An Roinn Sláinte
Department of Health

World Health Organization
European Region

Digital mental health roadmap for the WHO European Region (2027–2035)





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Abstract

Mental health conditions affect over 143 million people across the WHO European Region–around 16% of the population–yet mental health remains chronically underfunded, with care concentrated in hospital-based and crisis-oriented settings rather than accessible, community-based models. Workforce shortages, fragmented systems, stigma and widening inequalities compound this burden, further intensified by war, displacement and economic insecurity. Digital technologies cannot resolve these structural challenges alone, but when well governed, evidence-informed and equitably deployed, they offer a meaningful opportunity to extend the reach, quality and responsiveness of mental health systems.

The *Digital mental health roadmap for the WHO European Region (2027–2035)* supports Member States in realizing this potential coherently and safely. Grounded in the Second European Programme of Work 2026–2030 and developed through extensive multistage consultation, the Roadmap organizes action across six domains: policy and strategy; governance and accountability; standards and regulation; technology and infrastructure; engagement and capacity-building; and monitoring, evaluation and learning. Underpinned by principles of person-centred care, equity and co-production with people with lived experience, it traces a phased pathway from foundational readiness through to full normalization within health systems, offering a flexible, non-prescriptive framework to improve access, quality and mental health outcomes across the Region.

Keywords

MENTAL HEALTH, DIGITAL HEALTH, DIGITAL TECHNOLOGY

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Foreword by the Director of the Division of Health Systems, WHO Regional Office for Europe

Digital technologies are changing how people communicate, access information and seek health care. They offer new opportunities to improve access to mental health support, strengthen continuity of care and help services respond to people's needs. But they also raise important questions about equity, privacy and safety. Countries must consider how best to use these technologies while ensuring that no one is left behind.

Across the WHO European Region, one in six people are living with a mental health condition; yet many still struggle to access timely and appropriate care. Workforce shortages, persistent stigma and inequalities in access add to the pressure on health systems. Wider challenges, including conflict, displacement, economic uncertainty, loneliness and climate change, are also affecting people's mental health and well-being.

Developed in partnership with the Department of Health and the Health Service Executive of Ireland, this Roadmap reflects our shared commitment to mental health and provides Member States with a practical framework for using digital technologies to strengthen mental health systems. Grounded in the *Second European Programme of Work 2026–2030 – "United Action for Better Health" (EPW2)*, it recognises that successful digital transformation requires more than technology alone. It depends on sound governance, investment in workforce capacity, meaningful involvement of people with lived experience, and decisions informed by evidence and guided by human rights.

It is evident that technology has an important role to play in the future of mental health care, but we must not forget that it cannot replace human relationships, trust and compassion. Our responsibility is to ensure that digital innovation strengthens these foundations and helps more people access the support they need.

Natasha Azzopardi Muscat
Director, Division of Health Systems
WHO Regional Office for Europe

Foreword by the Government Chief Whip and Minister for Mental Health, Ireland

Every person should be able to access mental health support in a way that is timely, accessible and right for them. At its heart, the *Digital mental health roadmap for the WHO European Region (2027–2035)* is about people. It is about ensuring that people experiencing mental health difficulties, as well as their families, carers and communities, can access the right support at the right time. Across Europe, demand for mental health services continues to grow, and we must do everything we can to make those services more accessible, responsive and person-centred.

Digital technology is already an important part of our lives, how we communicate, and how we access services. If used thoughtfully and responsibly, it has the potential to improve access to mental health support, reduce barriers to care and help people connect with services in ways that work for them. At the same time, we must always remember that technology should support, not replace, the human relationships that are at the heart of effective mental health care.

I am particularly proud of the role Ireland has played in leading the development of this Roadmap. As the penholder, Ireland, through the Department of Health and the Health Service Executive, worked in close partnership with the WHO Regional Office for Europe and Member States across the Region to guide its development. The Roadmap reflects a truly collaborative effort involving policy-makers, clinicians, researchers, digital health experts and, importantly, people with lived and living experience, whose insights have helped shape its vision and priorities.

This work reflects Ireland's strong commitment to improving mental health and working with international partners to address shared challenges. By learning from one another and sharing knowledge and experience, we can build stronger mental health services that are better equipped to meet people's needs now and in the future.

The Roadmap provides a practical framework to help countries harness the benefits of digital innovation safely, effectively and equitably. It recognises that there is no one-size-fits-all solution, but it sets out a shared direction of travel: one where digital tools strengthen mental health services, support prevention and early intervention, and help more people access timely support.

I look forward to continuing to work with the WHO Regional Office for Europe, fellow Member States and partners across the Region as we move from ambition to action. Together, we can ensure that digital innovation strengthens our mental health services, promotes equity and inclusion, and most importantly, helps improve the lives and well-being of the people we serve.

Mary Butler TD
Government Chief Whip
and Minister for Mental Health, Ireland

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Abbreviations

AI	artificial intelligence
app	application
CBT	cognitive behavioural therapy
COVID-19	coronavirus disease
DiGA	*Digitale Gesundheitsanwendungen* [Digital Health Applications]
DMH	digital mental health
EPW2	Second European Programme of Work 2026–2030 – "United Action for Better Health"
EU	European Union
GDPR	General Data Protection Regulation
iCBT	internet-delivered cognitive behavioural therapy
NICE	National Institute for Health and Care Excellence
PHQ-9	Patient Health Questionnaire-9

Executive summary

Behind every governance structure, evidence standard and implementation timeline in this Roadmap is a person: someone living with a mental health condition, a family member, a clinician or a community member seeking support. This Roadmap exists because those people deserve better: better access to care, better quality of support and systems built with genuine concern for their well-being and dignity. Digital technologies, where deployed with care and integrity, offer a meaningful opportunity to deliver that.

Mental health conditions affect over 143 million people across the WHO European Region, about 16% of the total population, yet they remain among the most chronically underfunded areas of health. Service organization and financing are misaligned with population needs, with resources disproportionately concentrated in hospital-based and crisis-oriented care rather than accessible, community-based and preventive models. Workforce shortages, fragmented systems, persistent stigma and widening inequalities in access compound the burden. The ongoing convergence of conflict, displacement, economic insecurity and climate-related stress has intensified demand and deepened these inequities.

Digital technologies cannot resolve these structural challenges on their own. But where they are well-governed, evidence-informed and equitably deployed, they offer a meaningful opportunity to extend the reach, quality and responsiveness of mental health systems. The *Digital Mental Health Roadmap for the WHO European Region (2027–2035)* has been developed to help Member States realise that potential coherently, safely and in ways that strengthen rather than fragment existing systems.

The Roadmap is grounded in the Second European Programme of Work 2026–2030 – "United Action for Better Health" and the *Regional digital health action plan for the WHO European Region 2023–2030*. It reflects the priorities of Member States engaged through an extensive multistage consultation process, led jointly by Ireland's Department of Health and Health Services Executive, and the WHO Regional Office for Europe. It has been developed in partnership with clinical experts, people with lived experience, digital health specialists, civil society and policy leaders from across the Region.

The Roadmap organizes action around six Action Domains as outlined below.

- Policy and strategy (Action Domain 1).
- Governance and accountability (Action Domain 2).
- Standards and regulation (Action Domain 3).
- Technology and infrastructure (Action Domain 4).
- Engagement and capacity-building (Action Domain 5).
- Monitoring, evaluation and learning (Action Domain 6).

A set of cross-cutting principles (including person-centred approaches, equity and inclusion, collaboration and co-production with people with lived experience, and integration within wider health and social care systems) apply across all Action Domains and time horizons. These are complemented by a set of cross-cutting enablers and considerations that recur throughout the Roadmap, highlighted within different Action Domains where relevant: implementation capacity and sustainable financing; equity of access across the lifespan; human connection, choice and flexibility; research as a core component of standards and regulation; building digital mental health (DMH) capacity within both the workforce and the population; and good practice and knowledge exchange.

The Roadmap traces a pathway of change across three phases. In the first phase, countries build foundational readiness: establishing shared vision, governance structures, stakeholder engagement mechanisms and baseline standards. In the second phase, DMH moves from policy aspiration to routine practice, integrated into national plans, budgets and reform programmes, with governance arrangements becoming institutionalized and resilient. In the final phase, DMH is fully normalized within health systems, supporting sustained improvements in access, quality, equity and population mental health outcomes.

The Roadmap is designed to be flexible and adaptable. It does not prescribe specific technologies, platforms or models. Instead, it provides a structured framework through which Member States can identify priorities, sequence actions and make locally appropriate choices, which collectively advance the shared goal of digitally optimized and integrated mental health systems.

