop-outs? How do we communicate in the best way?



## Define regulatory path forward

Ethical concerns for users?

## **RADAR-AD User involvement program-Alzheimer Europe**

- **The Patient Advisory Board:**
  - All members of the ‘European Working Group of People with Dementia’ - set up by Alzheimer Europe – were invited to join
- **6 Focus groups**
  - 12 people with Mild Cognitive Impairment and 7 people with mild AD dementia
  - 20 people who cared for loved ones with mild to severe AD dementia
- UK, Netherlands, Greece
  - Collaboration with local project partners and non-partners (e.g. Alzheimer Nederland, Alzheimer’s Society in the UK )

**WP2**  
Identify  
functional  
domains



**WP3**  
Patient  
advisory  
board

Functional domain	Relevance	Predicts MCI -> AD conversion	Impaired in early AD	Predictive of decline	Reported by PAB
1.	HR	x	x	x	x
2.	R	x		x	x
3.	N	x		x	
4.	LR		x		

**WP2**  
Identify  
functional  
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**WP3**  
Patient  
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board

Functional domain	Relevance	Predicts MCI -> AD conversion	Impaired in early AD	Predictive of decline	Reported by PAB
1. Difficulties at work	HR	x	x	x	x
2. Spatial nav. & memory	HR	x	x	x	x
3. Planning skills & memory	HR	x	x	x	x
4. Managing finances	R	x		x	x
5. Self-care	R		x	x	x
6. Self-management,	R	x		x	x
7. Acquiring new skills	R		x	x	x
8. Sleep quality, circadian rhythm	R		x	x	x
9. Use of technology	R		x	x	x
10. Word finding difficulties	N		x	x	

