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European Platform for Neurodegenerative Diseases

WP3 – SOP development

D3.5 – Landscape assessment of the best practices of digital biomarker collections

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WP3	
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[1] Use one of the following codes:
R: Document, report (excluding the periodic and final reports)
DEM: Demonstrator, pilot, prototype, plan designs
DEC: Websites, patents filing, press & media actions, videos, etc.
OTHER: Software, technical diagram, etc.

[2] Use one of the following codes:
PU = Public, fully open, e.g. web;
CO = Confidential, restricted under conditions set out in Model Grant Agreement;
CI = Classified, information as referred to in Commission Decision 2001/844/EC.

Description of Action

V1.0	**17/11/2023**

Document History

Version	Date	Status
V1.0	**17/11/2023**	**Final**
V2.0	**06/09/2024**	**Revision 1**
V3.0	**14/10/2025**	**Revision 2: Addresses the observations highlighted by the IHI project officer on 22/06/2025**

Abstract

The aim of the deliverable was to evaluate current best practices for collecting, storing, and analysing digital biomarkers (DBM) generated by dedicated projects within the IMI portfolio and related projects. The collection was envisioned to be collected in the course of EPND. The outcome of this benchmarking will provide input in the design of the prospective study with digital biomarkers in T5.6 and will be revised based on learnings within the project.

Methods

An online questionnaire (Qualtrics) was developed to assess information on digital biomarkers from the EPND cohorts. In the first part “General RMT information” we asked for general information about the study/cohort. In the second part “Specific RMT information” we collected information on the different remote monitoring technologies (RMTs) the cohorts are using. The questionnaire was critically reviewed by digital technology experts from RADAR-AD (Remote Assessment and Relapse - Alzheimer’s Disease) and EPND members from Alzheimer Europe, Gates Ventures, BBMRI, and Novartis.

Results

Digital Biomarker Questionnaire (see Annex below) and current results.

Discussion

There were no deviations from the Description of Action.

Conclusion

The EPND cohorts using remote monitoring technologies (RMTs) mostly use wearable sensors, smartphone apps, and ambient sensors mainly targeting gait and cognitive functions. Key challenges in data collection included battery drainage, technical problems, and usability issues. Overall satisfaction with the sensors was generally good, but further improvements in usability were recommended to reduce data loss and increase compliance rates.

Feedback from the cohorts has been limited. To increase the sample size, we plan to distribute the questionnaire to additional cohorts.To motivate additional cohorts to participate in the questionnaire, we are planning to offer a workshop on digital biomarkers to those interested, which will also serve the

initiation of collaboration between different cohorts. The next version of the questionnaire will include more detailed questions on acceptability, usability, and feasibility to better capture perceived challenges and mitigating strategies.The final results of the questionnaire will be re-evaluated at the end of the EPND project period.

1: INTRODUCTION

Digital biomarkers (DBM) are a promising way to explain, influence, and/or predict health-related outcomes by seizing the opportunities offered by digital technologies. Digital biomarkers are a product of both advancements in different fields, such as healthcare, engineering, and analytics, and the commercialization of digital products. They are often perceived as an online extension of a traditional biomarker. Unlike traditional biomarkers, however, data for DMB may be collected using sensors and computational tools, typically across multiple layers of hardware and software, though the measurements are often made outside the “physical confines of the clinical environment using home-based connected products”.

There are a number of RMTs to assess digital biomarkers including:

- Wearable devices (for assessing and monitoring functions)
- Smartphone and tablet-based apps (with/without participant interaction)
- Sensors (e.g., in smart beds)
- Radars (e.g., for in-home gait analysis)
- Smart homes (e.g., presence, appliance use, doors/windows)

Examples of collected data include:

- Sleep, heart rate, physical activity, circadian rhythm
- Social behaviour and phone usage
- Wearable camera to contextualize activities
- Gamified cognitive tasks, self-report questionnaires, voice and speech analysis, typing dynamics
- Sensors to monitor movements, door/cabinet opening/closing, water usage
- Driving performance

2: METHOD

A first version of the questionnaire was developed by VUmc. KCL extended and refined the questionnaire in an iterative process in collaboration with Alzheimer Europe, Gates Ventures, BBMRI, and Novartis as well as feedback from members of the RADAR-AD (Remote Assessment of Disease and Relapse – Alzheimer’s Disease) project team. The questionnaire was implemented using Qualtrics with support from AE. We then identified and reached out to key partner cohorts using digital biomarkers to fill out the two parts of the questionnaire (Part 1: General information; Part 2: Sensor information) and to complete an evaluation of the survey to allow further improvement for the future implementation of the questionnaire in additional cohorts within and outside of EPND that use digital biomarkers.

