IMI2 Call 12 Topics with Janssen lead

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Development and validation of technology enabled, quantitative and sensitive measures of functional decline in people with early stage Alzheimer's Disease (RADAR-AD) (1)

- **Scope**: to develop a digital platform to measure a valid and meaningful combination of smartphone, wearable and/or home sensor based parameters that can detect subtle functional deficits in early Alzheimer's patients (mild AD, MCI or earlier), in the context of AD progression

- **Key deliverables**:
  - prioritized list of functional domains relevant to early Alzheimer's disease progression
  - prioritization of pre-existing wearable/home based sensors & devices and computerized functional tasks
  - development of continuous data-sensing solutions as shown to be needed for the monitoring of the identified relevant parameters in the AD functional domains
  - cross-sectional validation of the developed system/digital platform and ad hoc sensors and devices in clinical cohorts (normal, at risk, MCI, AD)
  - finalized version of the system ready for deployment in exploratory clinical trials and for real world evidence gathering studies, at home settings or in elder/dementia care facilities

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RADAR AD Topic (2)

- **Synergies with existing projects and consortia**:
  - IMI projects: RADAR CNS; EMIF; BD4BO ROADMAP
  - Neuronale Grundlagen des aktiven Alterns (Germany)
  - Ambient Assisted Living, AALIANCE2 consortium, CORAL
  - H2020 Societal Challenge 1, Health, Demographic Change and Well-being and European platforms and infrastructures
  - policy of DG SANTE on Alzheimer's and other dementias
  - CAMD Critical Path Institute in USA
- **Industry consortium**
  - EFPIA :Janssen (lead), Takeda, Eli Lily, Novartis, Nokia
  - IMI2 Associated Partner: Software AG
- **Indicative budget**
  - in kind of 3 550 000 euro
  - max. EU contribution: 5 000 000 euro

RADAR AD Topic (3)

Applicant consortium Expertise:

- AD clinical research and trials and disease area expertise, regulatory science, patients and patient organizations, data and knowledge management;
- design and conduct of clinical studies; 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 project management;
- project management and professional communication expertise

RADAR AD Topic (4)

Applicant consortium Resources:

- access to patient cohorts in all stages of Alzheimer's Disease (preclinical, MCI, mild to moderate AD) possibly with a biomarker characterization, and non-affected control subjects sharing 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: architecture, hosted SW platform, allowing the on-boarding and life cycle management of medical equipment in a communication secure environment that could be further developed or modified for use in assessing functional decline due to AD

FAIRification of IMI and EFPIA data (1)

- **Scope**:
  - will focus on IMI projects that have data that is scientifically valuable and amenable to being made FAIR
  - will strongly encourage making the IMI data as broadly accessible as possible to maximise the public value of the data through prioritising datasets with open public access.
  - Will encourage to make metadata available by the IP restricted projects, so the broader public can at least identify if data of interest are present, but access to the data itself can then be requested just to the data owners

- **Key deliverables:**
  - Development of transparent criteria for the selection of data sources within completed and ongoing IMI projects for FAIRification
  - Development of transparent criteria for the selection of data sources within pharmaceutical industry participants
  - Development of minimum metadata information standards for data from industry and IMI relevant scientific domains

FAIRification of IMI and EFPIA data (2)

- **Key deliverables:**
  - FAIR transformation of databases from at least 20 IMI projects to make them compliant with FAIR principles
  - Multiple FAIR databases per EFPIA company available internally
  - Publication and dissemination of guidelines, advice, and detailed processes partners to make databases compliant with FAIR principles and able to be integrated with their internal data systems and public databases
  - Dissemination of a data catalogue that lists all FAIRified databases handled by the consortium (optional for EFPIA databases)

- **Synergies with existing projects and consortia**
  - IMI projects: Open PHACTS and eTRICKs

- **Industry consortium**: Janssen (lead), Bayer, GlaxoSmithKline, Eli Lilly, AstraZeneca, Novartis, Boehringer Ingelheim

- **Indicative budget**
  - in kind of 3 730 000 euro
  - max. EU contribution: 4 000 000 euro

FAIRification of IMI and EFPIA data (3)

Applicant consortium Expertise:

- pharmaceutical research scientific subject matter
- scientific data vocabularies and ontologies, the existing database landscape
- legal expertise in database access
- FAIR data principles, data stewardship, database management, computer programming, data hosting organisations and solutions
- general project management and professional communication expertise

Main Outcome:

Joint public-private development of FAIR databases will create a broad acceptance and usability of the data produced in IMI projects, and will allow all scientists in public and private organisations to analyse their internal data in the context of all databases that they have access to.