Topic: Development and validation of technology enabled, quantitative and sensitive measures of functional decline in people with early stage Alzheimer's Disease (RADAR-AD)

All information regarding future IMI Call topics is indicative and subject to change. Final information about future IMI Calls will be communicated after approval by the IMI Governing Board.

Part of the Remote Assessment of Disease and Relapse Programme (RADAR)

Introduction to the RADAR programme and problem statement

With rising health-care costs, all health care stake-holders (payers, physicians, patients) are shifting the onus from a 'pay for intervention' to a 'pay for performance' model. This change in focus towards overall outcomes will drive a paradigm shift towards disease interception, i.e. move from a 'diagnose and treat' to a 'predict and pre-empt' approach. In this model, pre-emption, i.e. intervening early enough in the disease process to prevent serious effects of the disease associated with progression, becomes a critical component of managing chronic disease. Additionally, as the trajectory of chronic diseases is often cyclical, this offers multiple interception opportunities to prevent serious decline — for example, predicting and pre-empting recurrence/suicidality in severe depression, hypoglycaemic event in diabetes, or exacerbations in multiple sclerosis (MS), Chronic Obstructive Pulmonary Disease (COPD) or asthma.

Measuring physiological and activity-based parameters remotely and continuously via unobtrusive on-body sensors or smartphones has the potential to revolutionise our ability to predict and pre-empt harmful changes in disease trajectory. Developing methods for real-time identification of behavioural and physiological patterns (bio-signatures) that culminate in relapse is of great importance: early detection and communication of "red flags" to both patients, care-givers and providers can prompt help-seeking behaviour and deployment of just-in-time interventions that may prevent relapse episodes, effectively altering one's clinical trajectory. A platform to acquire data in a real world setting would also enable the development of measures of real world effectiveness of medicines.

RADAR is a multi-topic programme in IMI2 that aims to overcome three key bottlenecks in developing such methods:

1) a lack of fundamental disease understanding into the signals and fluctuations in disease state,

2) the lack of clear policy, guidelines and pathways to develop and license "pre-emptive" therapeutic strategies that use such digital monitoring and remote assessment technology, and

3) the immaturity of the technology platforms, including sensors technology, data exchange standards, continuous sensor data access and stream processing technology, and the analytical methodology, where today research is hampered by ad-hoc solutions that are not suitable to develop healthcare products in the longer term.

Need and opportunity for public-private collaborative research under the RADAR programme

The RADAR programme aims to test if new pre-emptive therapeutic development and clinical care strategies based on remote continuous monitoring are both scientifically feasible and also practically feasible as part of a wider healthcare system.

Scientific feasibility will be performed via the individual topics of the RADAR programme to focus on the specifics of different disease areas. The first topic, published as part of IMI2 Call 3, studied the fluctuation of

the chronic diseases of depression, Multiple Sclerosis and epilepsy, using remote monitoring technology, to provide a foundation for developing a novel paradigm based on prediction and pre-emption. The current topic, launched as part of IMI2 Call 12 will study the development and validation of technology-enabled, quantitative and sensitive measures of functional decline in people with early stage Alzheimer's disease.

Research in these areas needs to bring together physicians, patient groups, sensor manufactures, ICT providers, data management and analyst specialists with the pharmaceutical industry.

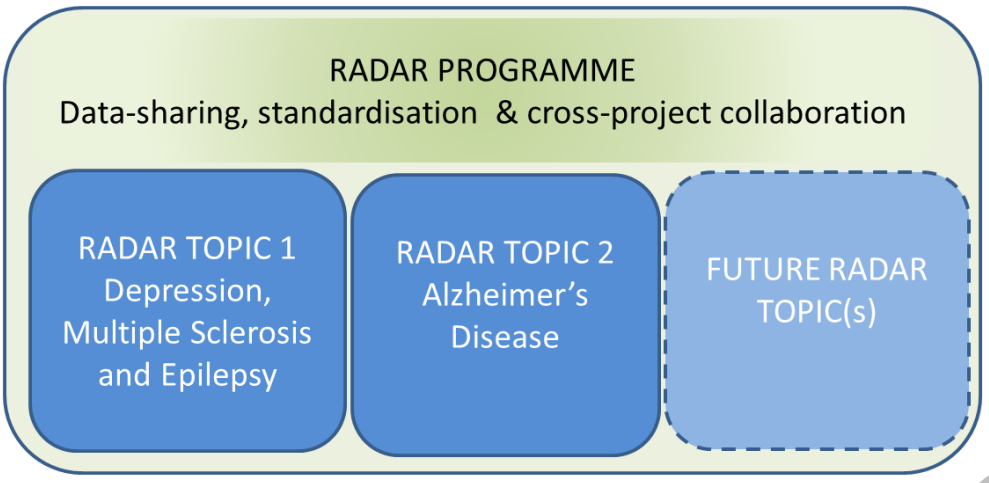
Introducing a drug development and a clinical care strategy based on such science and technology requires a second type of publicprivate research to be undertaken to 1) develop policy for the regulatory and licensing pathways to deliver a digital intervention 2) understand and develop a framework to support new digital based interactions between patients and health care providers. This will require key stakeholders such as patient groups, regulators, healthcare providers, communications organisations, device manufactures and infrastructure providers to understand and develop a roadmap of how such interventions can be deployed effectively and safely.