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3: RESULTS

The following cohorts answered the first and the second part of the questionnaire: ICICLE-PD (https://www.bam-ncl.co.uk/iciclepd), PARKNET, GMAD/COSCODE, CBAS (www.cbas.cz), Ataxia (SCA Registry, SPORTAX, ESMI, EOA Registry, EFACTS), CLEMENS, OPDC Discovery Cohort (www.dpag.ox.ac.uk/opdc/opdc-home), DEEPSPA, RADAR-AD (wwww.radar-ad.org), LuxPark Cohort (https://parkinson.lu/), HEBA Cohort (https://heba.lu/en/), RBD Cohort, and the Mobility-APP study. The Alzheimer Dementia Cohort (ADC, www.alzheimercentrum.nl) only answered the first part of the questionnaire. The cohorts Campaign and PICNICS only answered few questions of the first questionnaire. We therefore report results from 14 cohorts for the first part of the questionnaire and from 13 cohorts for the complete questionnaires. Note that the LuxPark, HEBA, RBD and Mobility-APP cohorts used the same sensor and were reported jointly in the second part of the questionnaire.

The first part of the study assessed general information (**Table 1**).
Populations studied: The largest population that is investigated in the key EPND cohorts is Alzheimer's disease (AD) (28%), followed by Parkinson's disease (PD) (24%) and Lewy body disease (DLB) (16%). Other forms of dementia are investigated in (20%) of the cohorts, including frontotemporal lobar degeneration (FTLD), subjective cognitive decline (SCD), mild cognitive impairment (MCI), vascular dementia, corticobasal degeneration (CBD), and progressive supranuclear palsy (PSP). 12% of the studies moreover investigate other diseases, including ataxia, atypical Parkinsonism, and hypochondria. The majority (78.6%) of studies furthermore studied subpopulations.

Types of RMTs used: The majority of studies use wearable sensors (25%) or other sensors (25%) such as smartphone cameras, phone connection, tablet-based questionnaires, followed by smartphone-based (16.7%) and tablet-based (16.7%) sensors with interaction and finally smartphone-based (8.3%) and tablet-based (4.2%) sensors without interaction. Only one cohort used fixed/ambient sensors.

Table 1. Overview of cohorts and studies using RMTs.

Cohort	Populations (N)	Types of RMTs	Objectives for using RMTs
ICICLE-PD	Parkinson's disease (N=212)	- Wearable sensors	- Longitudinal monitoring of motor function - Early detection of disease - Developing digital biomarkers - Assessment on a clinical trial (non-interventional)
PARKNET	Parkinson's disease, Atypical Parkinsonism (N=700)	- Wearable sensors - Smartphone sensors: with interaction - Tablet-based sensors with interaction - Tablet-based sensors without interaction	- Longitudinal monitoring of cognitive and motor function - One-time measurement of cognitive and motor function - Early detection of disease - Reaching remote patient populations - Developing digital biomarkers - Assessment on a clinical trial (interventional and non-interventional)
GMAD-COSCODE	Alzheimer's disease,Parkinson's disease,Dementia	- Wearable sensors	- Longitudinal monitoring of other function: physical activity, sleep