**WP2**  
Identify  
functional  
domains

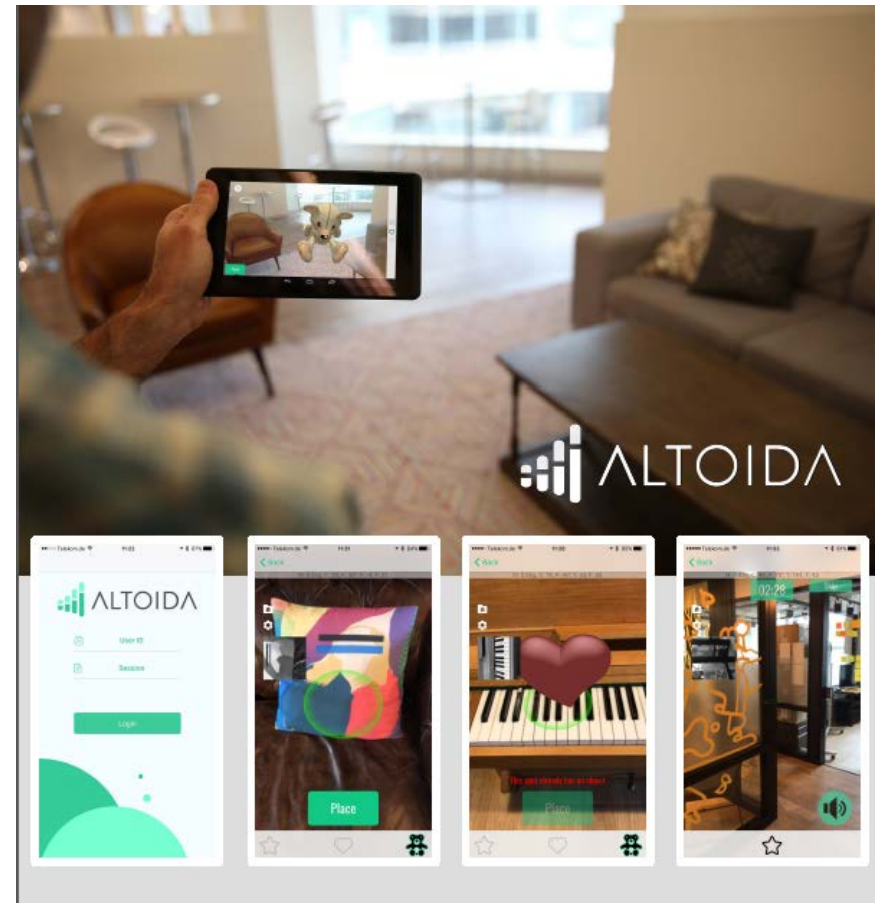