Overall objectives of the RADAR Programme

The key objective of the RADAR programme is to develop the foundational components of a digital platform to "Improve patient outcomes through remote assessment". These components will be split into several topics with some cross-cutting themes co-ordinated across all topics. Considering the overall objective of the RADAR programme, the actions stemming from the different topics will be deemed to be complementary to each other. Consequently, the selected consortia will have to conclude collaboration agreements to coordinate their work under the different Grant Agreements.The respective options of Article 2, Article 31.6 and Article 41.4 of the IMI2 Model Grant Agreement will be applied.

RADAR Programme Architecture

The full RADAR programme will consist of several topics that are resourced and managed independently but will join forces in key areas such as technological approach and data sharing. The RADAR-CNS action covering depression, MS and epilepsy was generated from the topic launched under IMI2 Call 3 and has developed a key part of the core platform for the collection, transmission, storage, analysis and visualization of the relevant functional measures for the whole RADAR platform, which can act as the basis for the integration of further modules provided by other RADAR initiatives. The core platform will be extended with new or enhanced capabilities wherever identified as beneficial for the topics at the core of the present project on patients with dementia, hence beyond RADAR-CNS, to make sure the platform can evolve with the state-of-the–art in the field. Applicants must reserve some resources to facilitate these cross-projects activities and consider this key aspect when developing their solutions to insure interoperability through the horizontal platform. Under IMI2 Call 12, one additional topic will be launched in Alzheimer's disease.



Future RADAR Topics

At a later stage, the IMI2 JU may publish additional topics which will become part of the RADAR programme.

In that respect, potential applicants must be aware that all or some of these additional topics, if exceptionally needed and so foreseen in the applicable annual work plan, may be restricted to those consortia already selected under this or previous calls in order to enhance their results and achievements by extending their duration and funding.

Consortia will be entitled to open to other beneficiaries as they see fit to fill critical skills gaps in the consortia that reflected the extensions in these work plans.

General Principles for all Projects Conducted under the RADAR Programme:
Data Sharing and interoperability

Data sharing and interoperability is paramount to the success of the RADAR programme. The framework supporting this data sharing (i.e., the type of data to be shared and the access governing data sharing) will be fully established during the preparation of the full proposals in line with IMI2 Intellectual Property (IP) policy and considering the overall approach agreed upon in the other RADAR projects. EFPIA members and consortia partners will be committed to sharing all data (clinical, bio-sensor etc.) available to, or generated by the RADAR program amongst all members of a RADAR topic, and across topics as required. In addition to data, RADAR constituents will also share, among others, domain practices and expertise developed with respect to data management procedures, usability, regulatory and policy pathways etc. across the RADAR program and externally as required by IMI policy and procedures. It is expected that any system built within the RADAR programme adheres to well accepted data standards, where applicable, to ensure compatibility and interoperability with other systems both within the RADAR programme and more widely. It is to be noted that the digital platform in development should be able to interface to different kind of sensors and devices, some of them will be tested in the frame of the present project.

Development and validation of technology enabled, quantitative and sensitive measures of functional decline in people with early stage Alzheimer's Disease (RADAR-AD)

Topic details

Action type	Research and Innovation Actions (RIA)
Submission & evaluation process	2 Stages

Specific challenges to be addressed

Alzheimer's Disease (AD) today is the leading cause of dementia and one of the most common causes of disability and loss of independence among the elderly. The World Health Organization estimates the cost of dementia disorders in the European Union alone to be more than 160 Billion Euro per annum. This cost will continue to rise dramatically as the numbers of people with dementia in European Union are projected to nearly double every 20 years, due to Europe's aging demographic.