	with Lewy bodies, vascular dementia (N=50)		
CBAS	Alzheimer's disease, Dementia with Lewy bodies, FTLD, PSP, CBD (N=3000)	Planned collaboration with www.terrapino.com mobile app	- Longitudinal monitoring of cognitive function and motor function - One-time measurement of cognitive function - Early detection of disease - Reaching remote patient populations - Supporting patients (e.g. prompting) - Developing digital biomarkers - Assessment on a clinical trial (interventional and non-interventional)
Ataxia (SCA Registry, SPORTAX, ESMI, EOA Registry, EFACTS)	Ataxia (N~350)	App based assessment via smartphone camera	- Longitudinal monitoring and one-time measurement of motor function - Developing digital biomarkers - Assessment on a clinical trial (interventional and non-interventional)
CLEMENS	Alzheimer's disease, Dementia with Lewy bodies, FTLD (N=5169)	Centralized electronic information system	- Longitudinal monitoring of cognitive and motor function - Longitudinal monitoring of affective function - One-time measurement of cognitive, motor and affective function - Early detection of disease - Developing digital biomarkers - Assessment on a clinical trial (interventional and non-interventional)
OPDC Discovery Cohort	Parkinson's disease (N=1600)	- Wearable sensors - Smartphone sensors with interaction - Tablet-based sensors with interaction	- Longitudinal monitoring of cognitive function and motor function - One-time measurement of cognitive function and motor function
DEEPSPA	Alzheimer's disease, MCI, SCD (N=140)	- Smartphone sensors with interaction - Tablet-based sensors with interaction - Landline or mobile phone connection	- Longitudinal monitoring of cognitive function and affective function - Early detection of disease - Reaching remote patient populations - Developing digital biomarkers - Assessment on a clinical study (non-interventional)
ADC	Alzheimer's disease, Dementia with Lewy bodies, FTLD (N~7000)	- Smartphone sensors without interaction	- Longitudinal monitoring and one-time measurement of cognitive function - Early detection of disease - Developing digital biomarkers

		- Tablet-based sensors with interaction - Tabletbased test/ questionnaire	
LuxPark cohort HEBA cohort RBD cohort Mobility_APP study	Parkinson's disease and PDD (N=743), PSP (N=51), DLB (N=19), MSA (N=12), VasP (N=12), Healthy controls N=811) Parkinson's disease (Target N=300) Parkinson's disease (N=107) Parkinson's disease (N=20)	- Wearable sensors	- Longitudinal monitoring and one-time measurement of motor function - Early detection of disease - Reaching remote patient populations - Developing digital biomarkers - Assessment on a clinical trial (interventional and non-interventional)
RADAR-AD	Alzheimer's disease (N=220)	- Wearable sensors - Smartphone sensors with and without interaction - Fixed/ambient sensors - Driving sensor	- Longitudinal monitoring and one-time measurement of cognitive and motor function - Early detection of disease - Developing digital biomarkers - Assessment on a clinical trial (interventional and non-interventional)

Abbreviations and study names: ADC - Alzheimer Dementia Cohort; CBAS - Czech Brain Aging Study; DEEPSPA - Deep speech analysis for cognitive assessment in clinical trials; EFACTS - European Friedreich's Ataxia Consortium for Translational Studies; EOA – Early Onset of Ataxia; ESMI – European Spinocerebellar Ataxia Type 3/Machado-Joseph Disease Initiative; FTLD – Frontotemporoal lobar degeneration; GMAD-COSCODE – Brain connectivity and metacognition in persons with subjective cognitive decline; HEBA –Healthy Brain Aging Study ; ICICLE-PD - The Incidence of Cognitive Impairment in Cohorts with Longitudinal Evaluation-PD; LuxPark – The Luxembourg Parkinson's Study; Mobility_APP – Mobility in Atypical Parkinsonism: a Multicentric Randomized Interventional Study of Gait Specific Physiotherapy: OPDC - Oxford Parkinson's Disease Centre; RADAR-AD – Remote Assessment of Disease and Relapse – Alzheimer's Disease; RBD – Rapid Eye Movement Behavior Disorder; SCA - Study of Cerebellar Ataxia; PSP – Progressive supranuclear palsy; CBD – corticobasal degeneration

Five out of 13 cohorts indicated having developed the sensor themselves. For the RADAR-AD cohort the web application "Banking App", has been developed by the CERTH-ITI research group and the Mezurio smartphone application has been developed by the University of Oxford. PARKNET developed the computer-based cognitive training (CoRe). The Ataxia cohort developed SARAhome. CLEMENS developed the centralized electronic information system CLEMENS Database. The OPDC Discovery Cohort developed the OPDC motor smartphone test.
Only three cohorts reported having had previous experience with sensors, of which PARKNET had used their self-developed sensor CoRe previously, while ICICLE-PD had used ActivPal, a wearable to assess physical activity, and the ADC had worked with Neurokeys, a digital health smartphone

keyboard and a tablet-based assessment developed by Winterlight labs, which monitors cognitive impairment through speech.

The second part of the study assessed specific sensor information. The main domain targeted throughout the projects is gait (**Table 2**).

Table 2. Overview of sensors used and targeted domains.

