Webinar │IMI2 – Call 12 Development and validation of technology enabled, quantitative and sensitive measures of functional decline in people with early stage Alzheimer's disease (RADAR-AD)

14.07.2017 • 13:30 CEST

Today's webinar

- **Will cover all aspects of the Call topic**
  - Objectives of the project
  - Need for public-private collaborative research
  - Structure of the project
  - Expected contribution of the applicants
  - Contribution of industry consortium
  - Key deliverables
- **Will not cover rules and procedures**
  - A webinar on rules and procedures will take place on Monday 17 July, 14:30-16:00 (Brussels time).
  - Register at https://register.gotowebinar.com/register/6218254309635248897

IMI – Europe's partnership for health

IMI mission

IMI facilitates open collaboration in research to advance the development of, and accelerate patient access to, personalised medicines for the health and wellbeing of all, especially in areas of unmet medical need.

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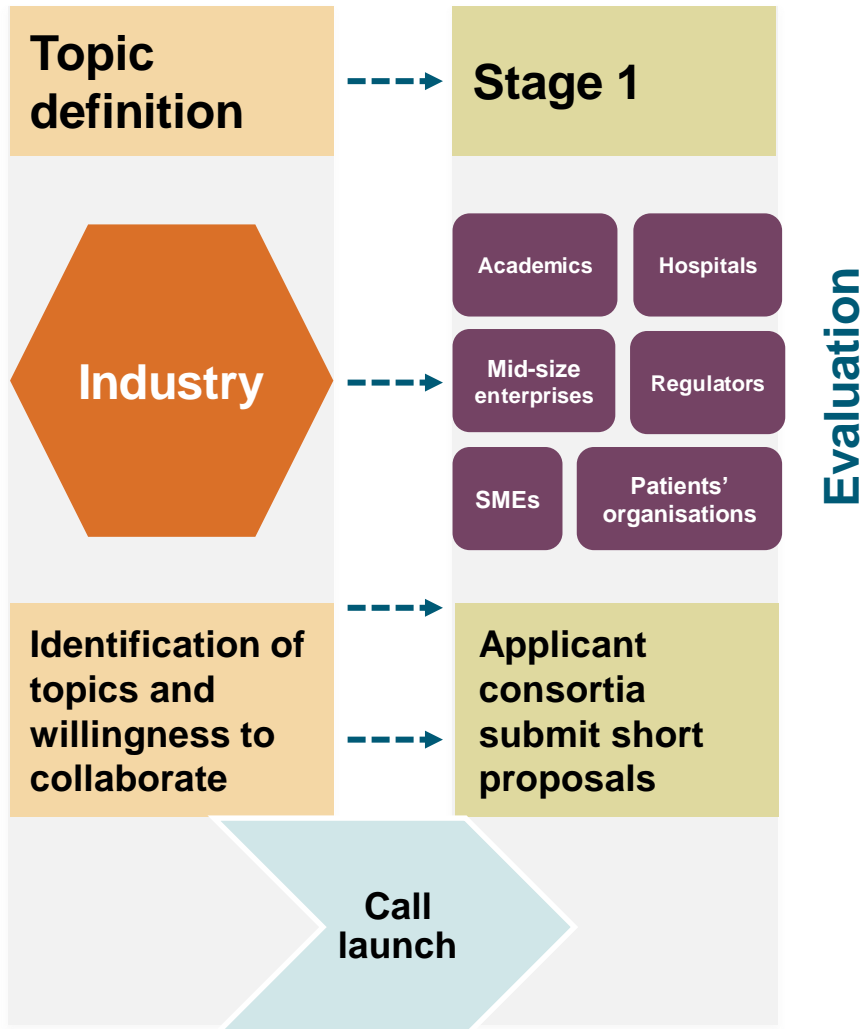# IMI – Ecosystem for innovative collaborations

- Allow engagement in a cross-sector, multi-disciplinary consortium at the forefront of cutting-edge research

- Provide the necessary scale by combining funding, expertise, knowledge, skills and resources

- Build a collaboration based on trust, creativity and innovative and critical thinking

- Learn from each other - new knowledge, skills, ways of working

- Take part in transformative research that will make a difference in drug development and ultimately patients' lives

