Are you submitting the idea:
☐ **in your personal capacity?**
☒ **on behalf of an organisation?**

Please indicate the name of the group organisation: Holmusk

Please select from the list below the type of stakeholders your organization represents: Small & medium enterprise (SME)

1   Title of your idea

Please provide a short title that accurately reflects the objective(s) of your idea:
Enabling Precision Medicine for Psychiatric Disorders in Europe through integrated Real-World Evidence Data Platform creation

2   Scope

Explain the specific challenges/problems to be addressed by your idea and how these affect relevant stakeholders, taking into account what is already known and/or available in the field:
Mental health disorders, including anxiety, depression, bipolar disorder, and schizophrenia, affect a significant portion of the European population, leading to substantial personal, social, and economic burdens. The COVID-19 pandemic has exacerbated these issues, highlighting the urgent need for innovative solutions to improve diagnosis, treatment, and management of psychiatric disorders. Today routine care is in psychiatry ins not provided on data and evidence, because no data infrastructure exists to efficiently generate information in relevant timing.

This proposal aims to leverage real-world data (RWD) to enhance precision medicine approaches in psychiatry, ultimately improving patient outcomes and reducing the societal impact of mental health disorders.

Please indicate which IHI specific objective(s) (SO), as described in the IHI Strategic Research and Innovation Agenda (SRIA), your idea addresses:

["SO4: exploit the full potential of digitalisation and date exchange in heath care"
"SO5: enable the development of new and improved evaluation methodologies and models for a comprehensive assessment of the added value of innovative and integrated health care solutions"]

Please select the keywords that are most relevant to your idea:
["Mental health"
"Diagnosis"
"Treatment"

"Digital health"
"Prediction"]

In alignment with the IHI specific objective(s) selected above, specify the objectives of your idea:

The objectives of this proposal are to:
1- Integrate RWD from the electronic health records (EHRs) – including clinical notes, patient registries, wearable devices, and patient-reported outcomes to create a comprehensive panEuropean data platform in mental health.
2- Develop predictive models to use machine learning to identify high-risk individuals as early as possible to improve early detection of mental disorders and diagnosis.
3- Support clinical decision-making and provide psychiatrists with tools to predict/tailor treatments based on individual patient profiles to move forward precision psychiatry.
4-Improve patient outcomes and focus on reducing the duration of untreated psychosis and major mood disorders, on improving treatment adherence, and enhancing quality of life.

3   Expected impacts to be achieved by your idea

Briefly describe the expected impacts to be achieved by your idea, ensuring that they contribute to IHI general and relevant specific objectives, as described in the IHI SRIA:

Impacts are wider long-term effects on society (including the environment), the economy and science, enabled by the outcomes of R&I investments. Impacts generally occur sometime after the end of the project, e.g. successful implementation of digital solutions supporting people-centred care.

IHI general objectives: 1. contribute towards the creation of an EU-wide health research and innovation ecosystem that facilitates translation of scientific knowledge into innovations, notably by launching at least 30 large-scale, cross-sectoral projects, focussing on health innovations; 2. foster the development of safe, effective, people-centred and cost-effective innovations that respond to strategic unmet public health needs, by exhibiting, in at least 5 examples, the feasibility of integrating health care products or services, with demonstrated suitability for uptake by health care systems. The related projects should address the prevention, diagnosis, treatment and/or management of diseases affecting the EU population, including contribution to 'Europe's Beating Cancer Plan'; 3. drive cross-sectoral health innovation for a globally competitive European health industry and contribute to reaching the objectives of the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe.

The panEuropean real-world data platform is directly addressing objectives 1 and 3:
1) The platform is aggregating data to create evidence based on routine care, to a) enable clinical research on one hand, and in parallel to b) support clinical decision making at the bed side. Supporting both research and routine care increases the incentive to capture comprehensive real world data and we hence create a process of continuous improvement. The process brings research and routine care closer together.
3) Today such integrated data sets only exist in the US. They are highly valued by the pharmaceutical industry, clinical research organizations and med tech companies to conduct retrospective research, support trial recruitment and run pragmatic trials. A full industry is created around these use cases. Today we leave this business opportunity to the US and Europe remains handicapped - non-existent really. Holmusk gets frequent request for comprehensive European data.

4   Why should your idea become an IHI call topic?

Explain why collaboration through a cross-sectoral and multidisciplinary public private partnership is needed in particular:

Why does it require collaboration among several industry sectors (*e.g.* pharma, vaccines, biotech, medical devices, in vitro diagnostics, radiotherapy, medical imaging health ICT)?

Why does it require collaboration between private (industry) and public partners (*e.g.* academia, healthcare practitioners, patients, regulators)?

The IHI's public-private partnership model is a necessity. History clearly provides the evidence that investment in underlying data platform infrastructure for psychiatry is not feasible for industry. , Too many unknowns in terms of regulations, return on investment, long lead time to results, high uncertainty, data ownership or segregation of duties.

Once basic infrastructure exists, it will become immediately attractive for the pharmaceutical industry, clinical research organizations and med tech companies to consume services and further develop the platform.

Building a panEuropean data platform in mental disorders requires collaboration across various industry sectors, including pharmaceuticals, biotechnology, medical devices, digital health, and also academics and patients' associations. Such an IHI will be able to drive innovation and maintain Europe's competitiveness in the global health industry.

Why is the contribution of industry needed to achieve the expected impacts?

Industry is indispensable to achieve the transfer of innovations to patients and to benefit the European competitiveness facing the economic challenge that RWE represents. Industry will be a major user of the platform by purchasing research projects and other services offered through the platform. Hence industry will be indispensable to support design, structure, information capture of the panEuropean data platform.

Achieving the objectives of this IHI topic is an important step for Europe and its place on the globe.