Cohort	Sensor name	Model	Version	Location	Targeted domains
ICICLE-PD	Axivity	AX3	NA	Lower back, chest, waist or pocket, wrists, ankle	Gait, functional mobility under lab-based assessment and 7-day real-world assessment
ICICLE-PD	APDM	Opals	2012	Head, C7, lower back, ankles	Gait and functional mobility under lab-based assessment
PARKNET	Computer-based cognitive training (CoRe)	NA	NA	Touch-screen computer	Cognitive function and gait
GMAD-COSCODE	ActiGraph	GT9X	NA	Wrist	Physical activity, sleep
CBAS	Planned collaboration with www.terrapino.com mobile app	NA	NA	App-based assessment	NA
Ataxia (SCA Registry, ESMI, SPORTAX)	SARAhome	NA	NA	App-based assessment via smartphone camera	Ataxia (severity)
CLEMENS	Centralized electronic information system	NA	NA	NA	Cognitive, motor, affective, functional, radiological, biological data
OPDC	Axivity	AX3 and AX6	NA	Hand/wrists	Motor (speech, tremor, dexterity, stand, walk, reaction time), gait, multiple cognitive domains
DEEPSPA	Delta application	NA	NA	Phone based	Memory, word fluency
LuxPark cohort; HEBA cohort; RBD cohort; Mobility_APP study	Portabiles	Mobile GaitLab	V1	Upper part of footwear (e.g. shoes)	Gait and mobility
RADAR-AD	pRMT	Available for Android	NA	At-home	Spatial navigation and memory, use of devices, interpersonal interaction,

					motivation, signs of apathy or withdrawal
RADAR-AD	Mezurio	Available for iOS and Android	At-home	RADAR-AD	Cognition, sleep quality and circadian rhythms, use of devices, motivation, signs of apathy or withdrawal
RADAR-AD	Wearable camera	Vicon Autographer	NA	At-home	Self-care, interpersonal interaction, motivation, signs of apathy or withdrawal
RADAR-AD	Fitbit	Fitbit Charge-3	NA	Wrist	Sleep quality and circadian rhythm
RADAR-AD	Physilog	Physilog 5	NA	Feet and hip	Gait (during timed up-and-go task), and cognition (during motor-cognitive dual-tasking)
RADAR-AD	CANedge	CANedge1	NA	Car	Driving behavior
RADAR-AD	Axivity	Axivity AX3	NA	Wrist	Physical activity, activities of daily living
RADAR-AD	Altoida	Available for iOS and Android	V1, V2	Tablet, at-home	Cognition, multiple domains
RADAR-AD	Banking App	Available for iOS and Android	NA	App-based assessment via smartphone	Managing finances
RADAR-AD	FIBARO	NA	NA	Fixed/ambient sensors in home environment (door/window, motion sensor, panic button, flood sensor)	Self-care, self-management
RADAR-AD	DREEM	Dreem3	NA	Head	Sleep quality and circadian rhythm

Data collection and data privacy: Participants are informed about data collection and intended use of data in the informed consent in most instances (95.2%). Before data entry, security was ensured using a password-protected access to a personal, anonymized account (31.8%) and/or a password-protected access to a dashboard of a manufacturer (researchers) (27.3%) or another means (18.2%). In some instances, data entry was not applicable (22.7%). The data collection and management is compliant with the GDPR in the majority of studies (95.4%), whereas a minority (4.6%) is compliant with HIPAA. A total of 3 of the sensors used in the cohorts collect identifiable data, while 17 sensors collect non-identifiable data. GPS and Bluetooth data is collected by 3 sensors while 17 sensors do not collect GPS or Bluetooth data. Data is encrypted in the majority of reported sensors (64.3%).
For most digital technologies the data is stored locally (offline) on the device and uploaded to a secure server upon returning the device (31.0%), directly uploaded to secure study server (27.6%), or temporarily cached on the device until an appropriate connection is available (20.7%). In 13.8% the data are first transmitted to manufacturer servers and then uploaded to secure study server from there. Data from the sensor is stored in another way in 3.45% of the devices (saved locally twice before

uploaded to secure server). Data are automatically deleted from the device after upload in 3.45% of the devices.
Security during storage is ensured mostly by only allowing cohort partners to access the platform (57.6%), followed by password-protected access (39.4%), or in one instance (3.0%) in another way (only PI or Head IT can access the platform).