IMI is a **neutral platform** where **all involved** in drug development can engage in **open collaboration** on **shared challenges**.
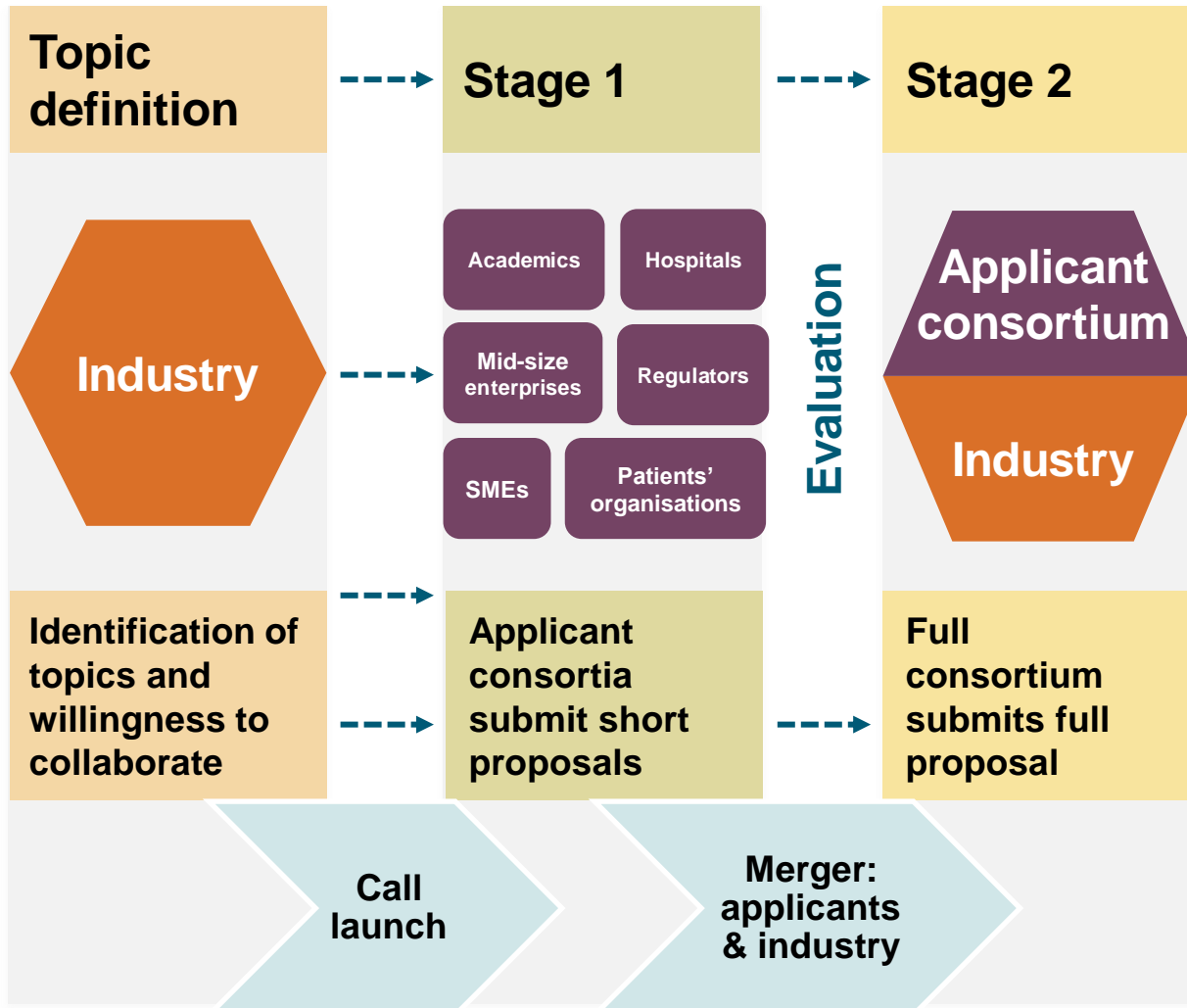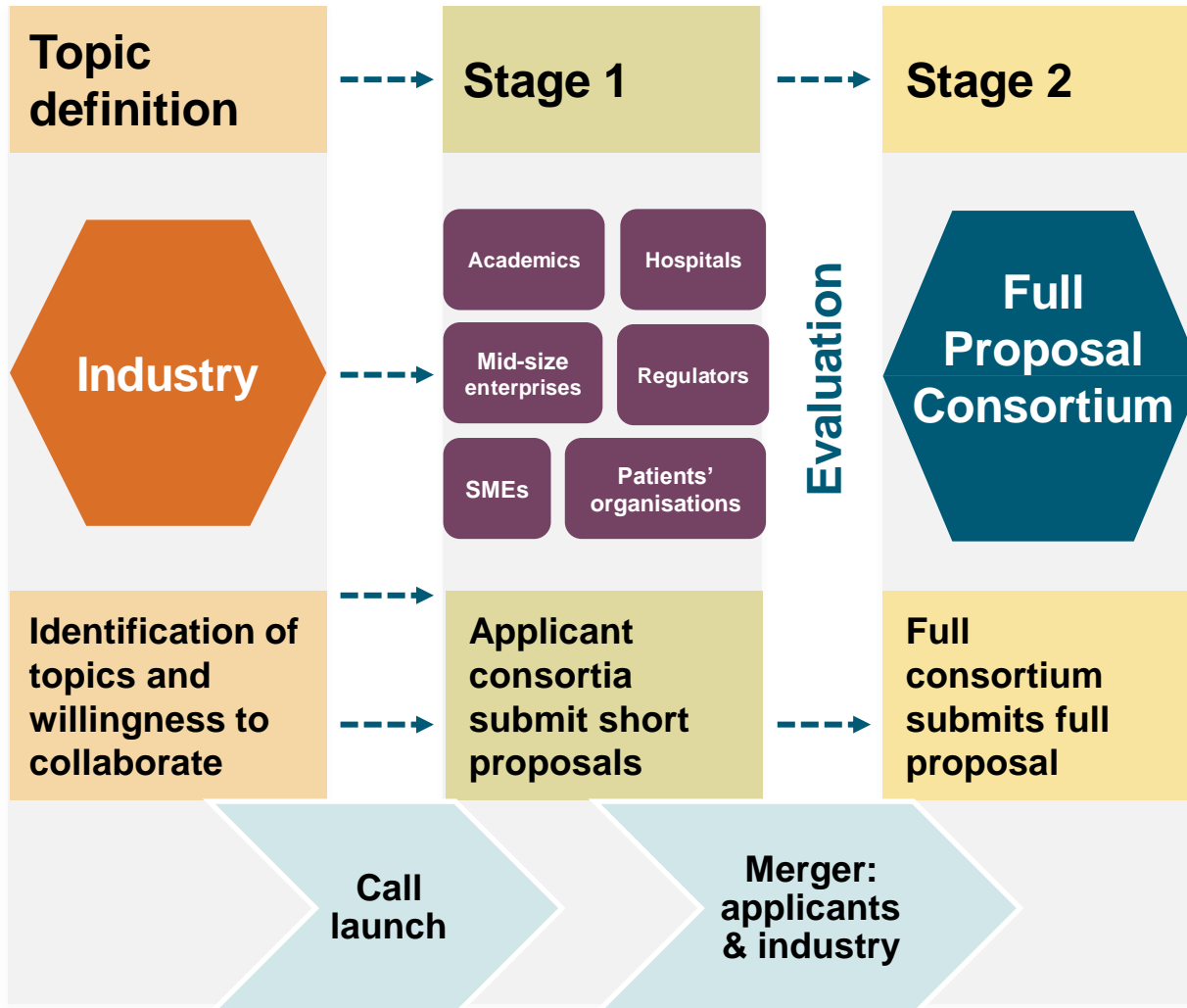
Typical IMI project life cycle

