

All information regarding future IHI Call topics is indicative and subject to change. Final information about future IHI Calls will be communicated after approval by the IHI Governing Board.

Topic 5: Digital health technologies for the prevention and personalised management of mental disorders and their long-term health consequences

Expected impacts to be achieved by this topic

The following impacts are expected:

- Enhanced cross-sectoral collaboration between healthcare industries, academia and all other relevant actors of the healthcare ecosystem. This will be achieved keeping the people with mental disorders in the centre, outreaching to the social and educational system as relevant to foster sustained and patient-centric innovation in digital health technologies (DHT) for mental health care.
- Preparedness of the healthcare system for the implementation and integration of DHT with existing clinical care strategies thereby also decreasing the burden on staff.
- Prevention (primary and secondary, relapses, chronification, long-term health consequences), earlier and more precise diagnosis, more clinically effective interventions and monitoring, better patient adherence, and reduced hospitalisation (reduction in re-admission/period of hospitalisation).
- Demonstration of the added value of DHT for better management and care and improved experience of people with mental disorders and their families/caregivers, paving the way for a broader and sustained application of DHT in healthcare.
- More cost-effective care pathway management for people with mental disorders.
- Contribute to the upcoming 'European Health Data Space' by promoting better exchange of and access to different types of health data and data generated by DHT and other medical health technologies (using standards in data, technologies...).
- Knowledge and learnings on mental disorders' long-term impact on physiology and physical health. This will contribute to the better overall health & well-being of the population, especially for people with mental health disorders.

Expected outcomes

R&I actions (projects) to be supported under this topic must contribute to all of the following outcomes:

- Robust evidence on the feasibility, acceptability, adherence, and personal satisfaction with digital health technologies (DHT) in people with mental disorders. People with mental disorders and their families/caregivers should be included in evidence generation. This includes pathways to maximise motivation and engagement with DHT of all relevant end-users and healthcare actors. This includes patient-centric selection of potential application features, measurement technologies and digital endpoints. Proper attention should be given to the issues of vulnerability, stigma and difficulties related to limited digital/eHealth literacy. Consideration should be given to ethical, cultural, gender and age-specific (e.g. adolescents') needs and preferences to ensure continued use of the DHT.

- A flexible, interoperable, and reusable digital platform that can be used across numerous conditions and scenarios (various mental disorders, comorbidities, long-term health consequences and other disease areas) to collect, analyse and integrate diverse multimodal clinical and patient data, including patient reported outcome measures (PROMs) and patient reported experience measures (PREMs), with an emphasis on those generated by DHT. Variability across countries should be addressed, as digital infrastructures and the availability of digital tools may differ. Mapping of the specific links between digital infrastructures and types of digital health technology (e.g. concepts, data types, standards, technological approaches) should be included. Consideration must be given to ethical, social, and legal aspects and to the FAIR (findable, accessible, interoperable, reusable) principles.
- Effective and agreed guidelines for the development and implementation of DHT in clinical research and as a part of everyday health and care, enabling the development of more patient-centric treatments, optimised health and care interventions and better disease prevention. Evidence from quantitative studies on potential favourable/unfavourable effects of the technologies on care, and on their impact on changing clinical research and clinical trials should be included. Relevant organisational and work processes, policy and regulatory aspects should be addressed to foster the sustained integration of DHT in real world practice.
- Robust knowledge for better understanding of mental disorders, their change over time and how all this relates to clinical outcomes including the remission, relapse, and recurrence of the conditions, long-term health conditions and mortality and/or surrogate outcome measures when relevant. Socioeconomic outcomes and family/caregiver burden should be addressed. Better insights into other aspects like patient adherence to therapy and adverse drug reactions should be gained.
- A robust body of data to enable the development of digital tools that optimise the engagement of people with mental disorders, caregivers and other relevant actors (healthcare professionals, social workers etc.) adapted to the needs of the patient population and age-specific needs, tackling the issues of stigma, vulnerability, lack of treatment seeking and overall poor adherence to treatment (including lifestyle related). Consideration should be given to providing intuitive equipment and user interfaces and easy troubleshooting.
- Enhanced and more reliable tools and methods (e.g. analytical tools and algorithms) able to provide (near) real time feedback on the DHT, including on the usability, efficacy/effectiveness, and long-term safety. Together, these enable healthcare professionals and providers to make more inclusive and efficient patient-centred decisions in collaboration with the people with mental disorders and their families.
- Robust evidence of how DHT may influence the treatment or behaviour of people with mental disorders. The inclusion of schools/social workers/psychologists in evidence generation should be considered where relevant.

Scope

Mental health disorders represent an area of severe unmet public health need. This has been further negatively impacted by the COVID-19 pandemic, with a substantial increase in the number and severity of people affected for example by anxiety and depression¹, which places substantial pressures on already strained mental health care systems. People with mental disorders have a reduced life expectancy compared to the general population, and this is linked to a greater risk of developing a range of chronic

¹ <https://www.who.int/news/item/02-03-2022-covid-19-pandemic-triggers-25-increase-in-prevalence-of-anxiety-and-depression-worldwide>

physical conditions². The long-standing separation of psychiatry from other branches of medicine and the lack of specific training on this issue further contribute to the poor attention dedicated to management of comorbidities of mental health disorders.

