

Topic idea submitted to IHI - Reference Number: TI_001277

- ☐ in your personal capacity?
☒ on behalf of an organisation?

Please select from the list below the type of stakeholders your organization represents:

Research/higher education organisation; Small & medium enterprise; Large company; •
Healthcare professional organisation/healthcare provider; Public authority; Patient/citizen organisation

1 Title of your idea

Please provide a short title that accurately reflects the objective(s) of your idea:

From Lab to Life : Driving Innovation in Reproductive Medicine

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:

The current separation of data into diagnostic silos and lack of their integration impedes IVD data usage beyond local realms. Integrated development of IVDs will benefit medical management in both common disorders and, particularly importantly in diagnostics of rare disorders, also improving the translational value chain from the academic to the manufacturing sector.

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

SO2: integrate fragmented health research and innovation efforts bringing together health industry sectors and other stakeholders, focusing on unmet public health needs, to enable the development of tools, data, platforms, technologies and processes for improved prediction, prevention, interception, diagnosis, treatment and management of diseases, meeting the needs of end-users;

Please select the keywords that are most relevant to your idea:

Non-communicable diseases; Immune system diseases; Metabolic diseases; Oncology; Mental health; Prediction; Prevention; Detection; Diagnosis; Interception; Treatment; Disease management;

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

Utilising the ReproUnion Partnership's research data and achievements developed since 2010, we will make use of a cross-border research infrastructure enhanced by an Open Science Partnership

model to build a long-term innovation platform. We will streamline the integration between scientific discoveries and clinical applications while expanding beyond the Øresund Region. By identifying new molecules, mechanisms, processes, and technologies, the initiative will facilitate interdisciplinary research and develop new treatment and diagnostic methods addressing male and female infertility. We will test and evaluate these discoveries for safety, health outcomes, and health economics.

We will develop and test biomarkers related to infertility based on the ReproUnion Biobank and Infertility Cohort data; this may allow us to diagnose diabetes, cardiovascular disease early, and support couples undergoing fertility treatments. Clinics and lab infrastructure will serve as a testbed for industry collaboration. These developments aren't directly commercialized, but rather address critical reproductive health challenges.

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 proposed innovation platform is expected to have a significant long-term impact. By fostering cross-border, interdisciplinary collaborations, it will contribute to the creation of an EU-wide health research and innovation ecosystem aimed at addressing reproductive medicine. It will also bridge the gap in understanding the reproductive biology of both the man the woman, and them as a couple. In line with the new Industrial Strategy for Europe and the Pharmaceutical Strategy for Europe, it could become one of the largest cross-sectoral collaborations supporting a competitive European health industry while potentially counteracting the effects of aging societies, a strategic unmet public health need within the EU.

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)?

Multi-sectoral collaboration is essential to overcoming the complexity of reproductive health challenges. Collaboration among pharma, biotech, medical devices, health ICT, and policy makers is crucial to developing a comprehensive toolkit for diagnosing, treating, and managing fertility issues. Each sector brings unique technologies and methodologies, from advanced biomarker analytics to innovative drug therapies, cutting-edge diagnostic tools, data management solutions, and new clinical guidelines.

Similarly, collaboration between private and public partners is essential. Industry partners provide technological innovation and scalability potential, while academic partners contribute to foundational scientific research (both basic and applied), early discoveries, and clinical validation. In addition, healthcare practitioners offer their insights into the practice of patient care, and regulators ensure that innovations comply with health policies and standards. Taking advantage of this cross-sectoral, multidisciplinary approach ensures that unmet reproductive health needs are addressed in a balanced, effective, and widely applicable manner.

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

***Contribution of industry:** Large companies that are members of the IHI industry partners (i.e. COCIR, EFPIA, EuropaBio, MedTech Europe, Vaccines Europe) contribute to the programme, primarily through 'in-kind' contributions (e.g. their researchers' time, laboratories, data, compounds). At least 45% of each project's total costs have to be in-kind contribution.*

Without industry partners, it is often difficult to access vital resources and expertise for commercializing innovations. Therefore, industry involvement is crucial from the early development phases as their experience in navigating regulatory landscapes, market dynamics, and production challenges not only accelerates the adoption of new solutions in healthcare systems but facilitates innovation-driven research. Their role is pivotal in the later phases of implementation and commercialization, ensuring that innovations can be effectively transitioned from the lab to market.

The in-kind contributions from industry not only fulfil funding requirements but also ensure the sustainability and long-term impact of the project, making it possible to undertake ambitious and large-scale initiatives that might otherwise be limited by public funding constraints.