Effective implementation requires sustained political commitment, cross-sectoral coordination and clarity about roles and responsibilities. The WHO Regional Office for Europe will support implementation through normative guidance, technical assistance and facilitation of regional peer learning. Member States are the primary agents of change. Partners, civil society, people with lived experience and the research community all play essential roles. This Roadmap provides a shared language and a practical foundation for that collective action.

Background 1

Introduction

This Roadmap is addressed principally to policy-makers, health system planners and national authorities across the WHO European Region with responsibility for planning, commissioning or governing digital approaches within mental health systems. It may also be of value to clinicians, researchers, civil society organizations and technology developers who seek to understand the system-level conditions required for safe, sustainable and equitable digital mental health (DMH). The Roadmap can be used to assess current system maturity, identify and sequence priority actions, and align DMH development with wider health reform and digital transformation agendas.

It is important to be explicit about what this Roadmap is and what it is not. This document is a system-level governance framework. It does not constitute a manual of digital interventions for specific mental health conditions, an evidence compendium of technologies mapped to diagnoses or a prescriptive guide to platforms, products or clinical protocols. Those seeking intervention-level guidance are directed to the companion documents to be published by the WHO Regional Office for Europe, including the findings from the Knowledge Community Platform on Digital Mental Health Regulations and a forthcoming scoping review of DMH interventions, which will provide more granular, condition-specific evidence synthesis. This Roadmap provides the governance architecture and system conditions within which that intervention-level work can be safely and sustainably embedded.

A further clarification is necessary regarding scope. Although this Roadmap builds upon the *Regional digital health action plan for the WHO European Region 2023–2030 (1)* and shares elements of its structural architecture, it is not a generic digital health document reapplied to a mental health context. The mental health context introduces considerations of clinical, ethical and human rights significance that have no close parallel in most other areas of digital health, and that together constitute the rationale for a dedicated Roadmap.

Mental health occupies a qualitatively distinctive position within health systems and that distinctiveness demands a dedicated framework. DMH tools routinely interact with individuals in ways that may simulate or mediate therapeutic relationships. A review by Gutierrez et al. *(2)* indicates that artificial intelligence (AI)-augmented interventions show promising, well-tolerated benefits for mental health symptom reduction with attrition comparable to or better than non-AI approaches. In the same review, the current evidence base builds the case that AI-augmented DMH interventions remain concentrated in adult (predominantly female and largely white) populations in high-income countries, with a recent synthesis in a scoping review *(3)* confirming that older adults, perinatal women, adolescents, ethnic minorities and populations from lower-income countries are consistently under-represented, and that AI models are frequently trained on demographically narrow datasets without systematic fairness auditing *(2)*. Simply put, populations who are not yet reflected in research, who may be frequently engaging with these tools, require particular clinical, ethical and safeguarding considerations *(4,5)* to ensure that marginalization and digital exclusion *(6)* – with concerns that telehealth and applications (apps) can worsen psychiatric inequities[1] if users lack digital literacy *(7)* – do not endure.

In order to understand how to ensure inclusion, a coordinated governance approach, rather than technology-focused solutions alone, is required. A systematic review of DMH implementation found that barriers and facilitators operate across patient, professional, organizational and policy levels *(8)*. At the individual level, barriers such as stigma, discrimination and social harm carry risks to mental health data, that have no close equivalent in most other clinical domains *(9)*. Furthermore, the evidence base for DMH is itself distinctive in character: internet-delivered cognitive behavioural therapy (iCBT) has accumulated

[1] As services move toward digital-by-default delivery, evidence indicates that people with severe mental illness are significantly more likely than the general population to lack essential digital skills, meaning device access alone is insufficient to prevent digital exclusion from mental health care.

the strongest and most consistent body of clinical evidence[2] within the field *(10)*, an intervention that has shaped the approach to evidence standards articulated in Action Domain 3 while the evidence for other modalities, including AI-enabled conversational agents and digital phenotyping tools,[3] remains emergent and context-dependent *(2)*. The governance, equity and ethical implications of DMH are therefore more exacting in important respects than those arising in other areas of digital health. This is why a dedicated Roadmap is warranted, and why the guidance it provides cannot be derived from a general digital health framework alone.

Rationale

Mental health conditions[4] and psychosocial disabilities represent a significant public health concern in the WHO European Region. Affecting over 143 million people (16%) of the Region's total population *(11)*, the substantial contribution of mental disorders to the total disease burden, 125 million disability-adjusted life years globally *(12)*, stands in stark contrast to the persistent underfunding and service gaps in mental health care *(13,14)*. The 125 million disability-adjusted life years signal that mental health challenges are emergent outcomes, often arising from interacting social and structural conditions, including social isolation *(15,16)*, economic insecurity *(17,18)*, stigma *(19)*, fragmented services *(20,21)* and limited workforce capacity *(22)*, which together shape the likelihood, severity and duration of mental health difficulties. These conditions interact and can reinforce each other over time, risking the production of a self-perpetuating cycle of unmet need and potential long-term disability.

However, mental health systems have not kept pace with this burden, and service organization and funding remain misaligned with population needs. Addressing these challenges requires new ways of delivering mental health support. Yet, despite this scale of need, mental health service provision remains one of the most underfunded areas of health *(13,22)*. Across the Region, mental health expenditure accounts for only a small proportion of total health spending, and resources are frequently concentrated in hospital-based or crisis-oriented care rather than accessible, community-based services *(23)*. Persistent workforce shortages across primary care, specialist mental health services and social care further undermine continuity, integration and the scaling of multidisciplinary, person-centred support *(22,24)*. Prevention and early intervention services remain limited or inconsistently implemented *(14)*, while stigma continues to constrain both political prioritization and care-seeking *(19,25)*.

The ongoing "permacrisis" (characterized by conflict, displacement, rising living costs and climate-related stress) has intensified demand and exposed the fragility of existing systems, with widening inequalities regarding who can access timely, appropriate care *(26)*.

These pressures are not evenly distributed, nor are the digital solutions equally relevant across all populations. Young people, older adults, people with severe mental illness, refugees and displaced populations, those in rural and remote communities, and groups experiencing poverty, exclusion or chronic mistrust of services face compounded barriers to mental health support. Barriers that digital technologies, if poorly conceived, may do little to address and may in some cases exacerbate.

A DMH strategy that treats digital delivery as a universal default risks not only failing these populations but actively deepening existing inequities. Reaching these populations requires sustained political commitment. It also requires targeted reinvestment toward community-based and primary health care

[2] Based on an individual patient data network meta-analysis of randomized controlled trials, which found that both guided and unguided iCBT for depression were more effective than control conditions in reducing depressive symptoms, measured using the Patient Health Questionnaire-9 (PHQ-9), over both the short and long term, with guided iCBT showing significantly greater effectiveness than unguided iCBT.

[3] 3 Conversational agents delivering AI-guided or self-guided therapy demonstrated the strongest and most consistently reported effects in this evidence base, while related passive-sensing approaches – also termed digital phenotyping – used behavioural and contextual data such as location, app usage and sleep patterns to personalize engagement and predict dropout.

[4] 4 In this research, the term "mental health conditions" includes both mental and substance-use disorders.

delivery, and coordinated action across health, social protection, education, employment and housing sectors to address the social determinants that shape mental health outcomes. Therefore, digital tools need to be positioned as one component of a broader response, deployed where and when they are genuinely appropriate (Box 1).

Box 1. What is DMH?

DMH encompasses the use of evidence-informed digital technologies including smartphone apps, asynchronous online platforms, virtual reality, digital phenotyping and generative AI (including large language models). DMH intends to support the prevention, identification, monitoring, treatment and recovery of mental health conditions and mental well-being. These technologies may operate as standalone supports, coach-guided tools or clinician-led interventions, and are increasingly integrated into blended care models that augment and extend in-person and synchronous telehealth services.

DMH is defined not only by the technologies themselves, but by their safe, ethical and effective integration into real-world systems. For example, within the DMH landscape, iCBT has accumulated the most robust clinical evidence base. Evidence shows that guided iCBT is more effective than waitlist conditions for depression and anxiety, and broadly equivalent to face-to-face CBT in effect. Therapist-guided formats outperform self-guided delivery, though even minimally guided iCBT (up to 10 minutes per week) produces clinically meaningful symptom reductions. Importantly, benefits are sustained: a meta-analysis of 15 studies found medium-effect maintenance of symptom improvement at follow-up (standardized mean difference -0.43), continued within-group gains beyond post-treatment and small but significant quality-of-life improvements at 6 and 12 months. Evidence spans depression, anxiety disorders, obsessive-compulsive disorder, post-traumatic stress disorder, insomnia, chronic pain and psychiatric comorbidities of physical illness, with promising reach across rural, multilingual and culturally diverse populations. Deterioration rates are similar to face-to-face treatment and lower than control conditions. Real-world implementation has broadly replicated trial findings, although national-scale delivery has typically depended on specialist or centralized services.

