

HORIZON-HLTH-2024-DISEASE-03-13-two-stage

Validation of fluid-derived biomarkers for the prediction and prevention of brain disorders

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Destination 3. Tackling diseases and reducing disease burden

Call : Tackling diseases (Two stage - 2024)

Call Identifier : HORIZON-HLTH-2024-DISEASE-03-two-stage

Call & deadlines

- TOPIC ID: HORIZON-HLTH-2024-DISEASE-03-13-two-stage
- Type Action : Research and Innovation Actions (RIA)
- Deadline model: Two stage
- Opening date : 26 April 2023
- Deadline dates Stage 1 : 19 September 2023 (17h00 CET)
- Deadline dates Stage 2 : 11 April 2024 (17h00 CET)
- Budget: EUR 25.00 million (6.00 and 8.00 million per project)

Destination 3. Tackling diseases and reducing disease burden

- Research and innovation supported in this destination aim to improve disease management and reduce the disease burden on patients.
- Efforts focus on enhancing understanding and treatment of infectious, poverty-related, neglected, non-communicable, and rare diseases, as well as implementing innovative health technologies.
- Additionally, research and innovation under this destination have the potential to contribute to a resilient EU, climate change mitigation and adaptation, and the provision of high-quality digital services for all.

Expected Outcome

- Effective use of information, data, technologies, tools, and best practices for diagnostics, therapeutics, and prevention.
- Advancement in understanding mechanisms of brain disorders at molecular, cellular, and systemic levels.
- Establishment and integration of open-access databases and infrastructures for data sharing.
- Early detection of disorders through biomarker tests.
- Active engagement of patients and caregivers in the research process.

Scope (1/2)

- Brain disorders under ICD-11 Chapter 6: 'Mental, behavioural or neurodevelopmental disorders' and Chapter 8: 'Diseases of the nervous system'.
- Validation of biomarkers for early-stage brain disorders and treatment/intervention selection.
- Providing evidence for regulatory acceptance of biomarkers.
- Utilization of existing data, biobanks, registries, and cohorts alongside new data generation.
- Strong encouragement for patient/patient organization involvement.
- Consideration of sex, gender, age, socio-economic, lifestyle, and behavioral factors.
- Use of existing infrastructures for sample sharing, quality data, and advanced tools.
- Demonstrating cost efficiency in managing brain disorders.
- Encouragement of SME participation.

Scope (2/2)

Notes:

- The brain disorders under the scope of this topic fall into two categories ICD-11 of WHO:
- Chapter 6 → “Mental, behavioural or neurodevelopmental disorders”
 - Schizophrenia spectrum and other psychotic disorders
 - Mood disorders
 - Anxiety and fear-related disorders
 - Neurocognitive disorders
 - Autism spectrum disorders
- Chapter 8 → “Diseases of the nervous system”.
 - Parkinson's disease and other movement disorders
 - Alzheimer's disease and other dementias
 - Epilepsy and recurrent seizures
 - Cerebrovascular diseases (e.g., stroke)
 - Multiple sclerosis
- Please note that this is a example/short list, and there are more diseases/subcategories or specific disorders within each category. <https://icd.who.int/browse11/l-m/en>

Clinical Studies

- Applicants invited to the second stage should provide details of their clinical studies using the provided template
- Definition of clinical studies can be found in the introduction of this work programme:
 - Clinical studies/trials/investigations/cohorts and is defined as any systematic prospective
 - Or retrospective collection and analysis of health data obtained from individual patients
 - Or healthy persons in order to address scientific questions related to the understanding, prevention, diagnosis, monitoring or treatment of a disease, mental illness, Or physical condition.
 - It includes but it is not limited to clinical studies as defined by Regulation 536/2014 (on medicinal products), clinical investigation and clinical evaluation as defined by Regulation 2017/745 (on medical devices), performance study and performance evaluation as defined by Regulation 2017/746 (on in vitro diagnostic medical devices).

See: https://ec.europa.eu/info/funding-tenders/opportunities/docs/2021-2027/horizon/wp-call/2023-2024/wp-4-health_horizon-2023-2024_en.pdf (page 10-11)

Conclusion

- This call offers opportunities to contribute to the prediction and prevention of brain disorders
- Collaboration between scientific, clinical, and patient communities is crucial
- Consideration of various aspects and utilization of existing resources is encouraged
- SMEs are welcome to participate

International Cooperation

- Pool expertise, know-how, and research infrastructures worldwide.
- Align with other funders to leverage investments for priority needs.
- Collaborate with international organizations to address global health challenges, combat infectious diseases, and strengthen patient safety.