Early stages of AD are associated with cognitive decline, overlapping with increasing functional decline (impairments in the ability to perform daily activities of living), leading to progressive loss of independence and escalation of caregiver burden and medical costs. While much effort has gone into developing sensitive measures of cognition, today there do not exist similar measures of subtle functional changes in early AD subjects which have direct impact on disease burden.

Recent data from long-term longitudinal cohorts have begun to delineate cognitive domains and functional tasks that are most affected by AD pathology. These include cognitive domains related to episodic memory, spatial orientation, processing speed and functional read-outs such as changes in ability to perform simple financial calculations, ability to use phone/computer, gait speed, driving performance, and ability to adhere to medications, amongst others. In addition, AD and related co-morbidities also have an effect on stress, mood and sleep. Impairment of these cognitive domains, functional capabilities and mood and sleep can be captured by new technology methods such as wearables, mobile devices and home based sensor technologies.

The overall goal of the action generated from the RADAR AD topic would be to measure functional status and some key underlying cognitive abilities of AD patients in order to identify meaningful differences compared to normal status using a robust, scalable technology-enabled system that can be deployed in real-world settings to monitor and improve real-world outcomes that are relevant to patients and their care-givers. While the main focus of the topic is to understand functional decline in subjects with Mild Cognitive Impairment (MCI) and in the early stages of AD, nevertheless the late stage AD monitoring should be also considered in order to validate the results and show relationship of functional measures with all stages of AD.

Need and opportunity for public-private collaborative research

The ability to track and measure functional decline in AD populations to shorten clinical development and generate payer-relevant evidence of real-world impact of therapeutic interventions is a precompetitive need in the field of Alzheimer's drug development. The development and validation of technology-enabled functional endpoints in AD will require public-private collaboration between AD clinical sites, home-based care-givers, sensor manufacturers, analytics experts and software developers. In addition, successful implementation will also require a collaborative partnership with AD patient advocacy groups, the care-giver community and privacy and bioethics experts to ensure that the technology solutions developed in the project can be adopted in the real world. The implementation of the project involving all these stakeholders will ensure the sustainability of the results. This need to have expertise from diverse fields and different industries as well need to align with patients and regulators implies that goals of the RADAR-AD topic are best accomplished in a public-private consortium setting.

Scope

The main goal of the action to be created from this topic is to develop a digital platform to measure a valid and meaningful combination of smartphone, wearable and/or home sensor based parameters that can detect early and subtle functional decline in early Alzheimer's patients (mild AD, MCI or earlier). However, the system generated should be tested in all stages of AD to establish validity.

The following activities will be within the scope of proposals to achieve the topic goals:

- analysis of existing longitudinal AD datasets to identify functional domains or markers that are specific and sensitive to early stages of Alzheimer's progression and most predictive of deleterious long-term outcomes such as loss of independence and nursing home entry. Such functional domains should include real-world activities such as ability to perform financial calculations, utilize the phone, navigate around the house/neighbourhood, adhere to medication schedule, and other everyday tasks that require episodic memory and executive function. The applicants should identify and gain access to the appropriate longitudinal datasets that allow retrospective analysis of cognition, function and care-giver/payer relevant long-term outcomes;
- obtain and incorporate feedback from regulators regarding potential use of technology-enabled functional end-points in registration studies of drugs;
- obtain and incorporate feedback from care-givers and payers to ensure that functional domains being measured are relevant and meaningful;
- implement a platform technology-enabled system of sensors and devices to continuously analyse data from identified functional domains, including smartphone, wearable and/or fixed home based sensors. This can concern measures that are passive (e.g. ability to use phone or computer key-board, gait speed etc.), or active (a challenge task requiring financial calculations etc.) with respect to patient interaction;
- validate the platform technology-enabled function assessment system in a real-world clinical setting. This validation study will require short-term (~ 3 months) assessment of function to establish a reliable cross-sectional measure of function using the built sensor-based system in cognitively normal, MCI,mild AD and moderate AD cohorts. The functional measures will be optimized for the following:
- ability to best differentiate different stages of the Alzheimer's disease (i.e. cognitively normal vs. MCI vs. mild AD vs. moderate AD). Main focus will be to identify functional measures that best separate cognitively normal from early MCI patients;
- correlation with cognitive domains known to be effected in Alzheimer's (e.g. episodic memory);
- correlation with established paper and pencil (self-reported) scales to measure function in AD.
- correlation with known biomarkers of pathology, such as Positron Emission Tamography (PET) and Cerebro Spinal Fluid (CSF) measure, if available;
- correlation with care-giver burden and health care utilization costs;
- ease of use and adherence by technology users in real-world clinical settings.