Understanding the effectiveness of iCBT is important because this shapes, for example, the standards applied in Action Domain 3. Realizing the potential of DMH more broadly requires attention to: the robustness of the clinical evidence base including the use of active controls, pre-registration and generalizable trial designs; the optimization of human support and user engagement; the equitable tailoring of tools for culturally and linguistically diverse populations; rigorous data governance and privacy protections; and the application of implementation science frameworks to support adoption and scale.

Note: CBT: cognitive behavioural therapy.

Sources: *(27–33)*.

DMH as a system opportunity

DMH tools – including online psychological interventions, digital therapeutics, crisis support platforms, blended care models, triage systems and digital self-help resources – have the potential to:

- increase accessibility and convenience for service users
- empower service users
- provide greater availability of support, including 24/7 options
- meet service user expectations through leveraging of prevalent personal technologies
- extend the reach and scale of services and supports
- expand service options and foster innovation
- improve service efficiency by enabling clinical staff to focus more on their core roles.

Several countries in the Region have already integrated DMH into routine care. Denmark has developed one of the most comprehensively scaled digital psychiatry systems in the Region through *Internetpsykiatrien* [Internet psychiatry] *(34)*, operated by the Centre for Digital Psychiatry in the Region of Southern Denmark. Launched in 2016 and expanded nationally across all five Danish health-care regions by 2020, this service provides free self-referral, text-based cognitive behavioural therapy (CBT) for mild-to-moderate depression and anxiety, with no general practitioner referral required and treatment commencing within 30 days of application. The service now supports thousands of patients with approximately 100 staff. Outcome data are notably strong: 93% of patients who complete treatment demonstrate symptom reduction on the PHQ-9, 93% report moderate-to-high satisfaction on the Client Satisfaction Questionnaire-8 and 80% complete or finish treatment ahead of schedule. A complementary self-help well-being platform (Mindhelper) and adolescent-targeted programmes (Coolminds, for those aged 12–17 years) complete the national DMH offer. In Finland, the national Mental Health Hub *(35)* is a well-established national portal operated by HUS Helsinki University Hospital that offers 12 evidence-based online therapy programmes (mostly CBT-based), self-help resources and professional training, accessible to the whole population. It is presented as part of a broader strategy to improve access and early intervention *(36)*. Latvia has begun piloting the integration of iCBT into national treatment pathways in attempts to increase reach in areas with limited specialist availability. Early findings indicate good engagement, symptom improvement and user-friendly implementation within the public mental health system *(37)*. In the Netherlands (Kingdom of the), 24-hour crisis chat services like *De Luisterlijn* [The Listening Line] *(38)* offer immediate support and link service users to ongoing care. A randomized controlled trial in Scottish (United Kingdom) primary care found that guided iCBT significantly reduced depressive symptoms compared with usual care, with benefits sustained over time *(39)*. Scotland offers a strong example of national-scale implementation: digital therapy services including Silver Cloud, Mindler, Sleepio and Daylight *(40)* received over 76 000 referrals and self-referrals last year, matching the volume of traditional face-to-face psychology services, and are fully integrated into clinical pathways and available across the entire country as part of substantive mental health service provision. Blended models, as observed across nine European countries *(41)*, and digital triage systems in Ireland *(42)* have supported more efficient use of clinical resources.

There has been a dramatic increase in the creation of DMH services and with that calls for increased safety, efficacy, privacy and application of AI in these services. Evidence of this expansion is visible across telehealth delivery: the 2023 WHO European Region digital health survey found that telepsychiatry had become the second most established telehealth service in the Region, with 42% of Member States (19 out of 45) reporting to be as an established programme. This was up from just 7% in 2015, a trend attributed in part to the disruption of in-person mental health care during the coronavirus disease (COVID-19) pandemic *(43)*. Over the last decade, governments across Europe have strengthened DMH governance by tightening standards for safety, privacy and evidence. European Union (EU)-wide regulations such as Regulation (EU) 2016/679 on General Data Protection Regulation (GDPR) *(44)* and Regulation (EU) 2017/745 on medical devices *(45)* set shared requirements for data protection and clinical quality. Belgium's mHealthBelgium validation pyramid links regulatory approval, interoperability standards and evidence of clinical and socio-economic value to progressive eligibility for public funding and reimbursement

(46). Germany introduced the *Digitale Gesundheitsanwendungen* [Digital Health Applications] (DiGA) pathway to enable evidence-based mental health apps to be prescribed and reimbursed *(36,47)*, although concerns about DiGA's limited evidence and real-world effectiveness despite high patient satisfaction, patients' lack of information from prescribing physicians and the literature's framing of transparency as key to acceptance all point to an underlying trust gap *(48)*. England (United Kingdom) has established the Digital Technology Assessment Criteria *(49)*, which is the national baseline for assessing any new digital health technology entering the National Health Service and social care sector, and has also updated National Institute for Health and Care Excellence (NICE) evidence standards to guide safe procurement and deployment *(50)*. Several countries – including Finland, Ireland and the Netherlands (Kingdom of the) – have also adopted centrally coordinated DMH platforms that have been integrated directly into care pathways. The WHO digital health survey *(43)* found that mental health was the single most commonly evaluated and approved category of mobile health app across the Region, with 12% of Member States (five out of 43) having formally assessed and approved mental health apps. This ranks it alongside fitness apps and ahead of diet, exercise and women's health, suggesting that, while governance frameworks remain uneven, mental health has emerged as a priority area for mobile health evaluation.

Across countries, there remains marked discordance in DMH policy and no international consensus on evaluation approaches, with many mental health apps operating in a largely unregulated space outside medical device classification, creating challenges in guiding service users toward safe and effective choices *(51)*. The above cases demonstrate that digital approaches can be integrated into routine care; however, options remain uneven. DMH is advancing rapidly yet, as described above, health systems often lack the governance structures, evidence standards and integration pathways required to implement solutions safely and equitably *(52)*. Where it is already implemented, DMH – specifically in the case of smartphone apps, generative AI and virtual reality – is hampered by wide variation in product quality and clinical effectiveness *(28)*. Health data systems in general have struggled with limited interoperability *(53)*, concerns about data protection implementation *(54)*, persistent inequities in digital access and literacy *(55)*, and fragmented benefit given the "digital divide" *(56)* and lack of trust in technologies *(57)* or the health system more broadly *(58)*.

Considering these challenges, the digital transformation of mental health systems requires coordinated and intentional action. These gaps underscore the need for consistent governance, standards and implementation frameworks.

The rapid proliferation of AI-enabled DMH tools across the Region is occurring in an environment of significant governance gaps. The *Roadmap for action on artificial intelligence in health in the WHO European Region 2026–2033 (9)* documents that fewer than 40% of Member States have any ethical guidelines for AI in health, and fewer than 10% have legal liability standards for AI systems. These gaps are particularly consequential in the mental health field, where AI-powered conversational platforms, already deployed by one half of Member States, interact with populations at heightened vulnerability. DMH occupies a distinctive position within the broader digital health landscape. Unlike many digital health apps, DMH tools routinely engage with individuals experiencing acute psychological distress, interact in ways that simulate therapeutic relationships and generate data that are uniquely sensitive to stigma and social harm. The ethical, clinical and governance implications of AI in mental health are therefore qualitatively different from, and in important respects more demanding than, those in other health domains.

Policy alignment and strategic foundation

Mental health and digital health are both embedded priorities within the Second European Programme of Work 2026–2030 – "United Action for Better Health" (EPW2) *(59)*. This Roadmap is firmly grounded in the regional and national commitments that flow from it. These include:

- the *WHO European framework for action on mental health 2021–2025 (60)*, which calls for the modernization of mental health services through local innovation, digital tools and peer support, and that will served as the basis for the upcoming WHO Regional Office for Europe mental health strategy for 2027–2035;
- EPW2 Priority 3: Living and ageing in good physical and mental health, which calls on the WHO Regional Office for Europe to support countries in integrating mental health into health and social systems, in developing community-based and youth-friendly mental health services, and to advance this Roadmap *(59)*;
- EPW2 Priority 5: Shaping the health systems of the future, which includes specific actions to leverage data and digital technologies – including AI – to strengthen health service delivery, expand digital health literacy and foster collaboration on DMH solutions across Member States *(59)*; and
- the *Regional digital health action plan for the WHO European Region 2023–2030 (1)*, providing strategic guidance for scaling digital transformation across health systems in the Region.