Data monitoring parameters: About one third of the sensors offer live data monitoring for study staff (31.6%), while live data monitoring for participants is available in 26.3%. 50% of the sensors allow real-time data transfer. Manufacturers offer solutions for troubleshooting for 65% of the sensors.
Raw data is available for 39.1% of sensors, while processed or compressed data is available for 26.1% and outcome parameters in 34.8% of the sensors.

Data analysis: The sensor has processing algorithms to extract meaningful outcome parameters that are developed by the manufacturer (40%) or by the study team (45%). 15% of the sensors do not have processing algorithms. For 75% of the sensors data is available to quantify the working of the sensor (e.g., commitment rate, compliance rate, task completion, wear time, etc.). And for 76.5% of the sensors data is available to quantify the clinical value of the sensor (e.g., discriminative power between (clinical) sub-groups, correlation with clinical gold standards, etc.).

General information about the sensor: Subjective data showing the working of the sensor from participant feedback is available for 57.1% of the sensors and from focus groups or patient advisory groups for 9.5% of the sensors. Two studies published results related to feasibility and usability of the AX6 (Debelle et al., 2023) and of the RMT's used in RADAR-AD (Muurling et al., 2024). The feedback was mostly collected at the end of study and were related to comfort, ease of use and likelihood of future use. Several cohorts used the System Usability Scale (Brooke, 1996). The challenges highlighted included rapid battery drainage (e.g., in phone and car apps), technical problems, the quality of the experience varying depending on the phone model, and wearables being made from uncomfortable materials. Additionally, some devices were considered too complex for individuals with cognitive impairments to use effectively or participants forgot to use them. To ensure high usability and feasibility and low data loss, two cohorts developed a SOPs for sensor set-up and programming and data download, cohorts suggested to regularly check battery levels and data quality, to not update an app in the middle of a study, to make sure all participants use the same device if possible, to ensure in-depth training when handing out the devices (e.g., instruct participants to not wear cameras during private activities (e.g., toilet) and to provide a helpline. Ambient sensors should be placed carefully and should not measure overlapping areas. Flood sensors were reported to often malfunction. Overall satisfaction with the sensors was generally good with the majority being satisfied (68.4%) and acceptable (21.1%), followed by very satisfied (10.5%). The current developmental status of the sensors is in most cases is a CE marking for consumer use (23.1%) and developmental stage (not CE marked) (23.1%), followed by being qualified for clinical use (15.4%). 11.5% of sensors are marked under EU medical device directive or regulation (MDR) and 7.7% FDA cleared as a medical device.

4: CONCLUSIONS

The EPND cohorts using remote monitoring technologies (RMTs) mostly use wearable sensors, smartphone apps, and ambient sensors. Fourteen cohorts answered the first part of the questionnaire,

while thirteen completed both parts. The largest populations studied were Alzheimer's disease (28%) and Parkinson's disease (24%) mainly targeting gait and cognitive functions. While 5 out of 14 cohorts reported having developed their own sensor, few reported having prior experience with sensor use. Most cohorts used sensors for longitudinal monitoring, early detection, and developing digital biomarkers, ensuring data privacy and security. Key challenges in data collection included battery drainage, technical problems, and usability issues. Overall satisfaction with the sensors was generally good, but further improvements in usability were recommended to reduce data loss and increase compliance rates.

Feedback from the cohorts has been limited. To increase the sample size, we plan to distribute the questionnaire to additional cohorts funded by IHI and external cohorts. To encourage participation, we will offer a workshop on digital biomarkers, which will facilitate collaboration among different cohorts. The next version of the questionnaire will include more detailed questions on acceptability, usability, and feasibility to better capture perceived challenges and mitigating strategies. The current version is focused on sensors used for assessment (digital biomarkers) rather than interventions or database systems/platforms. Nonetheless, results from a cognitive training application (PARKNET cohort) and a centralized electronic system (CLEMENS) were included in the analysis. The final results of the questionnaire will be re-evaluated at the end of the EPND project period.

Repository for primary data

A scoring criteria / evaluation document was developed to ensure consistency when engaging with all the potential cohorts. The documents titled “EPND Digital Endpoints survey, part 1_CLEAN” and “EPND Digital Endpoints survey, part 2_CLEAN” and the survey feedback have been filed in the relevant section within the EPND filing repository (EPND SharePoint/WP3/Task 3.5 Best practices of digital biomarker collection/Data Task 3.5).

References

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European Platform for Neurodegenerative Diseases

Questionnaire – Best practices of Digital Biomarker Collections

EPND T3.5 – Questionnaire template

This questionnaire concerns studies on remote measurement technologies (RMTs) in neurodegenerative patient populations.