Collaboration agreements

The key objective of the RADAR programme is to develop the foundational components of a digital platform to "Improve patient outcomes through remote assessment". To ensure the interactions between the projects under the RADAR programme which are paramount for its overall success, and the necessary data sharing and interoperability, the funded actions are expected to share data and collaborate in domain practices and expertise developed with respect to, among others, data management procedures, usability, regulatory and policy pathways. Therefore all grants awarded under the RADAR programme will be complementary Grant Agreements. The respective options under Article 2, Article 31.5 and Article 41.4 of the IMI2 Model Grant Agreement will be applied to the relevant Grant Agreements.

Expected key deliverables

- Prioritized list of functional domains relevant to early Alzheimer's disease progression (based on analysis of existing datasets and input from experts, payers, patient and care-giver advocacy groups);
- prioritization of pre-existing wearable/home based sensors & devices and computerized functional tasks that would best measure the target functional domains in early AD populations;
- development of continuous data-sensing solutions as shown to be needed for the monitoring of the identified relevant parameters in the AD functional domains. The members of the industry consortium of the RADAR-AD topic will make available facilitating tooling and horizontal platform assets to support such development, assuming the integration of pre-existing and newly added components to the evolving platform infrastructure. In this way interoperability of all solutions developed on the platform inside and outside the action will be ensured. The developed solutions, irrespectively of whether leveraging the foreseen facilitating common platform infrastructure or built independently from it, should in any case allow for cross-analysis, data stream sharing and aggregated visualisation both across all solutions developed by the action generated by this topic, and in combination with pre-existing solutions such as those being elaborated under the RADAR CNS action see what specified in the introduction to the RADAR programme. It is indeed paramount to the value of the project deliverables that they do not result in vertical, ad-hoc solutions as often seen in today's practice;
- deployment of the developed system/digital platform and ad hoc sensors & devices in clinical cohorts (normal, MCI, AD) to gather validation data and further refinement of the system based on the deployment;
- finalized version of the system ready for deployment in clinical trials and for real world evidence gathering studies at home or in elder/dementia care facilities.

Expected impact

Development of objective and sensitive functional measures will enable potential dementia therapies to demonstrate functional impact and clinical meaningfulness of early intervention without requiring long follow-on studies thus reducing time and cost required to bring Alzheimer's disease modifying drugs to market.

An objective, scalable, platform technology-enabled functional assessment system will also allow measurement of real-world impact of disease trajectory on individual patients in home and care-giver settings and help direct scalable and customized interventions that target specific functional deficits that promote independent living thus reducing cost and care-giving burden. Another valuable impact would be given by integrating organisations, e.g. Small-Medium-Size Enterprises (SMEs), having expertise in developing sensors and also in the area of processing and analyzing the data from sensors/ devices related to the scope of measuring the functional decline due to Alzheimer disease, as well as addressing the specific problem of the digital platform/user interface for these populations. This approach will allow the SME community to build up their skills and increase competiveness within this area.

Furthermore, adding AD to the RADAR programme will make the entire system more attractive to professionals involved in dementia care, thus helping with the dissemination and adoption of the entire RADAR platform, ensuring interoperability and technology-evolution without disrupting the continuous build-up and extension of the knowledge collection and research practices across the whole RADAR scope (i.e. without having to resort to ad-hoc, unreusable solutions for specific research topics, with their own visualisation etc.).

To maximise impact, it is expected that the system built within the action generated from the RADAR AD topic will adhere to well accepted data standards, where applicable, to ensure compatibility with other systems both within the RADAR programme and more widely. For example, many patients with Alzheimer's disease also have depression as a co-morbidity. The facility to deal with many diseases will make the entire system more attractive to professionals involved in elder care, thus helping with the dissemination and adoption of the entire RADAR platform.