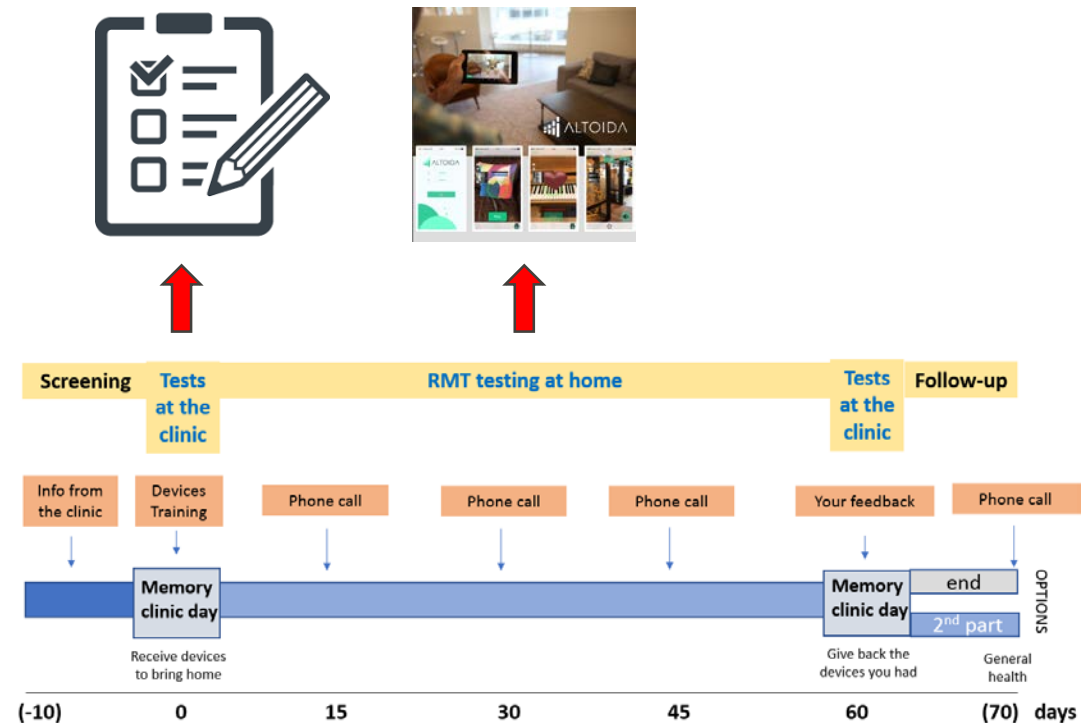
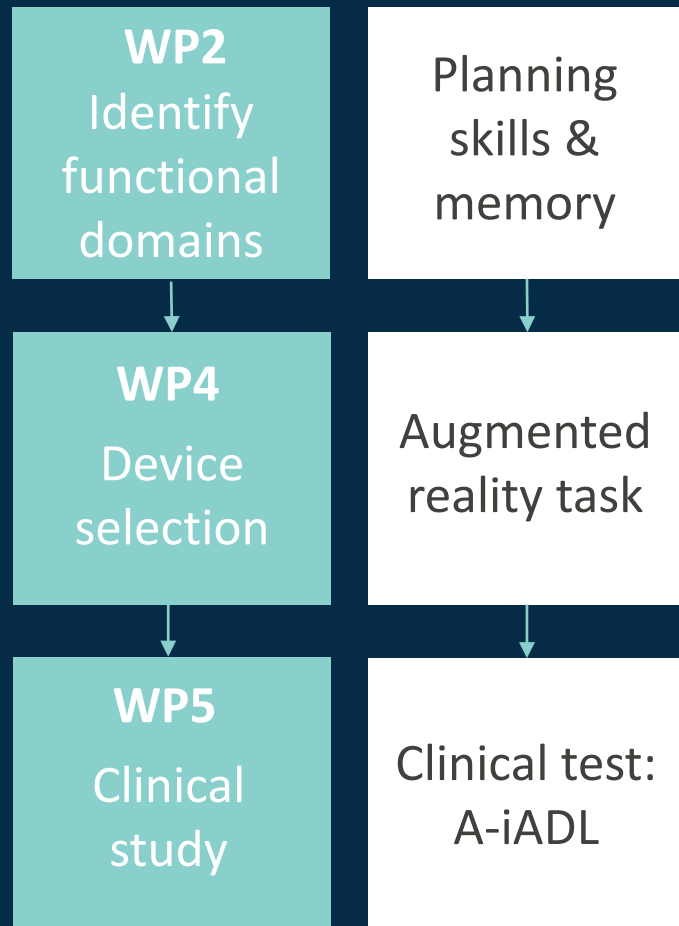
**WP4**  
Device  
selection