While this list is not exhaustive, together these frameworks position digital technologies as key enablers of modern, integrated and person-centred mental health systems. Systems that emphasize innovation, equitable access and the meaningful involvement of people with lived experience.

To accelerate implementation, the Pan-European Mental Health Coalition *(61)* was launched in September 2021. Through its Working Package 6: Supporting Countries to Transform Mental Health Systems, the Coalition prioritized the reconfiguration of services to be more person-centred, the improvement of access to evidence-informed technologies and the endorsement of the use of digital tools in promotion, prevention and care. By bringing together national leaders, professionals, civil society, international organizations and experts (by experience and by education), the Coalition aimed to address service gaps and promote mental health across the life course, particularly in the wake of the COVID-19 pandemic. The development of this Roadmap was an imperative provided by the various workstreams of the Coalition.

The Roadmap also reflects Member States' interest in:

- strengthening data protection
- aligning evidence standards
- improving quality assurance
- integrating emerging technologies safely
- supporting workforce readiness
- leveraging digital transformation more broadly across health systems.

A parallel *Roadmap for action on artificial intelligence in health in the WHO European Region 2026–2033* is in production *(9)* and addresses AI in several places, including AI Act compliance (Action Domain 3), AI-enabled tools within the definition of DMH and generative AI within evidence standards *(5)*. Where this Roadmap makes specific statements about AI regulation, these are intended to be consistent with the EU's Artificial Intelligence Act (Regulation (EU) 2024/1689) *(62)* and should be read alongside the *Roadmap for action on artificial intelligence in health in the WHO European Region 2026–2033 (9)*.

Objective and scope of the Roadmap

The objective of the Roadmap is to guide the effective planning, adoption and implementation of digital technologies across mental health promotion, prevention, care and system management. It translates the principles of the *Regional digital health action plan for the WHO European Region 2023–2030 (1)* into the specific realities and needs of mental health systems, where trust, therapeutic relationships and meaningful participation are central.

The Roadmap aims to:

- provide strategic and practical guidance for the integration of digital approaches within mental health systems;
- support alignment and coherence with regional and global priorities to avoid fragmentation and duplication; and
- promote safe, equitable and evidence-informed DMH that enhances human support and therapeutic connection.[5]

In response, the Roadmap will advocate for:

- shared principles and minimum actions across the Region;
- alignment with global frameworks, including WHO guidance and tools; and
- mechanisms for international collaboration in areas such as data protection, digital therapeutics, ethical oversight and workforce development.

The scope of the Roadmap includes digital strategies and services across the life course, from population-level mental health promotion to specialized clinical care. It focuses on the system-level conditions required for sustainable progress, including governance, standards, workforce capacity, infrastructure and evaluation. The guidance is high level and adaptable, allowing Member States to tailor actions according to their context, needs and stage of digital development.

The Roadmap does not prescribe specific platforms, technologies or target groups. Instead, it provides a coherent framework through which countries can determine their priorities, sequence actions and ensure that DMH developments are grounded in equity, lived experience and person-centred care.

[5] Of note, the aim is to deploy technology safely and to ensure that every implementation decision is guided by what genuinely benefits the people using these services.

The Roadmap

This Roadmap attempts to clarify how coordinated action across key system domains can, over time, lead to a digitally optimized and integrated mental health system and, ultimately, improved population mental health outcomes (see Annex 1 for detail regarding how the Roadmap was developed). It is important to be explicit: this is a Roadmap for DMH, not for digital health more broadly. Mental health systems carry particular obligations, such as to protect sensitive personal data and uphold human rights and dignity, to maintain therapeutic relationships and to reach populations that are often the most marginalized and the least digitally included. These obligations shape every element of the Roadmap, from the standards expected of digital tools to the principles that govern how they should be deployed and evaluated. Rather than presenting DMH as a set of technologies or isolated initiatives, the Roadmap frames it as a system transformation process. The Roadmap links cross-cutting principles (describing how DMH should be developed), Action Domains (the system levers through which change occurs) and short-, medium- and long-term outcomes (describing how readiness, embedding and sustainability are achieved), with actions to achieve these outcomes. Progress across Action Domains is expected to occur in parallel and at different speeds, depending on national contexts and system maturity. Sustainable financing and implementation capacity are treated as cross-cutting enablers, embedded throughout the Roadmap rather than treated as standalone concerns (Box 2).

Box 2. Implementation capacity and financing as cross-cutting enablers

Implementation capacity is embedded across all Action Domains rather than treated as a standalone area. Effective implementation requires capacity-building through explicit attention to readiness assessment, sequencing, adaptation and adoption. These are supported by appropriate implementation methodologies and tools. Across all Action Domains, implementation capacity should be guided by evidence from implementation science, with particular attention to scaling, sustainability, interoperability and ongoing performance monitoring.

Sustainable financing also underpins progress across all Action Domains. Financing for DMH is shaped through policy priorities, governance arrangements, regulatory assurance and evidence of impact. In the short term, financing may focus on enabling initial development and testing; in the medium term, on supporting scale and integration; and in the long term, on sustaining routine delivery. Regardless of the pathway, DMH services should be free at the point of use to maximize equity and access.

Implementation readiness is a prerequisite for sustainable adoption. Before deploying DMH tools, system-level readiness needs to be considered across three dimensions: technical readiness (infrastructure, interoperability and data systems); workforce readiness (digital competencies, change management capacity and clinical leadership); and organizational readiness (governance arrangements, stakeholder alignment and availability of implementation support). Validated tools such as the "WHO digital implementation investment guide" *(63)* can support structured readiness assessment and gap identification, informing the sequencing and resourcing of implementation activities.

Phased adoption is strongly recommended over wholesale deployment. A phased approach allows for the building of confidence, the early identification of problems and the embedding of learning before scaling. In practice, this means beginning with pilot or pathfinder sites that have sufficient readiness, clinical leadership and evaluation capacity; establishing clear go/no-go criteria between phases; and ensuring that scale-up decisions are grounded in evidence of both clinical effectiveness and implementation feasibility. Phased adoption is not sequential across the Roadmap's Action Domains because multiple domains may progress simultaneously; but within

Box 2. contd.

any given service or intervention, staged introduction with structured evaluation checkpoints significantly improves the likelihood of sustainable adoption and reduces the risk of costly failure at scale.

Iterative improvement cycles should be embedded from the outset. DMH systems are not static: technologies evolve, evidence accumulates, user needs shift and implementation contexts change. Building in regular review cycles enables continuous refinement. Iterative improvement also requires that services are designed to be adaptable: clear version control and governance processes for managing technology updates all support responsiveness without compromising safety or service continuity.

Final impact

The Roadmap is designed to support two closely linked and mutually reinforcing impacts:

1. a digitally optimized and integrated mental health system, in which digital approaches are embedded within care pathways, governance arrangements and service delivery models; and
2. improved population mental health outcomes, achieved through better access, quality, continuity, equity and responsiveness of mental health promotion, prevention and care.

Digital transformation is therefore positioned as a means, not an end, and its value lies in strengthening mental health systems and improving people's lives.

Principles as design foundations

A set of cross-cutting principles that were established with the consultative group (described in Annex 2) underpin all actions in the Roadmap and apply across all time horizons. These principles describe how DMH should be developed and implemented, rather than specifying what should be done or when.

These shared ethical commitments help to form the basis of what good DMH can look like in practice, and of the values that need to guide decision-making. Implementers are called upon to reflect on the following at each stage.

- Does this serve people well?
- Does it reflect genuine care for quality, for fairness and for the dignity of those who will use these services?

The principles include:

- person-centred approaches that enhance choice and respect individual preferences;
- equity, accessibility and inclusion;[6]
- quality and safety;
- collaboration, co-design and co-production with stakeholders, including people with lived experience;
- integration within the wider health and social care system; and
- alignment with national policy, reform and digital agendas.

[6] This principle requires explicit attention to populations that face compounded barriers to accessing and benefiting from DMH, including: young people; older adults; people with severe mental illness; refugees and displaced persons; people living in rural or remote areas; those with low digital literacy and groups experiencing poverty, social exclusion or mistrust of services; and people with psychosocial and other disabilities. DMH must not replicate or worsen existing inequities.