The system created via the RADAR–AD topic has the potential to become a widely used tool to measure and help improve quality of life in elder care homes and assisted-living facilities that focus on dementia and other age-related causes of functional decline. The platform developed to measure function in AD patients by the action will be made available for further refinement and validation in longitudinal clinical studies to each of the industry partners members of the consortium. Consequent incorporation in any controlled clinical trials will help gain regulatory acceptance of the platform as a valid efficacy endpoint. The platform will also be made available to broader set of clinical studies that may be ongoing in various IMI funded projects. Opportunities to deploy the platform will also be explored in more real-world settings such as elder care and dementia care facilities. In the long term it is expected that the platform created by the action will be used both in AD clinical trials as a valid and sensitive efficacy measure as well as in real-world settings such as homes and senior care facilities to track functional decline in patients with AD in a way which will lead to better interventions that improve the quality of life.

Potential synergies with existing consortia

Applicants should take into consideration, while preparing their short proposal, relevant national, European (both research projects as well as research infrastructure initiatives), and non-European initiatives. Synergies and complementarities should be considered in order to incorporate past achievements, available data and lessons learnt where possible, thus avoiding unnecessary overlap and duplication of efforts.

As indicated in the introduction to the RADAR programme the action generated from this topic is expected to actively synergise with the already generated RADAR CNS action (http://www.radar-cns.org/), as well as with future actions that will be generated under the programme. Thus applicants must reserve some resources to facilitate these cross-projects activities and consider this key aspect when developing their solutions to insure interoperability through the horizontal platform.

In addition synergies should be considered with existing IMI projects in the AD field such as:

- **EMIF** (http://www.emif.eu/) explore collaborations with EMIF to access the datasets required to evaluate functional domains in AD patients. The applicant consortium should seek to utilize the output of IMI EMIF to acquire longitudinal datasets for evaluation of functional changes in AD subjects;
- **BD4BO ROADMAP (**http://www.roadmap-alzheimer.org/index.html) the applicant consortia should strive to form a collaboration with the ROADMAP consortium to obtain input from regulators and payers which will be important in developing valid and meaningful functional measures and can be obtained via mechanisms developed in ROADMAP;
- **EPAD (**http://ep-ad.org/) explore the possibility of deploying the system developed iunder this topic in forthcoming clinical studies run by EPAD to accurately measure longitudinal changes in function and to correlate these to changes in cognitive scores, PET/CSF markers and drug treatment. This will provide the necessary validation for the output of this topic to be accepted by regulators as a valid and qualified measure of function in AD patients.

Synergies with other relevant initiatives/projects should also be explored. State-of-the-art research and innovation on early-risk detection and intervention in the area of active and healthy ageing should explore synergies with relevant EU-funded projects, such as those supported by H2020 Societal Challenge 1, Health, Demographic Change and Well-being and other relevant project results.

Industry Consortium

The industry consortium will contribute the following expertise and assets: program leadership, project management, financial management ; expertise in longitudinal analysis of AD cognition, function, biomarker and clinical data; expertise in payer and regulatory perspective; expertise in data analysis, biosensor evaluations; clinical study design, biostatistics, expertise in clinical assessment of AD patients, including cognitive and functional endpoints; expertise in patient association and ethical aspects; biosensor evaluations; clinical study design, biostatistics, data management expertise and monitoring/data review tools, especially with data on demand approaches for visualisation and monitoring of studies utilizing smart phone apps; expertise in functional assessments, such as Activities of Daily Living (ADL) gained through clinical studies in

AD and eventually clinical datasets that may be made available; AD therapeutic area expertise and data analysis along with years of digital and clinical endpoint strategy knowledge.

Indicative duration of the action

The indicative duration of the action is 36 months.

Applicant consortium

The applicant consortium will be selected on the basis of the submitted short proposals.
The applicant consortium is expected to address all the research objectives and make key contributions to the defined deliverables in synergy with the industry consortium which will join the selected applicant consortium in preparation of the full proposal for stage 2. Therefore, the applicant consortium should be able to demonstrate the full scope of experience and expertise needed in order to address effectively and meet all goals outlined in this topic.

This may require mobilising, as appropriate the following expertise: AD clinical research and trials and disease area expertise, regulatory science, patients and patient organizations, data and knowledge management; project management and professional communication expertise, design and conduct of clinical studies (end-points, inclusion criteria etc.); expertise in clinical data management and clinical statistics; expertise in device and sensor development (including SMEs); IT/Analytics expertise (including SMEs); expertise in data privacy and security; regulatory expertise and experience in development and qualification of novel end-points using digital technologies; clinical and general project management.

