IHI Call Days | Call 9

ValBioMS: Validation of Fluid, Neuroimaging and PROM Biomarkers in Multiple Sclerosis and related Neuroimmunological Diseases – covering aspects of neurodegeneration and chronic disease activity

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Link to the IHI brokerage platform:

- Proposal sharing tool
- Participant profile

Challenges and objectives

IHI SRIA specific objectives adressed: SO1, SO2, SO3, SO4

- Multiple Sclerosis (MS) and other neurodegenerative diseases as Alzheimer's Disease (AD) have a high global socio-economic burden, especially in the EU
- High-cost biological therapies are available but result in limited relieve of burden of disease and disability and mental health problems
- Prevention: biomarkers to detect presymptomatic & early disease are lacking (SO1)
- Prediction: biomarkers to predict disease course, chronic disease activity & disability and treatment response are needed (SO1)
- Accessibility: standardized and easily accessible biomarker detection methods and platforms are rare (SO2)
- People and patient-centred: standardized patient reported outcome measures (PROM) are needed to guide more personalized therapies and decision-making (SO2, SO3)
- Multimodality&BigData: more personalized combined multimodal biomarkers from clinical, biofluids, neuroimaging and patient reported outcomes (PROM) are still to be established (SO4)

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Our approach to solve the problem

- We have established the EU-wide international consortium **ValBioMS** including patient organizations, academic & industry experts in clinical neurology, neuroimaging, biofluid biomarker research, patient related outcome measures (PROM) & data science in the field of **neuroimmunology and neurodegeneration** with the shared aim of:

1. Validation of multimodal candidate biomarkers for disease prediction, early detection & prevention including biofluid, neuroimaging and patient reported outcomes biomarkers in MS and related neurodegenerative conditions as Alzheimer's Disease

2. Development and validation of novel technologies (including digital technologies) to make biomarkers more accessible and to discover novel biomarkers

In **ValBioMS** we have established a working group strategy for different lines of research:

- WG1: Clinical Studies (prospective and retrospective multicentric studies)
- WG2: Biofluid biomarkers (blood, CSF, other biofluids, NfL, GFAP&other, proteomics)
- WG3: Neuroimaging biomarkers (MRI (CVS, CL, PRS), OCT, UHF-MRI)
- WG4: PROM (SymptoMScreen, MSIS-29, PROMIS FatigueMS-8a, wearable devices etc.)
- WG5: Data Science (Multimodal data integration, machine learning & AI, LLM)

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Is our project suitable for IHI?

- We establish a large-scale public-private collaboration to address the unmet European public health need of neurodegeneration and neuroinflammation and related disability in MS and AD.
- Therefore, it is essential to include and synergize public and private partners and patient organizations to reach our shared goal of bringing health innovation to the European patients in form of effective, modern technology-based, available & patient-centred biomarkers for early detection and prediction of disease.
- Our industrial collaborators are essential to provide technical expertise and products (medical devices, in vitro diagnostic, medical imaging, data science) and clinical data & samples from pharmaceutical companies.

Outcomes and Impact

Expected impact:

- Healthcare professionals: more precise, evidence-based treatment guidance; novel biomarker-aided prevention strategies
- Patients: improved outcomes; avoidance of ineffective treatment and accumulation of disability
- Healthcare systems: more efficient & sustainable use of resources
- Pharma and Biotech: more efficient clinical trials with novel outcome measures, distribution of novel technologies and products
- Economically: reduce EU-wide & global economic burden of MS- and AD-related disability.

Innovative solutions:

- Point of care tests, multimodal biomarker assessments & related technology can be implemented in the healthcare ecosystem
- Advance competitiveness of the European Union's health industry in technology and expertise related to the global health burden of neuroimmunology and neurodegeneration
- Novel biomarkers and related technology that will be made available to the European patients will improve personalized monitoring and decision making and reduce burden of disease

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Expertise and resources

We have: **the ValBioMS consortium**

- Coordination: Prof. **Friedemann Paul (lead) &** Dr. Felix Wohlrab (Charité University Medicine Berlin) PD Dr. Sonia Waiczies (Max Delbrück Center, Berlin)
- Committed Partners
  - **Academic:** Spinoza Centre for Neuroimaging, CHU de Montpelier, Hospital Del Mar, Hospital Clinic Barcelona and Hospital Sant Pau, Charles University Prague, University of Milan, Medical University of Graz, University Hospital Erlangen, University Magdeburg, Lund University, Aix Marseille University, University of Southern Denmark, University of Luxembourg, Amsterdam UMC, Lviv National Medical University, University of Verona, DZNE Bonn, DZNE Munich, University of Montpellier, Aarhus University, Bergen University, PROMS (Charcot-MS), BioMSeu, MAGNIMS, 3TR, CLAIMS
  - **Industry:** Siemens Healthineers, Fujirebio, Biocrates, Alamarbio, Aptashape, Omiics, Dehaze
  - Public: German Multiple Sclerosis patient organizations: DMSG, KKNMS, PROMS (Charcot-MS)
- Potential Partners
  - **Academic:** CemCat (Xavier Montalbán), Queen Mary University London (Claudia Langenberg), University of Gothenburg (Henrik Zetterberg), University of Olsztyn (Marcin Mycko)
  - **Industry:** Roche, Sanofi, Merck, Amgen, Olink, Icometrix, Flywheel, UCB, Quanterix, Novartis, Somalogic

- **We are looking for:**
  - **Large and small/medium-sized industry partners in neuroimaging, in-vitro diagnostics and pharmaceutical companies**
  - **Consultancy firm**

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