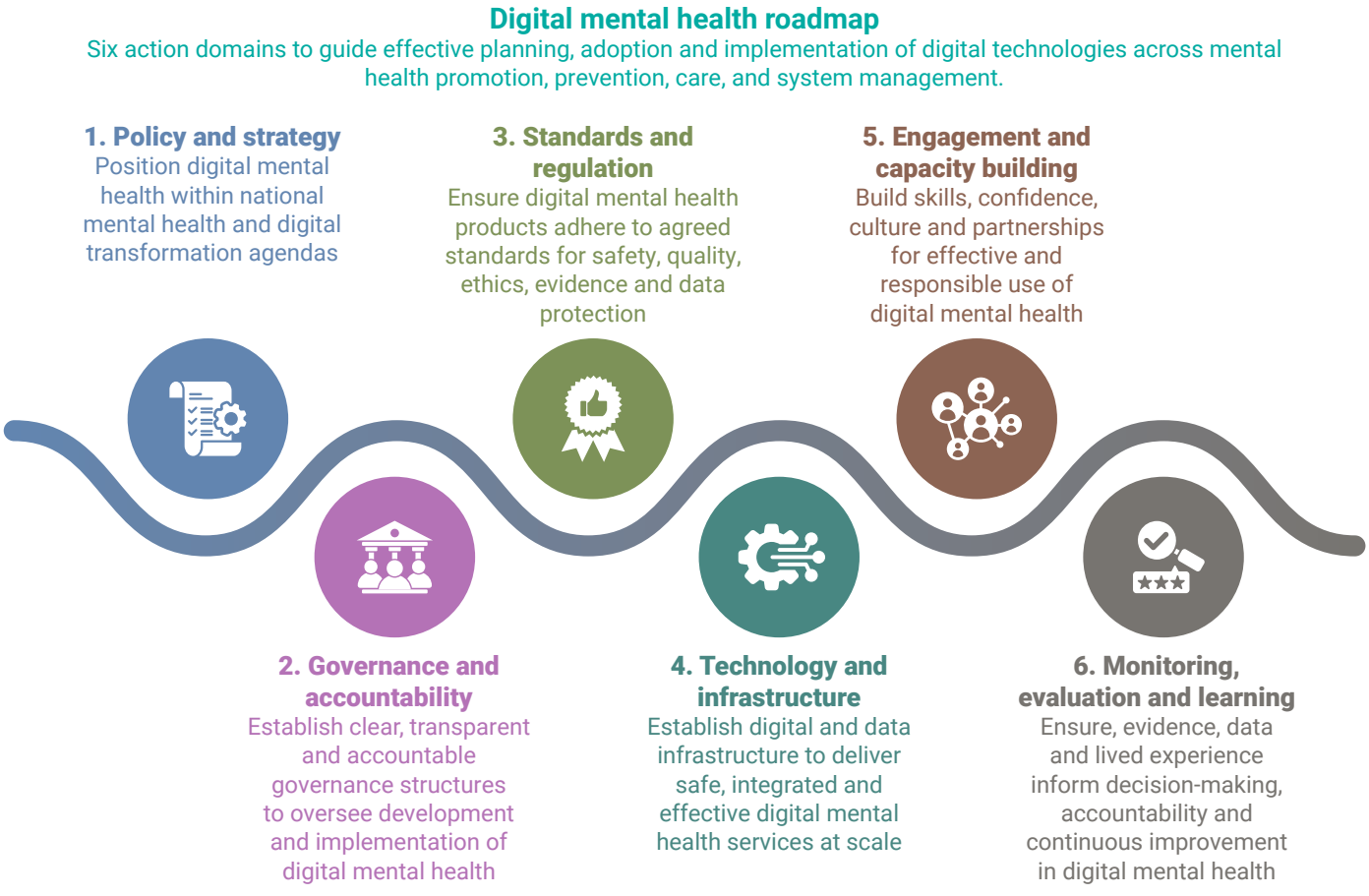
These principles act as design constraints and decision guides, ensuring that short-, medium- and long-term actions reinforce a coherent, ethical and system-oriented approach to DMH. More than that, they call on Member States, developers, clinicians and policy-makers to make genuinely good ethical decisions about how DMH should work, and to consider with care what DMH should achieve for the people it exists to serve. All principles are found in Annex 2.

Action Domains as levers for change

The Roadmap organizes action into six Action Domains (Fig. 1). These Domains represent the key system levers through which change must occur if the final impact is to be achieved. Each Action Domain has a clear purpose and contributes to multiple outcomes over time, requiring action in the short, medium and long term. Progress across Action Domains is intended to occur in parallel, not sequentially.

As DMH is a broader and more clinically sensitive field than general digital health, areas such as standards and regulation warrant distinct visibility given the particular considerations around mental health data, privacy, safeguarding, ethics and AI.

Fig. 1. The Action Domains



Note: Implementation capacity and financing are treated as cross-cutting enablers that support all Action Domains, rather than as standalone areas of activity.

Pathway of change over time

The Roadmap structures progress across three phases because meaningful change in DMH systems cannot be achieved all at once. Member States across the WHO European Region differ widely in governance capacity, financing, infrastructure and experience of implementing DMH tools. A phased approach acknowledges this diversity and allows countries to begin where they are, building confidence and evidence through early action before scaling. Critically, the mental health context makes phased, iterative implementation pragmatic and clinically essential: these tools interact with people experiencing acute psychological distress, generate uniquely sensitive data and carry ethical and safeguarding obligations that require trust to be built deliberately over time. The phases are not rigid sequential gates; progress across Action Domains may advance at different speeds, and countries will enter and move through them at their own pace. What the phases provide is a shared framework for sequencing ambition.

Phase one: building readiness and shared direction

In the short term, action focuses on establishing the foundational conditions required for safe, credible and coordinated DMH development.

Across the Action Domains, this includes:

- articulating a shared vision and priorities for DMH within existing policy and strategic frameworks;
- establishing clear governance, leadership, accountability and clinical oversight;
- identifying and adopting appropriate standards for quality, safety, evidence and data protection;
- assessing existing technology infrastructure and defining minimum data requirements;
- engaging key stakeholders, building trust, and strengthening digital literacy and early capacity; and
- putting in place initial monitoring and evaluation expectations.

At this stage, success is reflected in clarity, legitimacy and readiness, rather than scale.

Phase two: embedding and scaling within the system

In the medium term, DMH moves from conceptual alignment to routine practice with a specific focus on adoption through actively driving up usage by building awareness, knowledge, acceptance and confidence among both providers and populations.

Key outcomes might include:

- DMH being integrated into national mental health plans, budgets and reform programmes;
- governance and accountability mechanisms becoming routinized and resilient beyond individual champions;
- standards and regulatory requirements being embedded in procurement, commissioning and approval processes;
- technology and data systems supporting interoperability, service integration and informed decision-making;
- workforce competencies and co-design practices becoming standard components of service development; and
- monitoring, evaluation and research informing adaptation, commissioning and resource allocation.

At this stage, DMH becomes institutionalized rather than project-based.

Phase three: normalization, sustainability and population impact

In the long term, coordinated action across Action Domains results in DMH being fully normalized within the mental health system.

This includes:

- stable policy and regulatory frameworks that balance innovation with safety and rights;
- mature governance and financing arrangements that support sustainability and equity;
- robust, interoperable digital infrastructure that enables continuity of care;
- a digitally confident workforce and population with increased clinical digital leadership; and
- a learning mental health system in which data and evidence continuously inform improvement.

These conditions enable sustained improvements in access, quality, equity and outcomes at population level.

Using the Roadmap in practice

Member States can use this Roadmap flexibly:

- to identify priority short-term actions based on current system maturity
- to map existing initiatives against Action Domains and time horizons
- to support sequencing, coordination and resourcing decisions
- to communicate a coherent long-term vision while delivering achievable early progress.

The Roadmap does not prescribe specific technologies or models. Instead, it provides a structured pathway for decision-making, supporting locally appropriate choices that collectively move systems toward the shared final impact.

The Roadmap: Action Domains

2

Action Domain 1: Policy and strategy

Purpose

The purpose of this Action Domain is to ensure that DMH is deliberately positioned within national mental health and digital transformation agendas as a mechanism for addressing access gaps, service fragmentation, workforce pressures and inequities in mental health systems.

Actions

Actions are organized across three phases. Short-term actions are the minimum required to begin; they are deliberately focused on what is essential to start safely, rather than prescribing the ideal end state before any implementation has occurred. Medium-term actions build on what has been learned through early experience. Long-term actions address sustainability and the ecosystem conditions needed to support continued development over time. DMH is an iterative cycle of activity with the same core processes of planning, deploying, learning and improving repeated for each new technology, implementation cycle or development phase.