It may also require mobilising, as appropriate, the following resources: access to biomarker characterized patient cohorts in all stages of Alzheimer's Disease (preclinical, MCI, mild to moderate AD); data management architecture, hardware/software plaform, state-of-the-art algorithms to process and analyze data from sensors/devices; device, data and connectivity management: architecture, hosted SW platform, allowing the on-boarding and life cycle management of medical equipment in a communication secure environment (including SMEs); latest remote assessment technologies (wearable, off-body) that could be further developed or modified for use in assessing functional decline due to AD.

Suggested architecture of the full proposal

The applicants should include in their short proposal their suggestions for creating the full proposal architecture, taking into consideration the industry contributions and expertise as indicated.

The final architecture of the full proposal will be defined together with the industry consortium and should enable activities designed to achieve all objectives and deliverables as indicated in the previous relevant sections and in collaboration with EFPIA and the associated partner. The final architecture of the full proposal will be defined by the participants in observance of IMI2 rules and in contemplation of the achievement of the project objectives.

In the spirit of the partnership, and to reflect how IMI2 Call topics are built upon identified scientific priorities agreed together with EFPIA beneficiaries/large industrial beneficiaries, it is envisaged that IMI2 proposals and projects may allocate a leading role within the consortium to an EFPIA beneficiary/large industrial beneficiary. Within an applicant consortium discussing the full proposal to be submitted at stage 2, it is expected that one of the EFPIA beneficiaries/large industrial beneficiaries may elect to become the coordinator or the project leader. Therefore, to facilitate the formation of the final consortium, all beneficiaries are encouraged to discuss the weighting of responsibilities and priorities therein. Until the roles are formally appointed through a Consortium Agreement, the proposed project leader shall facilitate an efficient negotiation of project content.

In its short proposal, the applicant consortium is also expected to have a strategy on the translation of the relevant project outputs into regulatory practices, regulatory, clinical and healthcare practice. A plan for interactions with Regulatory Agencies/health technology assessment bodies with relevant milestones, resources allocated should be proposed to ensure this e.g. qualification advice on the proposed methods for novel methodologies for drug development, qualification opinion.

A plan for aspects related to sustainability, facilitating continuation beyond the duration of the action should also be proposed.

Work package 1: Management, coordination, dissemination and sustainability

1.1. Setting-up of project management boards: governing, steering, communication, Intellectual Properties

1.2. Development and implementation of dissemination programme

1.3. Development and implementation of internal and external communication tools

1.4. Finacial management, monitoring and project management support and implementation

1.5. Development of a sustainability plan facilitating continuation beyond the duration of the action

Industry contribution: Program leadership, project management, financial management; development and implementation of Data Management plan and correlated activities; contribution to communication and information diffusion.

Expected Applicant consortium contribution: it is expected that the applicant consortium has the necessary skillsets to contribute effectively to all the tasks foreseen in the WP description and in a manner compatible with contributions of the industry consortium.

Work package 2: Assesment of functional domains relevant to early Alzheimer's disease progression

2.1. Identify and gain access to the appropriate longitudinal datasets that allow retrospective analysis of cognition, function and caregiver/payer relevant long-term outcomes

2.2. Analysis of existing longitudinal AD datasets to identify functional domains that are specific and sensitive to early stages of Alzheimer's progression and most predictive of deleterious long-term outcomes

2.3. Prioritization of functional domains relevant to early Alzheimer's disease progression

Industry contribution: Expertise in longitudinal analysis of AD cognition, function, biomarker and clinical data; expertise in cognitive and clinical functional measures gained through clinical studies in Alzheimer's' disease; functional measures gained through clinical studies in Alzheimer's' disease and eventually clinical datasets that may be made available; identifying and accessing appropriate datasets, interpreting analyses of longitudinal datasets and prioritization of functional domains relevant to early Alzheimer's disease progression; Analysis of existing longitudinal AD datasets to identify functional domains that are specific and sensitive to early stages of Alzheimer's progression and most predictive of deleterious long-term outcomes; Prioritization of functional domains.

Expected Applicant consortium contribution: it is expected that the applicant consortium has the necessary skillsets to contribute effectively to all the tasks foreseen in the WP description and in a manner compatible with contributions of the industry consortium.