PART I: General information

Please forward this survey to the person responsible for device selection and/or management.
The **European Platform for Neurodegenerative Diseases EPND** (https://epnd.org/) aims to accelerate biomarker discovery, development, and validation across Europe and the world. To address the growing challenge of data sharing and collaboration, EPND is building a scalable and self-sustaining platform to facilitate access to neurodegenerative disease data and clinical samples. The neurodegenerative disease research community can use this secure, accessible platform in a collective effort to develop diagnostic tools and treatments.
The aim of this survey is to gather information on the use of remote measurement technologies (RMTs) in projects investigating neurodegenerative patient populations and provide an overview of best practices of digital biomarker collection. For this, we will evaluate current best practices for collecting, storing, and analyzing digital biomarkers from projects within the IMI portfolio and related projects. Upon completion of the survey, the analysis and deliverable will be made available to the information sources.

In the first part "*General RMT information*" we are asking for general information about the study/cohort. In the second part "*Specific RMT information*" we collect information on the different RMTs you are using.

Tick multiple answer boxes where applicable. If you wish to edit previous responses, navigate back through the survey using the "previous page" button.

Please copy/paste the second part for each RMT you are using.

Please enter your name:

Please enter your email address:

What is your current job position?

Name of the cohort or research study:

Study website (if available):

Clincialtrials.gov ID or similar (if available):

What institution(s), department(s) or clinic(s) is the study/cohort associated with?

Please indicate the population(s) you study:
☐ Alzheimer's disease
☐ Parkinson's disease
☐ Lewy body disease
☐ Other form of dementia, namely:
☐ Other diseases, namely:

Study population size:

Does your study include specific sub-populations? *E.g., preclinical/prodromal stages, mixed pathology.*
Yes ☐ No ☐
If yes, please specify:

Please share references to any papers (related to RMTs) that were published from this study/cohort:

If relevant, please describe any other special features of your study/cohort:

General information on the sensors

What types of RMTs are used in your study? (select all options that apply)

- ☐ Wearable sensors (e.g., wrist-worn)
- ☐ Smartphone sensors: WITH interaction (e.g., cognitive test)
- ☐ Smartphone sensors: WITHOUT interaction (e.g., typing dynamics)
- ☐ Tablet-based sensors: WITH interaction (e.g., cognitive test)
- ☐ Tablet-based sensors: WITHOUT interaction (e.g., typing dynamics)
- ☐ Fixed/ambient sensors (e.g., door sensors)
- ☐ Other, namely:

What are your objectives for using RMTs? (select all options that apply)

- ☐ Monitoring functions (longitudinal)
  - ☐ Cognitive ☐ Motor ☐ Affective ☐ Other, please specify:
- ☐ Assessing functions (one-time measurement)
  - ☐ Cognitive ☐ Motor ☐ Affective ☐ Other, please specify:
- ☐ Early detection of disease
- ☐ Reaching remote patient populations
- ☐ Supporting patients (e.g., prompting)
- ☐ Supporting carers/health professionals
- ☐ Developing digital biomarkers
- ☐ Assessment on a clinical trial (interventional, e.g., study drug)
- ☐ Assessment on a clinical trial (non-interventional, e.g., observational)
- ☐ Other, namely:

Have you developed some of these sensors yourself?

Yes ☐ No ☐

If yes, please specify:

Have you used (other) sensors previously?

Yes ☐ No ☐

If yes, please specify:

Please explain why you selected these sensors and how you selected them:

PART II: Specific sensor information

This part will be repeated for each sensor. Please copy-paste this part for each sensor.

For each sensor, please answer the following questions.

Sensor 1 (name): **Please enter your name:**

General information on the sensor:

Sensor name (e.g. Fitbit smartwatch):

Sensor model (e.g. Fitbit Charge 4):

Sensor version (e.g. v2.1):

Sensor location (e.g. wrist, door):

Data collection and data privacy:

Which cognitive, motor, affective or functional domain(s) was/were targeted with the sensor?

Is the data collection and intended use of data (e.g., future data sharing) explained in the informed consent?

- ☐ Yes
- ☐ No
- ☐ I'm not sure
- ☐ Other, please specify.

How is security ensured before data entry?

- ☐ Password protected access to personal anonymous account (participants and researchers)
- ☐ Password protected access to dashboard of manufacturer (researchers)
- ☐ Not applicable
- ☐ Other, please specify.