Phase one: minimum foundation to begin

- Map the current DMH landscape: what exists, what governance covers it and where the critical gaps are. This mapping is the prerequisite for all subsequent action.
- Articulate a strategic intent for DMH within at least one existing national policy or programme framework, even if a dedicated strategy does not yet exist. A clear statement of direction is required before investment decisions can be made.
- Identify a lead body or individual with responsibility and seniority to convene stakeholders and drive early action. Without this, coordination is unlikely to happen.
- Agree minimum equity and rights requirements that any DMH initiative must meet, to prevent piecemeal deployment that deepens existing inequalities (Box 3).
- Establish a financing baseline: identify what funding currently supports DMH and what gaps must be addressed to sustain even early pilots.

Phase two: embedding and building on early learning

- Develop or formalize a dedicated national DMH policy or strategy, informed by what has been learned from initial implementation.
- Integrate DMH explicitly into national mental health plans, reform programmes and budget cycles.
- Establish cross-sectoral coordination mechanisms across health, social care, education and housing.
- Define sustainable financing and reimbursement models, informed by cost and outcome data from early initiatives, and covering development, implementation and ongoing delivery.
- Institute policy review cycles, at least every 2–3 years, to update strategy in response to technological change, new evidence and service user feedback.

Phase three: sustainability and continued development

- Establish durable legislative or regulatory frameworks that provide a stable mandate for DMH independent of political cycles, while remaining adaptable to technological change.
- Build innovation infrastructure that encourages the development of next-generation DMH tools to replace those that age out or are decommissioned.
- Develop international collaboration mechanisms for joint standard-setting, evidence sharing and co-development of DMH approaches that no single country can resource alone.

Short-term outcomes

In the short term, countries establish clarity regarding the role of DMH within existing policy frameworks. This includes recognizing digital approaches as enablers of mental health promotion, prevention, early intervention and care, and explicitly linking them to prevailing policy objectives. For example, these might include improving access, strengthening community-based services, supporting primary care and addressing workforce and capacity constraints. In this way, strategic intent is articulated even where formal policy instruments are not yet in place, providing an initial mandate for coordinated action.

Medium-term outcomes

As implementation progresses, DMH is formally integrated into national mental health plans, programmes of work and associated financing and reform processes. Strategic alignment strengthens across health, social care, education and wider digital policy agendas, reducing siloed development and enabling more coherent prioritization and investment. Policy direction increasingly supports scale, interoperability and sustainability, rather than isolated or short-term initiatives. As DMH matures in national systems, Member States are encouraged to consider whether existing voluntary policy frameworks provide a sufficient mandate for sustained and equitable implementation, and to explore formal legislative or regulatory instruments where these would strengthen accountability.

Long-term outcomes

In the long term, policy frameworks provide a durable, system-level mandate for DMH that endures beyond individual projects or political cycles. Policies are designed to accommodate rapid technological change while maintaining consistent expectations regarding quality, safety, equity and rights. DMH is embedded as a routine component of mental health system planning and reform, directly supporting improved population mental health outcomes.

Box 3. Equity across the lifespan

DMH policies must explicitly address equity across the full life course, recognizing that mental health needs, digital capabilities and risks of exclusion vary substantially by age, and that no single approach will serve everyone equally well. This box focuses primarily on adults, including older people.

A life-course approach to equity

A life-course perspective recognizes that access to and benefit from digital health *(64)* is shaped by cumulative social, economic and structural factors – including poverty, rurality, disability, displacement, literacy and social isolation – that interact with age in distinct ways. Policy frameworks should therefore address equity not as a universal add-on but as a dimension that requires tailored attention at each stage of life.

Adults and older people

Adults across the life course face varied barriers to DMH access, often referred to as the digital divide *(65)*. The Organisation for Economic Co-operation and Development notes that older adults are disproportionately affected by the digital divide, with lower digital literacy, negative perceptions of ageing and limited access to technology restricting their engagement with digital health and social services. Technology-based interventions show potential for reducing social isolation among older adults, although evidence on loneliness reduction is inconclusive, and digital tools can carry unintended consequences such as heightening awareness of loneliness rather than alleviating it *(66)*.

For many older adults, these barriers are often compounded: lower digital literacy, limited access to devices, physical or cognitive impairments affecting usability, social isolation that reduces supported access, stigma and fragmentation of services. A systematic review of 35 qualitative studies found that older adults' engagement with DMH interventions is shaped by a complex interplay of individual, interpersonal and technological factors, including digital literacy, stigma, privacy concerns and the design and relevance of the intervention itself *(67)*. Crucially, older adults consistently preferred DMH treatment to complement rather than replace face-to-face support, and trusted recommendations from health-care professionals and social networks were key facilitators of uptake.

Policies should ensure that DMH services are designed for accessibility across the adult age spectrum, including through plain-language interfaces, adjustable text and contrast, voice-enabled options and co-design with older adults. A review found that DMH technologies designed for older adults should incorporate sensory-friendly interfaces, simplified navigation and emotionally resonant features – such as facilitated connection with caregivers or reassuring health feedback – recognizing that emotional meaningfulness, not just functional utility, drives sustained engagement in older age *(68)*. DMH therapies should avoid inadvertently reinforcing ageist assumptions that older people are unwilling or unable to engage with digital tools.

Particular attention is needed for older adults who face intersecting forms of disadvantage: those living in rural or remote areas with poor connectivity, those in residential or long-term care settings, those with limited formal education or low digital literacy, and those who are socially isolated. Without deliberate policy attention, DMH services risk deepening existing inequalities for these groups.

Box 3. contd.

Monitoring for equity across the life course

Monitoring and evaluation frameworks should include age-disaggregated data to assess whether DMH interventions are reaching adults equitably across the life course, and whether they are reducing or widening existing inequalities. Indicators should capture access, engagement, safety, user experience and outcomes, stratified by age, gender, socioeconomic status, geographical location and other relevant dimensions.

For consideration. Voluntary frameworks to binding instruments

Across the WHO European Region, a primary driver of variable and inequitable DMH implementation has been the soft-law nature of policy frameworks. Many argue for stronger proportionate regulation and evaluation to ensure safety, efficacy and timely oversight of these technologies. Without binding instruments and enforcement mechanisms, uptake is uneven and accountability is limited.

Member States are encouraged to consider the progression from voluntary guidance to formal legislative or regulatory mandates as DMH matures within their systems. The appropriate pace and form of this transition will vary according to national legal traditions, governance arrangements and system maturity, but the direction should be toward frameworks that carry meaningful accountability *(54,69,70)*.

Progress in policy and strategy development may be influenced by cross-cutting enablers and constraints, including political prioritization, competing reform agendas and financing pressures. Common barriers and enabling approaches underscore the importance of alignment with wider system priorities and sustained political commitment.

Action Domain 2: Governance and accountability

Purpose

The purpose of this Action Domain is to establish clear, transparent and accountable governance structures that oversee the development, implementation and ongoing stewardship of DMH. This domain includes responsibility for leadership, oversight, clinical governance, implementation stewardship, resourcing coherence and long-term system sustainability for DMH. Governance structures should ensure that lived experience expertise informs decision-making and oversight in a systematic and accountable manner, including safeguarding service users' choice over the balance between digital and human support in their care (Box 4). DMH governance should be integrated with wider health system governance, digital transformation agendas and mental health reform processes to avoid siloed or fragmented development. In many contexts, a national or central coordinating mechanism may improve consistency, efficiency and accountability, while still allowing flexibility for regional and local adaptation.

Governance arrangements for DMH should be developed in alignment with, and where possible nested within, the national AI governance structures called for in the *Roadmap for action on artificial intelligence in health in the WHO European Region 2026–2033 (9)*. Where Member States establish national AI-in-health governance bodies, mental health should be explicitly represented, given the distinctive ethical, clinical and human rights dimensions of AI-enabled mental health interventions. This includes ensuring that designated ministerial focal points for AI in health have clear lines of accountability for DMH, and that monitoring and evaluation frameworks for national AI governance capture mental health-specific indicators.

Box 4. Human connection, choice and flexibility in DMH

DMH services should complement rather than replace human contact, recognizing that therapeutic relationships, trust and continuity remain central to engagement, recovery and outcomes. Service users should retain choice regarding whether and how digital technologies are used within their care, including the extent to which support is delivered digitally or in person.

Service models should be flexible so that the balance between digital and face-to-face care can be adapted according to clinical need, severity, service user preference and local context. Different levels of human support may be appropriate for different interventions, ranging from light-touch guidance to more intensive clinician, peer or family support, depending on the needs of the user and the nature of the intervention.

Where there is disagreement between service users, families and clinicians regarding the use of digital technology, collaborative decision-making processes should be used to identify an approach that is appropriate, acceptable and person-centred.