Digital health technologies (DHT) applied via electronic devices such as wearable sensors, implanted equipment, and handheld instruments and smartphones have already shown significant promise for the prevention and disease management of chronic conditions (e.g. cardiovascular disease, diabetes, obesity). DHT, by making it possible to virtually perform medical activities that have traditionally been conducted in person, also have the potential to decrease the pressure on healthcare systems and their personnel. Thus, DHT might have the potential to address some of the challenges in the prevention, prediction, monitoring and personalised management of mental disorders and their long-term health consequences, as well as to tackle some of the organisational issues in providing mental health care³.

The scope of this topic is to investigate how DHT might positively impact the healthcare pathway for people with mental disorders.

Applicants should demonstrate how DHT may enable:

1. better prevention and prediction of disorder onset or relapse;
2. better disease management;
3. tackling comorbidities;
4. addressing long-term health consequences (such as cardiovascular disease or diabetes).

The choice of the specific mental disorder should be justified based on unmet public health need, its impact on quality of life of people with mental disorders and their families/caregivers as well as the feasibility and preliminary evidence available on the use and value of DHT.

To contribute to breaking the silos between psychiatry and other medical branches and better address the impact of co-morbidities in people with mental disorders, applicants should consider relevant co-morbidity/ies where DHT data, learnings and technologies are already available and can be further developed/applied to mental disorders. Co-morbidities can significantly exacerbate mental health disorders, impacting quality of life and the development of long-term health consequences. The choice of comorbidity/ies must therefore be justified accordingly.

Ways of decreasing the burden on caregivers and families should be considered, and applicants should actively engage these actors as well as the people with mental disorders in addressing critical issues and research questions, including about (sustained) engagement with DHT⁴. Consortia should propose ways to foster the future integration of digital and clinical mental healthcare, as well as how DHT might enhance the outcomes of interventions by social and healthcare professionals while decreasing the burden on the healthcare system. Applicants should adequately describe how they plan to measure such burden.

Resources, and learnings from previous initiatives at European and national level (Innovative Medicines Initiative funded⁵ among others) should be taken into consideration.

² <https://annals-general-psychiatry.biomedcentral.com/articles/10.1186/s12991-021-00374-y>; <https://www.nature.com/articles/s41569-020-00463-7>

⁴ <https://www.frontiersin.org/articles/10.3389/fdgth.2021.764079/full>

⁵ https://www.imi.europa.eu/projects-results/project-factsheets?keywords=digital+technology&status=All&call=All&programmes=All&disease_areas=All&products=All&tools=All;
https://www.imi.europa.eu/projects-results/project-factsheets?keywords=radar+cns&status=All&call=All&programmes=All&disease_areas=All&products=All&tools=All

Applicants should aim to deliver robust evidence on how DHT may be:

- a. made easy to adopt and use in a sustained way for both people with mental disorders, their families/caregivers and health and care providers;
- b. effectively incorporated into clinical research and in clinician workflows.

Early engagement with regulators should be sought to ensure the future acceptance and usability of the results for example through scientific advice, qualification advice or qualification opinion.

Applicants are expected to implement activities to achieve all expected outcomes.

Applicants are expected to consider allocating appropriate resources to explore synergies with other relevant initiatives and projects.

Why the expected outcomes can only be achieved by an IHI project

Digital health technologies (DHT) have enormous potential to improve the prevention, prediction, diagnosis and treatment of health disorders, especially in areas of high unmet public health need such as mental disorders. To achieve this, all stakeholders — healthcare professionals and systems, academic researchers, including from the social sciences, technology developers, regulators, reimbursement authorities and, most of all, people with mental disorders, families and caregivers, and citizens need to be involved in the discussions. There is thus the need for an appropriate multi-stakeholder and cross-sectorial, public-private platform delivering learnings and sustainable outcomes of value across the ecosystem to foster the development, evaluation, and best use of DHT. IHI offers an ideal setting to bring the relevant stakeholders together and achieve the requested impacts.

People with mental disorders and their families/caregivers must be active partners in all activities of such an initiative to ensure the results fit their needs for effective adoption and continued use.

Indicative budget

Applicant consortia will be competing for the maximum financial contribution from IHI of up to EUR 24 000 000.

IHI estimates that an IHI financial contribution of between EUR 6 000 000 and EUR 8 000 000 would allow a proposal to address these outcomes appropriately. Nonetheless, this does not preclude submission and selection of a proposal requesting different amounts.

Applicant consortia must ensure that at least 45 % of the action's eligible costs are provided by contributions from industry members, their constituent or affiliated entities, and contributing partners.

Additional activities from industry members and their constituent or affiliated entities may also contribute towards this 45 % threshold, providing these activities are related to the project. Contributing partners do not contribute additional activities.

Indicative duration of the actions

Applicants should propose a project duration that matches the project's activities and expected outcomes and impacts.

Dissemination and exploitation obligations

The specific obligations described in the Conditions of the calls and calls management rules under “Specific conditions on availability, accessibility and affordability” apply⁶.

INDICATIVE TEXT

⁶ See section 4.2.3.2 of this second amended Work Programme.