Topic definition

Industry

Identification of topics and willingness to collaborate

Call launch

Typical IMI project life cycle

Topic definition

Stage 1

Academics

Hospitals

Industry

Mid-size enterprises

Regulators

SMEs

Patients' organisations

Evaluation

Identification of topics and willingness to collaborate

Applicant consortia submit short proposals

Call launch

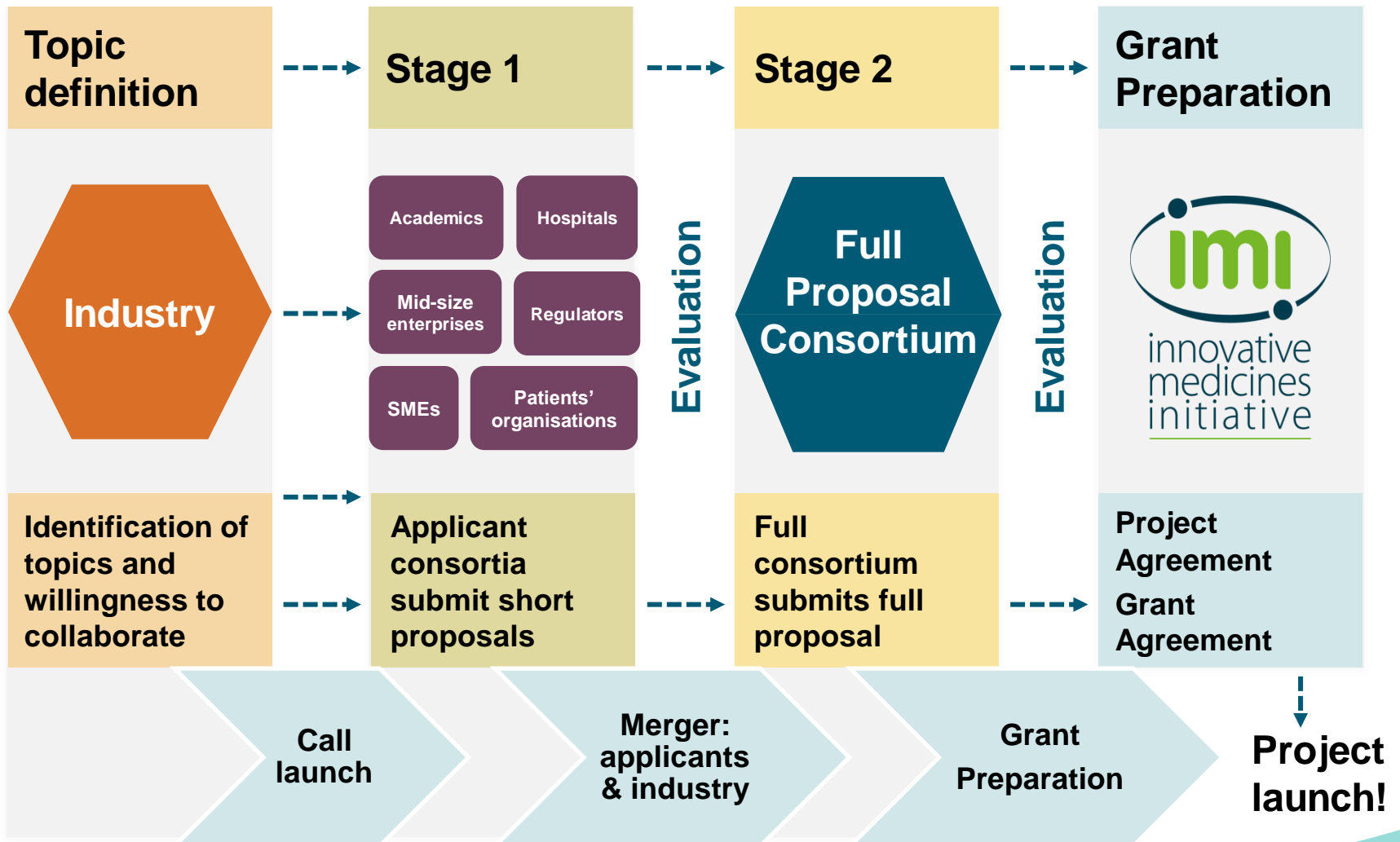innovative medicines initiative

Typical IMI project life cycle

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Typical IMI project life cycle

Submitting a proposal

- https://ec.europa.eu/research/participants/portal/desktop/en/opportunities/h2020/index.html

Proposal Template

- Available on IMI website & H2020 submission tool
- For first stage proposals, the page limit is **30 pages**.