Is the data collection and management compliant with local privacy applicable laws?

- ☐ GDPR compliant (Europe)
- ☐ HIPAA compliant (USA)
- ☐ Other, please specify.

Does the sensor collect identifiable data?
Yes ☐ No ☐ I don't know ☐
If yes, please specify.

Does the sensor collect GPS data?

Yes ☐ No ☐ I don't know ☐

Does the sensor collect Bluetooth data?
Yes ☐ No ☐ I don't know ☐

Are the data encrypted?
Yes ☐ No ☐ I don't know ☐

How and where do you store data from this sensor? (please tick all options that apply)
☐ Data are first transmitted to manufacturer servers and uploaded to secure study server from there
☐ Data are directly uploaded to secure study server
☐ Data are temporarily cached on the device until an appropriate connection is available
☐ Data are automatically deleted from the device after upload
☐ Data is stored locally (offline) on device and uploaded to secure server upon returning the device
Other, please specify.

How do you ensure security during storage (e.g., how is access to the database controlled)?
☐ Only cohort partners can access the platform
☐ Password protected access
Other, please specify.

Data monitoring:

Did the sensor offer solutions for live data monitoring for the study staff?
Yes ☐ No ☐ Not applicable ☐
If yes, please specify.

Did the sensor offer solutions for live data monitoring for the participant?
Yes ☐ No ☐ Not applicable ☐
If yes, please specify.

Did the sensor offer solutions for real-time data transfers (*e.g., application programming interface API*)? Yes ☐ No ☐ Not applicable ☐
If yes, please specify.

Did the manufacturer offer solutions for troubleshooting/helpdesk in case of issues with data flow?
Yes ☐ No ☐
If yes, please specify.

Which type of data is available from the sensor (please check all that apply, and provide the relevant details):
☐ Raw data at a frequency of Hz.
☐ Processed/compressed data at temporal level (e.g.., daily, hourly).
Please specify temporal level:
☐ Outcome parameters. Please specify:

Data analysis:

Does the sensor have processing algorithms to extract meaningful outcome parameters?
☐ Yes, developed by manufacturer
☐ Yes, developed by study team
☐ No

Is there data available to quantify the working of the sensor (*e.g., commitment rate, compliance rate, task completion, wear time, etc.)*?
Yes ☐ No ☐ Not applicable ☐
If yes, please specify.

Please provide references if available:

Is there data available to quantify the clinical value of the sensor (e*.g., discriminative power between (clinical) sub-groups, correlation with clinical golden standard, etc.)*?
Yes ☐ No ☐ Not applicable ☐
If yes, please specify the main outcomes.

Please provide references if available:

General information:

Do you have any subjective data showing the working of the sensor (*e.g., personal experiences, patient logs/interviews, focus groups, etc.)*?

☐ No
☐ Participant feedback after the end of the study
☐ Feedback from focus groups or patient advisory boards

Please specify the main outcomes (e.g., ease of use, comfort).

To the best of your knowledge, what is the current developmental status of the sensor? Please tick all options that apply.

☐ Development stage (not CE marked, for research purposes only)
☐ Qualified for clinical use
☐ CE marked for consumer use
☐ CE marked under EU medical device directive or regulation (MDR)
☐ FDA cleared as medical device (USA)
☐ Other, please specifcy:

If it is a medical device, what is the current classification?
Please specify:

Please share specific best practices regarding the sensor (e.g., do not update an app in the middle of a trial, ensure weekly monitoring, sensor placement/overlap etc.).

How satisfied are you with the sensor (*i.e., would you recommend it to others*)?

Very satisfied	Satisfied	Acceptable	Poor	Very poor
☐	☐	☐	☐	☐

Additional comments:

Survey evaluation

How did you find the following aspects of the survey:

	Very good	Good	Acceptable	Poor	Very poor
Aim of the survey	☐	☐	☐	☐	☐
Content of the questions	☐	☐	☐	☐	☐
Answer options	☐	☐	☐	☐	☐

Did you have all the necessary information to answer the questions?

Yes ☐ No ☐ I don't know ☐

If no, what information were you missing?

How do you estimate the effort to complete the survey?

☐ Too high
☐ High
☐ Moderate
☐ Low

Was the survey intuitive to navigate?

☐ Yes
☐ Somewhat
☐ No

Please provide suggestions for improvement: