HORIZON-HLTH-2024-DISEASE-03-13-two-stage: Validation of fluid-derived biomarkers for the **prediction** and **prevention** of brain disorders

Dead lines
19 Sep 2023 (First Stage)
11 Apr 2024 (Second Stage)

The Commission estimates that an EU contribution of between EUR 6.00 and 8.00 million would allow these outcomes to be addressed appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

The total indicative budget for the topic is EUR 25.00 million > 3 projects will be funded

This topic is part of the blind evaluation pilot under which first stage proposals will be evaluated blindly.

Expected Outcome:

This topic aims at supporting activities that are enabling or contributing to one or several expected impacts of destination 3 "**Tackling diseases and reducing disease burden**". To that end, proposals under this topic should aim for delivering results that are directed, tailored towards and contributing to most of the following expected outcomes:

- The scientific and clinical communities make effective use of state-of-the-art information, data, technologies, tools and best practices to underpin the **development of the diagnostics, and as such can also facilitate the development of effective therapeutics and/or preventive strategies**.
- The scientific and clinical communities advance the field through a better **understanding of mechanisms underlying brain disorders at the molecular, cellular and systemic level**
- The scientific and clinical community make wide use of newly established and where relevant open access databases and/or integrate them with existing infrastructures for storage and sharing of collected data according to FAIR principles, thereby encouraging further use of the data.
- Policy makers, funders, scientific and clinical communities, patient organizations, regulators and other relevant bodies are informed of the research advances made, while health professionals envisage use of the biomarker tests for early detection of the disorder and for guiding patients in the selection of personalized treatments/interventions.
- Patients and caregivers are sufficiently engaged with the research, which also caters for their needs.

Scope

Treatments for some high-burden brain disorders are potentially on the horizon. Consequently, many patients and citizens will want to know if they are eligible for these treatments. For some disorders, a definitive diagnosis is difficult, expensive and time-consuming. **Simple blood or other fluid-derived (e.g. saliva, urine, sweat) tests for markers**

that may indicate early signs of the disorder, and which can be deployed for widespread clinical use are needed.

The brain disorders within the scope of this topic fall under two categories, namely those listed under chapters **six and eight** of the International Classification of Diseases (Chapter 6: 'Mental, behavioural or neurodevelopmental disorders'; Chapter 8: 'Diseases of the nervous system'). Proposals in the area of **mental disorders** are encouraged.

Proposals should address all of the following aspects:

- Proposals should aim to **validate biomarkers** that can reliably confirm **early stages** of the human brain disorder and **guide treatment/ intervention selection.**
- Proposals should aim to **provide evidence supporting the regulatory acceptance of the biomarkers.**
- Exploitation of existing data, biobanks, registries and cohorts is expected, together with the generation of new key data.
- Inclusion of patients or patient organizations in the research is strongly encouraged, as to ensure that their views are considered.
- Sex and gender aspects, age, socio-economic, lifestyle and behavioral factors should be taken into consideration in the study.
- To enable sharing of samples, quality data and advanced analytical and digital tools, consideration should be made for using infrastructures already developed at the European or national level.
- To enable the management of brain disorders, **consideration should be made in demonstrating the gained cost efficiency.**
- **SME participation is encouraged.**

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Applicants invited to the second stage and envisaging to include clinical studies should provide details of their clinical studies in the dedicated annex using the template provided in the submission system. See definition of clinical studies in the introduction to this work programme part.