Title of Proposal

List of participants

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1.3	Concept and approach
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1	Expected impacts

3.	IMPLEMENTATION
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3.2	Management structure and procedures
3.3	Consortium as a whole
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4.	PARTICIPANTS
4.1.	Participants (applicants)

Evaluation Criteria (1/2)

- **Excellence**
  - Clarity and pertinence of the proposal to meet all key objectives of the topic;
  - Credibility of the proposed approach;
  - Soundness of the concept, including trans-disciplinary considerations, where relevant;
  - Extent that proposed work is ambitious, has innovation potential, and is beyond the state of the art;
  - Mobilisation of the necessary expertise to achieve the objectives of the topic, ensure engagement of all relevant key stakeholders.

- **Impact**
  - The expected impacts of the proposed approach as mentioned in the Call for proposals;
  - Added value from the public private partnership approach on R&D, regulatory, clinical and healthcare practice as relevant;
  - Strengthening the competitiveness and industrial leadership and/or addressing specific societal challenges;
  - Improving European citizens' health and wellbeing and contribute to the IMI2 objectives.

Evaluation Criteria (2/2)

- **Quality and efficiency of the implementation**
    - Coherence and effectiveness of the outline of the project work plan, including appropriateness of the roles and allocation of tasks, resources, timelines and approximate budget;
    - Complementarity of the participants within the consortium (where relevant) and strategy to create a successful partnership with the industry consortium as mentioned in the topic description in the Call for proposal;
    - Appropriateness of the proposed management structures and procedures, including manageability of the consortium.

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Tips for writing a successful proposal

- Read **all the call-relevant material:**
  www.imi.europa.eu

- Begin forming your consortium **early**
  Partner search tools & networking events

- Provide **reviewers** with all the information requested to allow them to evaluate your proposal

- **Finalise and submit your proposal early**

- Contact the **Programme Office** (**NOT** EFPIA topic writers):
  infodesk@imi.europa.eu

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Common mistakes

- Admissibility/Eligibility criteria not met**:**

    - submission **deadline** missed

    - minimum of **3 legal entities** from **3 member states** not met

- The proposal does **not address all the objectives** of the topic

- A proposal is **scientifically excellent** but will have **limited impact**

- **Complementarity** with Industry consortium not well described.

Find project partners

- Network with **your contacts**

- **Network** with fellow webinar participants

- Use **Partner Search Tools:**

  - IMI http://www.imi.europa.eu/content/partner-search

  - German NCP version: http://www.imi-partnering.eu

  - Fit for health: http://www.fitforhealth.eu/

- Get in touch with your **local IMI contact point**:
  www.imi.europa.eu/content/states-representatives-groups

- Talk to your **Health National Contact Point** (NCP)

- Network on **social media** (e.g. IMI LinkedIn group)

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

Vaibhav Narayan
14.07.2017 • IMI webinar

The RADAR PROGRAMME

This topic is part of the Remote Assessment of Disease and Relapse Programme (RADAR)
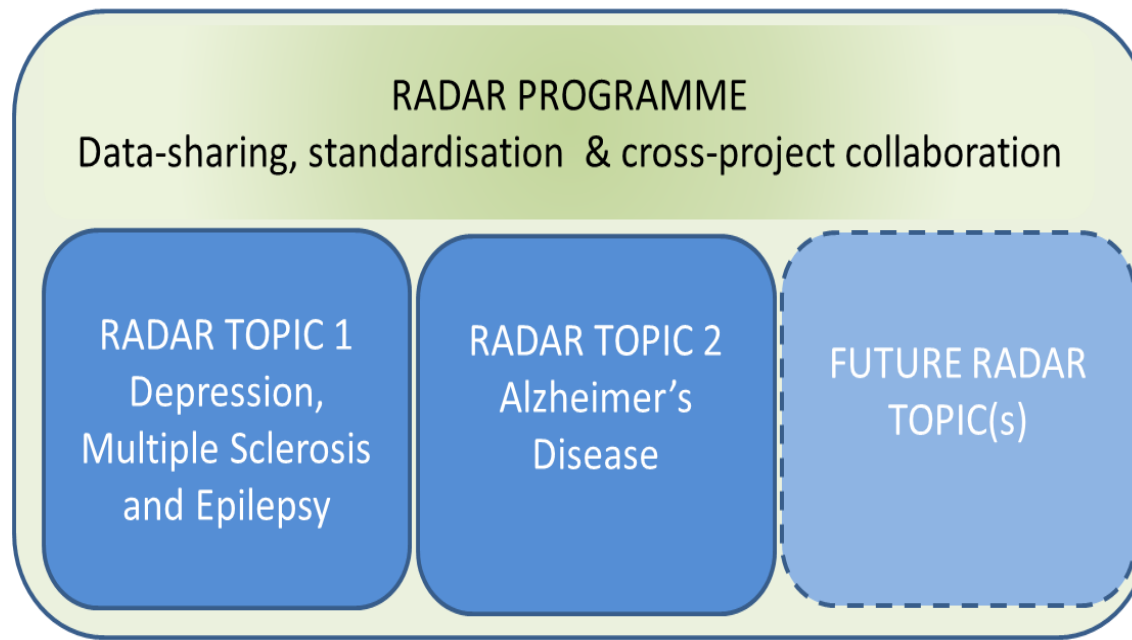
RADAR is a multi-topic programme in IMI2 that aims to overcome three key bottlenecks in developing such methods:

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

- 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

- 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.

The RADAR PROGRAMME

Architecture of the RADAR programme

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.

RADAR PROGRAMME
Data-sharing, standardisation & cross-project collaboration

RADAR TOPIC 1
Depression, Multiple Sclerosis and Epilepsy

RADAR TOPIC 2
Alzheimer's Disease

FUTURE RADAR TOPIC(s)

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General Principles for all Projects Conducted under the RADAR Programme

- Data sharing and interoperability is paramount to the success of the RADAR programme.

- 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.

- 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 AD OBJECTIVES

Development and validation of technology enabled, quantitative and sensitive measures of functional decline in people with early stage Alzheimer's.

- 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 caregivers

- While the main focus of the topic is to understand functional deficits in subjects with early stages of AD, nevertheless late-stage AD monitoring should be also considered in order to validate the results and show the relationship of functional measures with all stages of AD.

Need for public-private collaboration

- Reaching these objectives requires the inclusion of expertise from diverse fields and different industries as well need to align with patients and regulators

- This implies that goals of the RADAR-AD topic are best accomplished in a public-private consortium setting that will provide the necessary neutral infrastructure for an efficient and effective collaboration.

- The implementation of the project involving all these stakeholders will also ensure the sustainability of the results.

Pre-competitive nature

- 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 caregivers, sensor manufacturers, analytics experts and software developers.

- Successful implementation will also require a collaborative partnership with AD patient advocacy groups and patients, the caregiver community and privacy and bioethics experts to ensure that the technology solutions developed in the project can be adopted in the real world.

Key activities of the full project

- Literature Review/Data Analysis: Identify functional domains most sensitive to early AD and predictive of cost generating long term outcomes.

- Implement the IT system to measure, transmit, analyze and interpret function data

- <u>Cross-sectional</u> validation in a normal vs. MCI vs. AD cohort. Look for:

  - ➢ Correlation with disease state. Sensitivity and specificity in early AD

  - ➢ Correlation with Cognition, CSF/PET biomarkers

  - ➢ Correlation with care-giver burden, health-care utilization

  - ➢ Comparison with paper and pencil measures of function

- Assessment of patient acceptability, relevance, privacy, ethics and regulatory pathways for future qualification.

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Key deliverables of the full project

- 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.

- 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

- Enable potential dementia therapies to demonstrate functional impact and clinical meaningfulness of early intervention without requiring long follow-on studies, thus reducing the time and cost required to bring Alzheimer's disease modifying drugs to market

- Allow the measurement of the real world impact of disease trajectory on individual patients in home and caregiver settings and help direct scalable and customised interventions that target specific functional deficits that promote independent living, thus reducing cost and care-giving burden

- 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

Suggested architecture of the project

- **Work package 1:** Management, coordination, dissemination and sustainability

- **Work package 2:** Assessment of functional domains relevant to early Alzheimer's disease progression

- **Work package 3:** Communication with regulatory authorities, patient associations, payers and ethical boards

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

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

Expected contributions of the applicants (1)

EXPERTISE IN (among others, refer to topic text for full list):