Planning  
skills &  
memory



Augmented  
reality task





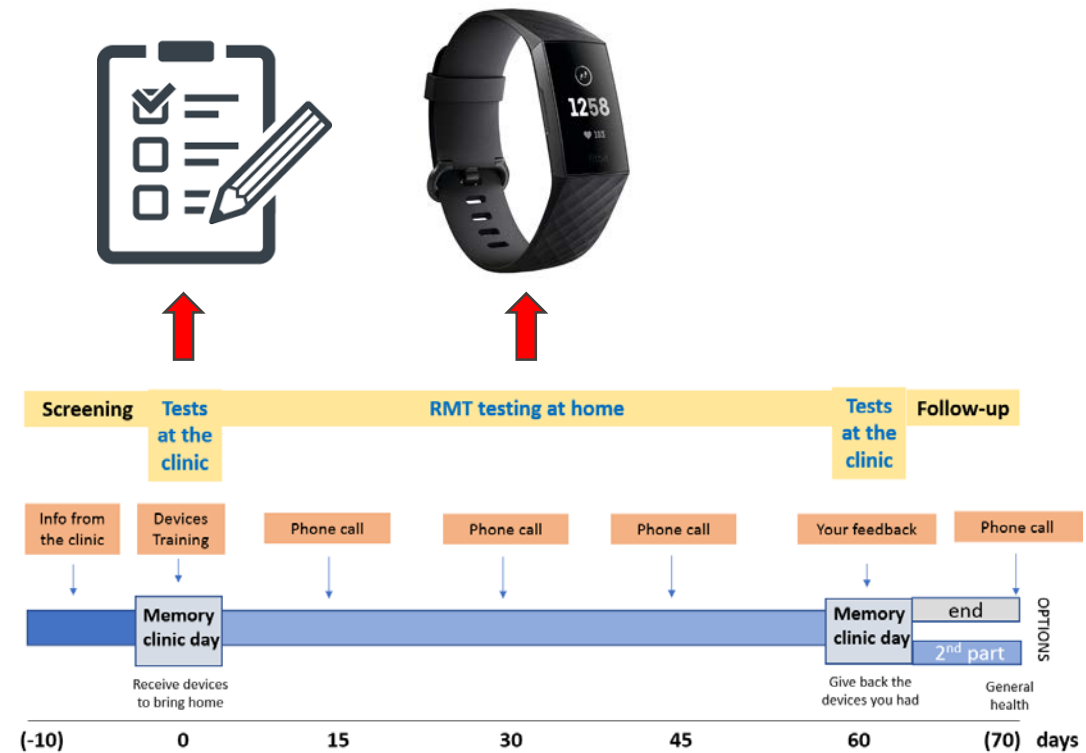
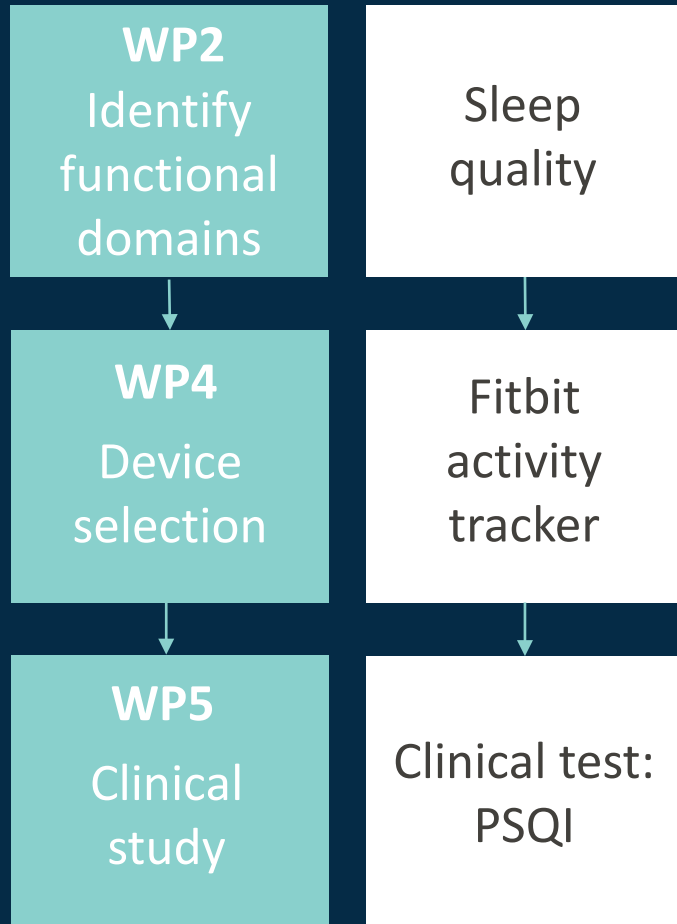
**WP2**  
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**WP3**  
Patient  
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Functional domain	Relevance	Predicts MCI -> AD conversion	Impaired in early AD	Predictive of decline	Reported by PAB
1. Difficulties at work	HR	x	x	x	x
2. Spatial nav. & memory	HR	x	x	x	x
3. Planning skills & memory	HR	x	x	x	x
4. Managing finances	R	x		x	x
5. Self-care	R		x	x	x
6. Self-management,	R	x		x	x
7. Acquiring new skills	R		x	x	x
8. Sleep quality, circadian rhythm	R		x	x	x
9. Use of technology	R		x	x	x
10. Word finding difficulties	N		x	x	





