() ai·prognosis



Funded by the European Union AI-PROGNOSIS / Artificial intelligence-based Parkinson's disease risk assessment and prognosis

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SPBTU

The EU call (HLTH-2022-STAYHLTH-01-04-two-stage)

Trustworthy artificial intelligence (AI) tools to predict the risk of chronic non-communicable diseases and/or their progression





Artificial intelligence-based Parkinson's

disease risk assessment and prognosis



Our why







Most common neurodegenerative movement disorder

~10M persons worldwide; heterogeneous (non-) motor symptoms; no cure Parkinson's disease (PD) is often missed or misdiagnosed

Subtle early symptoms; common with other diseases 'Trial & error' medication regimen selection

Leading to unnecessary suffering and additional costs



Our vision

Advance Parkinson's disease diagnosis and care through Al-enabled tools



Implementation at a glance

Consortium	18 partners	6	Work packages
Budget	~6M €	27	Tasks
Duration	Jul 2023 – Jun 2027	39	Deliverables
EU Funding Agency	EU Health and Digital Executive Agency (HaDEA)	>700	Person-months



Consortium





External Expert Advisory Board



Dr. Alvaro Sanchez-Ferro

Director of Clinical Outcomes Programme at Movement Disorders Society

Neurologist at Hospital 12 de Octubre / Chief Medical Officer at Leuko Labs



Dr. Angela Kehagia

Clinical Medical Manager at Novo Nordisk ex-Deputy Director and Health Technology Analyst at KiTEC



Prof. Lynn Rochester

Professor of Human Movement Science at Newcastle University, Coordinator of MOBILISE-D IMI





Our research



Digital biomarkers

Passively measured



- Rest tremor
- Slowness of movement
- Sleep-related symptoms
- Dyskinesias
- Physical activity



Points: 7 Last troad: 0 Total: 0

Active tests

← Get ready! ← Function Motor Test veive Euroction Motor Tee you will be asked to do a sequence of motor tests, including 1) Leg Agility & Arising from chair, 2) Posture, and 3) Gait Leg Agility Arising from chair · Ensure you have a chair, a phone, an enough space to walk Posture Place the phone on a table or similar surface about 3m from the chair. Turn the hair about 45° (see figure above). · Adjust the phone camera (in landscape mode) to capture the floor 3m from the chair Gait and your entire body when standing. Use a tripod if possible

Standardized tests (BART, N-back, Signal) to assess cognitive function



Body-tracking motor test to assess posture, balance and gait





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Data in the spotlight

Accessed and harmonising multisource sets of relevant in-depth health and genetic data including:

- Incident PD diagnoses and at risk cohorts
- PD progression long-term follow-up
- PD-specific medication history and response (incl. side effects)
- Digital phenotyping data (from wearables and smartphones)





Our envisioned tools



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Our envisioned tools



Our methodological pillars







Co-creation

User research and engagement of key stakeholders over the course of R&D

Trustworthy AI

Compliance in practice with Trustworthy and Responsible Al regulations (i.a. ALTAI, EU Al act & MDR)

Clinical validation

Well-designed, sufficientlypowered studies for proofof-concept (PoC) prospective validation



Clinical studies



Ongoing

dBM-DEV study

Development, validation and verification of digital biomarkers

Germany, France, Spain 90 participants / 17 months **İİİİ**

To start in 2025

AI-PRA study

PoC* validation of PD risk model and associated software

UK, France, Spain 60 participants / 21 months To start in 2025

AI-PMP study

PoC validation and utility of PD progression model and associated software; PoC validation of medication response model

France, UK, Germany, Spain 100 participants / 21 months

*Proof of concept

Work breakdown

Work Package	Title	Duration
WP1	Management and coordination	M1-M48
WP2	Foundation, data curation and co-creation	M1-M48
WP3	Predicting PD risk, progression and medication response	M4-M27
WP4	The AI-PROGNOSIS digital health ecosystem	M3-M47
WP5	Clinical studies	M3-M48
WP6	Dissemination, communication and exploitation	M1-M48





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WP1 Management and coordination															Milestone
T1.1 Consortium and financial management															
T1.2 Scientific and technical coordination		D													D
T1.3 Quality assurance & risk management															U
T1.4 Ethics, legal and data management		[D D					D						D	Deliverable
T1.5 Innovation and intellectual property management								D						D	Deliverable
WP2 Foundation, data curation and co-creation															
T2.1 Domain and data landscape review				D					D						
T2.2 User research and co-creation		[D						D						
T2.3 Trustworthy AI development and evaluation framework			D						D						
T2.4 Datasets retrieval, harmonisation and curation															
WP3 Predicting PD risk, progression and medication response															
T3.1 RBD and daytime somnolence tracking						n			D						
T3.2 Motor and cognitive function tracking						U			U						
T3.3 Genetic profiling for PD risk assessment and prognosis															
T3.4 PD risk predictive modelling															
T3.5 PD progression predictive modelling						U			D						
T3.6 Medication response predictive modelling															
WP4 The AI-PROGNOSIS digital health ecosystem															
T4.1 Technical specification, system architecture and product backlog			D						D						
T4.2 Application design and development															
T4.3 Data storage and analytics infrastructure						D			D					D	
T4.4 System orchestration, verification and monitoring															
WP5 Clinical studies															
T5.1 Clinical study and eCRE management system															
T5.2 Digital biomarkers development, validation and verification (dBM-f	EV) study			D	D				D						
T5.3 Al-based PD risk assessment (Al-PRA) study					_				D	D				D	
T5.4 Al-based progression and medication response prediction (Al-PMF) study													D D	
WP6 Dissemination, communication and exploitation	, chang													5	
T6.1 Dissemination and communication planning, implementation and	nonitoring [D D													
T6.2 Clustering and networking activities						D				D				D	
T6.3 PD educational content development															
T6 / Regulatory approval and exploitation strategy								1						D	



Key R&D achievements so far

Digital health ecosystem

Clinical

studies

- Digital biomarkers of slowness of movement with good cross-dataset correlation with the clinical gold standard
- PD risk assessment model relying on digital measurements of mobility and sleep in daily life with promising performance in at-risk cohort
- Predictive model of progression sub-groups based on patients' phenotypic data and daily life digital measurements of physical activity
- Models predicting dyskinesia appearance based on multi-cohort clinico-demographic and medication history data

- >350 stakeholders engaged in cocreation activities leading to user requirements identification and translation to product features
- Study app on Google Play Store implementing the core smartwatch and active test data collection
- Alpha versions of mAl-Health, mAl-Care, and mAl-Insights
 Minimum Viable Products
- >40 participants in the ongoing dBM-DEV study on digital biomarkers
- AI-PMP study protocol submitted for ethics approval

Current tasks Answer question about la sleep Your partner can help you Motor function test Acquire a video during a s movement sequence. Show all tasks (3) Upcoming tasks Memory test

33 Days In Study

Last data sent August 27, 2024

Hello



response

Remember the image show

Respond rapidly or withho

previous step.

Reaction test

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Data analysis & Al

What's next

- Successful completion of the ongoing dBM-DEV study
- Cross-dataset validation of digital biomarkers
- Ethics approval and initiation of prospective clinical validation studies (AI-PRA and AI-PMP)
- Successful completion of the AI-PRA and AI-PMP studies
- Proof-of-concept validation of predictive models and early clinical utility evidence
- User acceptance evidence of AI-PROGNOSIS tools
- Delivery of AI-PROGNOSIS digital health ecosystem minimum viable products
- Mature exploitation and regulatory approval plan

2025

to

2027





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