- Project management and professional communication
- AD clinical research and trials:
    - expertise, design and conduct of clinical studies (end-points, inclusion criteria etc.)
    - expertise in clinical data management and clinical statistics
    - Patients and patient advocacy
- Device and sensors (including SMEs)
- IT / analytics expertise (including SMEs)
- Data privacy and security
- Regulatory expertise
- Development and qualification of novel end-points using digital technologies

Expected contributions of the applicants (2)

RESOURCES (among others, refer to topic text for full list):

- Access to patient cohorts in all stages of Alzheimer's disease (preclinical, MCI, mild to moderate AD), possibly with a biomarker characterisation, and non-affected control subjects sharing a similar environment;

- Data management architecture, hardware / software platform, state-of-the-art algorithms to process and analyse data from sensors / devices; device, data and connectivity management

Expected (in kind) contributions of industry consortium (1)

- programme leadership, project management, financial management;

- expertise in longitudinal analysis of AD cognition, function, biomarker and clinical data;

- expertise in payer and regulatory perspectives;

- 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;

Expected (in kind) contributions of industry consortium (2)

- clinical study design, biostatistics, data management expertise and monitoring/data review tools, especially with data on demand approaches for visualisation and monitoring of studies utilising smartphone 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;

- Nokia will bring IMPACT SW platform licence and support;

- Software AG will bring Apama, Universal Messaging, MashZone, Terracotta, Apama Predictive Analytics add-on, and Device Integration Platform software licences.

What's in it for you?

- **Academic researchers:** novel ways to characterize disease and patients (digital biomarkers). Access to new types of data.

- **SMEs**: advance sensor technologies and IT infrastructure to fulfil unmet clinical leads in collaboration with experts, access to patients

- **Patients' organizations and patients:** ability to harness and control use of their own data and revolutionary advances in sensor and mobile computing technologies towards advancement of their health and well-being. Potential for more targeted interventions

- **Pharma and tech companies:** new ways to engage and understand patients. Move to a predictive and preemptive paradigm. Shorter clinical trials. Early decision of drug efficacy.

Key facts

- Members of the industry consortium: Janssen (lead), Takeda, Eli Lilly, Novartis, Nokia

In addition the industry consortium includes the following IMI2 Associated partner: Software AG

- Duration of the action:

The indicative duration of the action is 36 months.

- Budget figures

The financial contribution from IMI2 is a maximum of EUR 5 000 000.

The indicative in-kind contribution is EUR 3 555 000.

Thank you

Contact the IMI Programme Office
infodesk@imi.europa.eu • www.imi.europa.eu

www.imi.europa.eu
@IMI_JU

SME Participation

IMI encourages the participation of SMEs in applicant consortia as they can offer a complementary perspective to other organisations.

Being closer to the market, SMEs can drive the tangible outputs of the project, and help ensure these outputs are sustained beyond the project lifetime and therefore help lead to faster impact on healthcare.

SMEs could enhance the value proposition of an applicant consortium by among others:

- Contributing expertise in developing sensors and also in the area of processing and analysing the data from sensors/ devices related to the scope of measuring the functional decline due to Alzheimer disease,

- 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.

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Patient Participation

In an initiative as that to be created by RADAR-AD patient involvement is a must, in particular for:

- understand and develop a framework to support new digital based interactions between patients and health care providers.
- input into the selection of real world outcomes that are relevant to patients and their care-givers
- input into clinical protocols and into operationalisation & monitoring of patient recruitment
- development of materials to encourage patient recruitment
- input into the wording of informed consents
- input into benefit risk discussions
- community outreach and dissemination

"The patient, doctor and researcher – each is a different kind of expert."

Interaction with Regulators

To maximise impact of science generated by projects

Engage dialogue with Regulatory Authorities

- Consider having a plan for interaction with relevant milestones, resources allocated

- When relevant need for formal regulatory processes to ensure regulatory acceptance of projects results (e.g qualification procedure for biomarkers)

- Get familiar with various services offered for dialogue (e.g at EMA through qualification advice, Innovation Task Force, briefing meetings)

- If not participant, consider Regulators in the advisory board

- For more info see ''Raising Awareness of Regulatory Requirements: A guidance tool for researchers'' available at http://www.imi.europa.eu/sites/default/files/uploads/documents/RegulatoryRequirementsGuide.pdf

- Consider also plan for dialogue with HTA bodies/payers as relevant

Questions & answers