Actions

Phase one: minimum governance to begin safely

- Identify or designate a lead governance body with clear responsibility for DMH, defined membership and sufficient seniority to make decisions and access budgets.
- Define minimum accountability arrangements: who is responsible for clinical safety, who for technical assurance and who for implementation oversight?

- Establish an initial mechanism for lived experience input into governance decisions.
- Agree a process for reviewing and, where necessary, stopping DMH initiatives where safety or evidence concerns arise.

Phase two: routinizing and strengthening governance

- Embed governance arrangements formally into organizational structures with documented terms of reference, reporting lines and accountability obligations.
- Develop transparency and performance reporting frameworks, including public disclosure of service quality data.
- Build governance capacity across teams through succession planning, documentation and distributed responsibility.
- Establish processes for overseeing software updates, algorithm changes and version control for DMH tools.
- Define how national, regional and local governance arrangements interact to prevent duplication and gaps.

Phase three: sustaining governance through system maturity and change

- Develop binding accountability mechanisms where voluntary oversight has proved insufficient.
- Establish independent audit functions with authority to assess governance effectiveness and make recommendations to senior decision-makers.
- Build governance arrangements that manage the full lifecycle of DMH tools, including active planning for replacement of services that age out.
- Develop governance frameworks that support responsible innovation: creating structured space for new approaches to be evaluated safely.

Short-term outcomes

In the short term, countries identify gaps in governance arrangements and establish or strengthen leadership structures for DMH at an appropriate level of seniority. Clear roles and responsibilities are defined for strategic oversight, clinical governance, technical assurance, implementation coordination and stakeholder engagement. Clinical leadership is explicitly embedded to ensure that DMH initiatives respond to identified clinical needs, align with care pathways and uphold patient safety and effectiveness.

Medium-term outcomes

Over time, governance arrangements become embedded and routinized, enabling consistent decision-making across national and subnational levels. Governance structures increasingly utilize data from DMH services to inform prioritization, commissioning and resource allocation. Capacity is built across teams to reduce dependence on individual champions, support succession planning and ensure continuity of oversight as initiatives scale. While core governance principles and assurance standards should remain consistent, governance structures and expertise may need to adapt over time in response to evolving technological and clinical contexts, such as the introduction of AI-enabled tools or expansion into specialist mental health services. This requires ongoing monitoring of governance needs across the portfolio of DMH services and adjustments to governance arrangements where necessary. As governance arrangements mature, it becomes important to assess whether accountability mechanisms carry meaningful consequences: voluntary models and informal oversight have historically underperformed in sustaining equitable implementation, and governance frameworks should increasingly be accompanied by clear reporting obligations and, where appropriate, binding commitments.

Long-term outcomes

In the long term, mature governance systems support sustainable delivery, continuous improvement and responsible innovation. Impact analysis and performance monitoring strengthen accountability and provide the evidence base required to secure long-term funding. Governance frameworks are sufficiently robust to oversee scaling, integration, adaptation and, where necessary, decommissioning of DMH services in line with system needs and performance.

For consideration

Effective governance must support not only the scaling of DMH services, but also their modification or decommissioning where evidence indicates limited effectiveness, safety concerns or misalignment with system priorities.

Effective governance and accountability can be constrained by leadership capacity, organizational fragmentation and reliance on individual champions. These cross-cutting challenges – and strategies to address them through strengthened coordination, leadership development and implementation support – are described in the sections concerning enablers and barriers to implementation.

Action Domain 3: Standards and regulation

Purpose

The purpose of this Action Domain is to ensure that DMH products, services and emerging technologies adhere to agreed standards for safety, quality, ethics, evidence and data protection. The ethical and regulatory considerations for DMH tools are among the most complex and consequential in the AI-in-health landscape. AI-powered mental health tools – including conversational agents, diagnostic support systems and crisis detection algorithms – interact with populations at elevated clinical and social risk; their failure modes may be less visible but more harmful than in other clinical settings *(9)*. Meaningful involvement of people with lived experience should be embedded within standards and regulatory processes through formal and sustained mechanisms, rather than ad hoc consultation. This includes participation in national advisory groups, regulatory committees and ethics panels, supported by clear roles, appropriate resourcing and accessible processes. Embedding lived experience expertise in this way ensures that standards, evaluation criteria and approval decisions reflect real-world needs, priorities and risks from the outset. Standards should be developed through inclusive, transparent processes involving regulatory authorities, clinical experts, people with lived experience, industry representatives and technical specialists, with regular review and updating to reflect technological advances, emerging evidence and changing system needs.

Scope and risk typology

The scope of DMH spans a spectrum of uses that are important to distinguish for purposes of governance, evidence requirements and workforce support. Population-level well-being and mental health promotion tools – such as psychoeducation platforms, digital self-help resources and well-being apps – are viewed as relatively low risk and require a light regulatory approach. Guided or therapeutic digital interventions for mild-to-moderate mental health difficulties such as iCBT, peer-support platforms and digital therapeutics require proportionate evidence of clinical effectiveness and clear safeguarding standards. Technologies used within specialist psychiatric care for severe mental illness – including digital phenotyping, AI-assisted clinical decision support and crisis management systems – carry the highest risk profile and require the most rigorous evidence, governance and clinical oversight.

Recent guidance from the United Kingdom's Medicines and Healthcare products Regulatory Agency *(71)* reinforces an emerging risk-proportionate approach, whereby lower-risk well-being apps require lighter-touch oversight, while technologies claiming to diagnose, treat, manage or support decision-making in mental health care require progressively greater levels of evidence, regulation, safeguarding and clinical governance.

This Action Domain also includes expectations for evidence generation and research, ensuring that DMH is evaluated proportionately to risk and linked explicitly to quality improvement, commissioning decisions and public trust. Research should encompass clinical effectiveness, implementation science, health economics and equity monitoring across diverse populations, ensuring that evidence generation addresses not only whether interventions work, but how they work, for whom and at what cost within real-world health systems. Research should be understood not as a separate academic activity but as a core regulatory and quality assurance function that supports standards development, approval decisions, market surveillance and continuous improvement (Box 5).

Box 5. Research as a core component of "standards and regulation"

As noted in this Action Domain, research within DMH should be treated as a core regulatory and quality assurance function rather than a standalone academic activity. Embedding research expectations within standards and regulatory frameworks ensures that DMH products and services are evidence-based, proportionate to risk and accountable to service users, clinicians and the public *(50,69,72)*.

Standards and regulatory processes should define clear evidence requirements across the lifecycle of DMH tools. Within the EU regulatory framework, this aligns with Regulation (EU) 2017/745 on medical devices *(45)*, which requires comprehensive clinical evaluation and post-market clinical follow-up for medical devices, including digital health apps. Minimum expectations should encompass safety, effectiveness, usability, equity and data protection prior to approval, alongside requirements for ongoing real-world evidence generation once services are deployed *(73,74)*. Evidence thresholds should be proportionate to the level of clinical risk and system impact, recognising the diversity of DMH interventions. The EU's Artificial Intelligence Act (Regulation (EU) 2024/1689) further reinforces this approach by classifying AI systems used in medical devices as "high risk", triggering comprehensive compliance requirements including risk management, data governance, technical documentation and human oversight *(62,75)*.

Research evidence should be explicitly linked to quality assurance, procurement, reimbursement and commissioning decisions, ensuring that only DMH solutions meeting agreed standards are scaled or sustained. Evidence-based frameworks such as NICE's Evidence Standards Framework for Digital Health Technologies provide structured approaches to assess clinical effectiveness, economic impact and system requirements proportionate to the level of risk and clinical claim *(73)*. Germany's DiGA pathway exemplifies this integration by linking evidence requirements directly to reimbursement eligibility, with ongoing real-world evidence generation mandatory for sustained market access *(43)*.

Regulatory frameworks should also support decisions to adapt, pause or decommission services where emerging evidence indicates limited effectiveness, safety concerns or inequitable impact. Real-world performance monitoring has emerged as essential for adaptive digital health technologies, particularly those incorporating AI or machine learning, enabling continuous assessment of safety and effectiveness in diverse populations beyond controlled trial settings *(69, 76–79)*.

To support consistency, standards should align with international guidance and best practice, including frameworks and tools developed by WHO, while allowing adaptation to national contexts. WHO's 2019 recommendations on digital interventions for health system strengthening emphasize the importance of evidence-informed implementation, interoperability and continuous quality improvement throughout the digital health lifecycle *(72)*. Meaningful involvement of people with lived experience in defining evidence criteria and interpreting findings should be embedded within regulatory processes, strengthening relevance, legitimacy and public trust. Systematic reviews demonstrate that co-designed DMH interventions show improved acceptability, engagement and sustained use compared with interventions developed without meaningful patient involvement *(79)*.