Work package 3: Communication with Regulatory Authority, Patient Association, Payers and Ethical Board

3.1. Linkage activities with regulatory bodies regarding potential use of technology-enabled functional end-points in registration studies of drugs

3.2. Linkage activities with care-givers and payers on the relevance of the functional domains chosen to be measured

3.3. Leveraging activities for the implementation of the feedback from the regulators, care givers and payers

Industry contribution: Expertise in payer and regulatory perspective; expertise in policy, regulatory affairs, patient associations and payers.

Expected Applicant consortium contribution: it is expected that the applicant consortium has the necessary skillsets to contribute effectively to all the tasks foreseen in the WP description and in a manner compatible with contributions of the industry consortium.

Work package 4: Development of a technology-enabled system to measure identified functional domains via smartphone, wearable and fixed home based sensors

4.1. Prioritization of pre-existing wearable/home-based sensors and computerized functional tasks that would best measure the target functional domains in early AD populations

4.2. Development of plug-in solutions for monitoring the parameters relevant to AD in order to be fully interoperable with a pre-existing platform

4.3. Extention of the assets of the already existing continuos monitoring and remote assessment platform in order to permit the connection of the developed plug-in solutions

Industry contribution: Expertise in data analysis, biosensor evaluations; software licences (Apama, Universal Messaging, MashZone, Terracotta, Apama Predictive Analytics add-on, and Device Integration Platform software licences); Software licenses (IMPACT CDP device and subscription management, IMPACT secure data gateway, IMPACT connectivity management), related application hosting services; experience with digital biomarkers collected through smart phone apps and other wearable for continuous monitoring and data analysis; expertise in both the Activities of Daily Living (ADL) and digital biomarkers collected through smart phone apps for continuous monitoring from previous studies; prioritization of pre-existing digital tools that would best measure the target functional domain in early AD; Scientific search of technologies used in studies to measure functional domains of AD; Market research of technologies commercially available, and proposed prioritization along pre-defined criteria; Identification of gaps / functional domains that cannot be covered by adequate technology (or are not satisfactorily understood).

Expected Applicant consortium contribution: it is expected that the applicant consortium has the necessary skillsets to contribute effectively to all the tasks foreseen in the WP description and in a manner compatible with contributions of the industry consortium. Additionally, it is expected that the applicant consortium will be able to utilize relevant hardware/software (e.g. those made available by industry partners) and extend any relevant pre-existing platform in order to meet the needs of the action selected under this topic.

Work package 5: Validation of the technology-enabled function assessment system in a real-world clinical setting

5.1. Deployment activities of the system developed by the action in clinical cohorts (normal, MCI, AD) to gather validation data

5.2. Optimization work of the system based on the deployment activities

5.3. Finalization of the system ready for deployment in clinical trials, real-world evidence gathering studies and elder/dementia care facilities

Industry contribution: Clinical study design, biostatistics; data management expertise and monitoring/data review tools, especially with data on-demand approaches for visualisation and monitoring of studies utilizing smart phone apps; clinical protocol expertise for neurological studies, statistical analysis and disease model implementation; analysis of validation data from the action system in clinical cohorts (normal, MCI, AD); Validation and deployment activities of the action technology enabled function assessment system in clinical cohorts (normal, MCI, AD) to gather validation data.

Expected Applicant consortium contribution: it is expected that the applicant consortium to have the necessary skillsets to contribute effectively to all the tasks foreseen in the WP description and in a manner compatible with contributions of the industry consortium. It is expected that applicant consortium will provide the clinical cohorts needed for validation studies.

Glossary

AD	Alzheimer's disease
ADL	Activities of Daily Living
CNS	Central Nervous system
COPD	Chronic Obstructive Pulmonary Disease
CSF	Cerebrospinal Fluid
EFPIA	European Federation of Pharmaceutical Companies and Associations
EMIF	European Medical Information Framework
EPAD	European prevention of Alzheimer's dementia consortium
EU	European Union
H2020	Horizon 2020 Framework Programme
ICT	Information and Communication Technology
MCI	Mild Cognitive Impairment
MS	Multiple Sclerosis
PET	Positron Emission Tomography
RADAR	Remote Assessment of Disease and Relapse
RADAR CNS	Remote Assessment of Disease and Relapse in Central Nervous System Disorders
ROADMAP	Real World outcomes across the AD spectrum for better care: Multi-Modatal data Acces Platform
SMEs	Small and Medium Sized Enterprises
SW	Semantic Web
WP	Workpackage