**WP2**  
Identify  
functional  
domains

**WP4**  
Device  
selection

**WP5**  
Clinical trial



**WP2**  
Identify  
functional  
domains

Functional domain	Activities	Preclinical MCI or AD symptoms	Impairment in early AD	Impairment in late AD	Impairment in very late AD
1. Difficulties at work	100	x	x	x	x
2. Spatial navigation & memory	100	x	x	x	x
3. Planning skills & memory required for task completion	100	x	x	x	x
4. Managing finances	10	x	x	x	x
5. Self-care	10	x	x	x	x
6. Self-management, e.g., learning, interests & shopping	10	x	x	x	x
7. Managing one's life	10	x	x	x	x
8. Sleep quality & circadian rhythms	10	x	x	x	x
9. Use of technology/Internet	10	x	x	x	x
10. Transport, social driving, difficulties	10	x	x	x	x
11. Fall	10	x	x	x	x
12. Communication	10	x	x	x	x
13. Information processing	10	x	x	x	x
14. Motivation, signs of apathy or withdrawal	10	x	x	x	x

**WP4**  
Device  
selection



**WP5**  
Clinical trial



Study population (N=55 per group):

- Controls
- Preclinical AD
- MCI due to AD
- Mild-to-moderate AD dementia

# The RADAR AD Clinical trial

## Primary Objective:

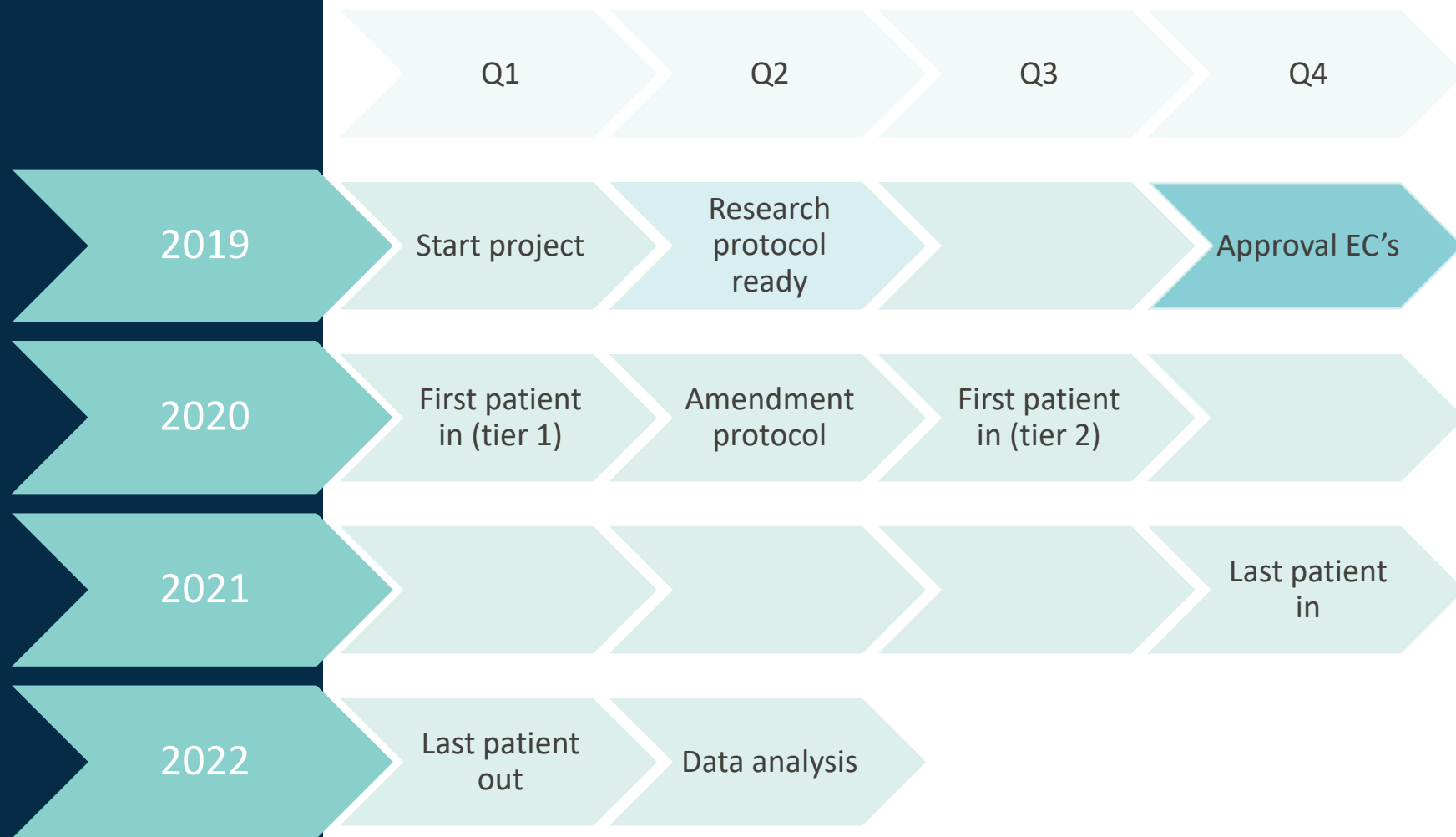
- assess the performance of selected RMTs against standard ADL rating scale

## Secondary objectives

- to evaluate associations between RMTs and standard clinical scales
- to investigate the patient acceptability of selected RMTs
- to assess the technical performance of RMTs and digital platform in a real-life setting

- A multicentre observational cross-sectional cohort digital assessment study lasting 8 weeks
- A sub-study extension of at-home monitoring for 4 weeks

# Timeline



## Partners



# THANK YOU FOR LISTENING

[www.radar-ad.org](http://www.radar-ad.org)

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