In this way, research functions as a quality safeguard and system learning mechanism, reinforcing standards, supporting responsible innovation and ensuring that DMH contributes to safe, effective and equitable care. The EU's Medical Device Regulation's requirement *(73)* for post-market clinical follow-up formalizes this continuous learning approach, mandating that manufacturers systematically gather, record and analyse real-world data on device performance, safety and quality throughout the product lifecycle *(76)*.

Actions

Phase one: minimum regulatory foundation to deploy safely

- Map existing national and international regulatory frameworks relevant to DMH (data protection, cybersecurity, clinical safety and medical device regulation). This mapping is required before any procurement or deployment decision.
- Adopt or adapt minimum safety and quality standards for the risk level of services being deployed first. Begin with the intervention categories already in use, rather than waiting for a complete regulatory architecture.
- Define proportionate minimum evidence requirements for each risk tier of DMH intervention. Services should not be deployed where they cannot meet these requirements, however modest.
- Designate initial regulatory responsibility: which existing body will handle oversight, and what is the process for raising a safety concern? This does not require a bespoke regulator at this stage.
- Establish the right to digital erasure as a baseline standard for any DMH service from the outset.

Phase two: building a regulatory system

- Develop dedicated regulatory capacity for DMH oversight, assessment, market surveillance and post-market monitoring. This should be informed by the gaps identified during early implementation.
- Embed standards and evidence requirements into procurement, commissioning, licensing and reimbursement processes, so that compliance becomes a condition of market access rather than a retrospective check.
- Establish structured processes for standards review and updating, operating on defined cycles and triggered by significant technological change, safety events or new evidence. Standards that cannot be updated are not fit for a fast-moving field.
- Develop regulatory coordination mechanisms with other jurisdictions to support mutual recognition where standards are aligned and reduce duplicative assessment burdens, including alignment with the EU's Artificial Intelligence Act (Regulation (EU) 2024/1689) *(62)*.
- Formally incorporate lived experience into standards development and regulatory advisory processes.

Phase three: sustaining regulatory quality and enabling the right innovation

- Develop controlled innovation pathways or regulatory sandboxes that enable novel technologies to be evaluated under regulatory oversight, with defined conditions of use and enhanced monitoring.
- Establish regulatory frameworks that support decommissioning as clearly as they support approval: services that no longer meet evidence or safety standards should have a defined exit pathway, with appropriate user transition support.
- Build international regulatory partnerships for shared surveillance of emerging technologies, cross-border incident reporting and harmonized approaches to AI governance in mental health contexts.
- Explicitly name and operationalize the right to erasure of personal mental health data (as established under GDPR Article 17) *(44)* within DMH service standards. Service providers should establish clear, accessible processes by which users can request deletion of their data from DMH services, including from apps they accessed in the past. Governance bodies (Action Domain 2) should include oversight of erasure compliance as a formal accountability function.

Short-term outcomes

Initially, countries review existing national and international regulatory frameworks and standards relevant to DMH, including those relating to data protection, cybersecurity, clinical safety and medical devices. Where possible, existing standards are adopted or adapted to the mental health context to establish minimum expectations for quality, privacy, dignity and effectiveness. These standards provide early assurance to service users, clinicians and policy-makers, while avoiding unnecessary duplication of regulatory effort.

For consideration

The right to digital erasure

Mental health data are among the most sensitive personal data categories, carrying heightened potential for stigma and long-term social harm if they persist beyond their intended use. The right to erasure (GDPR Article 17) *(44)* is a substantive protection for the autonomy and safety of people who have accessed DMH services. Standards should ensure this right is explicitly named, that service providers establish accessible erasure processes and that governance bodies oversee compliance. The long-term retention of mental health app data by commercial providers, including from services no longer in active use, demands particular regulatory attention.

Clinical confidentiality and regulatory data protection

Regulatory data protection addresses how data are stored, processed, transferred and deleted. Clinical confidentiality addresses the expectation that therapeutic disclosures, session content and clinical records are protected from third parties as a condition of the therapeutic relationship. These two concepts require separate treatment in standards, service design and workforce training. The distinction is particularly acute in digital care contexts: video therapy conducted in domestic settings, asynchronous messaging on shared devices and AI-assisted clinical tools that store conversation data all create confidentiality risks that data protection compliance alone does not address.

Early evidence expectations are clarified, including minimum evaluation requirements for safety, usability, equity and effectiveness, with evidence requirements explicitly stratified across the intervention spectrum from low-risk prevention and promotion tools to high-intensity therapeutic interventions. Initial regulatory capacity for oversight, assessment and enforcement is established, recognizing that effective regulation requires adequate resourcing and expertise.

Medium-term outcomes

As DMH activity expands, standards and regulatory requirements are systematically embedded within procurement, licensing, reimbursement and approval processes. Dedicated structures and processes are established to assess and regulate the use of new and emerging technologies, including AI and virtual or immersive tools, ensuring that innovation is guided by ethical, clinical and evidence-based considerations. Evidence standards are operationalized through defined decision thresholds proportionate to risk level and embedded into procurement and reimbursement pathways, so that only services meeting agreed evidence and quality requirements are scaled.

Effective regulatory frameworks are supported by adequate capacity for market surveillance, post-market monitoring, complaint investigation and enforcement action where non-compliance is identified, protecting service users and maintaining market quality. Third-party conformity assessment by notified bodies or authorized certification organizations, combined with quality management systems meeting recognized international standards, such as International Organization for Standardization standard ISO 13485 *(80)*, strengthens confidence in product safety and performance, while reducing the regulatory burden on individual national authorities. Adaptive regulatory pathways accommodate the iterative nature of digital technologies – including software updates, algorithm refinement and feature evolution – while maintaining oversight of changes that materially affect safety, performance or clinical claims.

Regulatory coordination across jurisdictions supports mutual recognition of assessments where standards are aligned, reducing duplicative evaluation while maintaining national discretion on adoption and reimbursement decisions. Regional coordination mechanisms accelerate approval timelines and reduce barriers to cross-border implementation where appropriate.

Long-term outcomes

In the longer term, regulatory and standards frameworks are sustained and updated in response to rapid evolving technologies, scientific evidence and system priorities. Beyond product regulation, professional standards and clinical guidance define appropriate use cases, integration into care pathways, workforce competencies and clinical governance arrangements for DMH, ensuring that regulatory approval is complemented by clinical oversight within service delivery contexts. Mature regulatory frameworks balance innovation with protection, incorporating controlled innovation pathways or regulatory sandboxes where appropriate to support evaluation of novel technologies under regulatory oversight while managing risk through defined conditions of use, time-limited approval and enhanced monitoring arrangements. Alongside regulatory oversight, national standard operating procedures for service delivery – such as nationally agreed approaches to risk management, safeguarding, escalation pathways, clinical documentation and data retention – can help maintain consistency and quality across services, while providing greater assurance regarding safety, accountability and suitability for different populations and care contexts.

For consideration

The Roadmap does not assess or endorse specific digital tools or apps, including those based on AI or immersive technologies. Instead, it establishes the system-level conditions required for their safe, ethical and evidence-informed use within mental health care.

The development and application of standards and regulatory frameworks may be affected by variability in regulatory capacity, awareness and enforcement across systems. Common barriers and enabling strategies – including mechanisms to strengthen trust, transparency and consistent application of standards – are outlined in the sections concerning enablers and barriers to implementation.

Action Domain 4: Technology and infrastructure

Purpose

The purpose of this Action Domain is to establish the digital and data infrastructure required to deliver safe, integrated and effective DMH services at scale. This includes meeting core system requirements for interoperability, adaptability, cybersecurity and integration with existing service models and care pathways. It also includes an opportunity to change approaches to overcome wider delivery issues, such as equality of service provision and accessibility of services in remote and rural areas.

DMH technologies should be designed to meet core system requirements while remaining adaptable to diverse national contexts and levels of digital maturity. Solutions should align with existing regulatory, ethical and data governance frameworks, and be capable of operating within current infrastructure constraints while supporting future system development. Where infrastructure limitations exist, phased and adaptive implementation approaches should be adopted to enable safe and effective service delivery in the short term while progressively strengthening system capacity over time.

Actions

Phase one: minimum infrastructure to enable first services

- Conduct a structured infrastructure readiness assessment covering connectivity, device access, health information systems and cybersecurity. This assessment determines what is feasible within current constraints and must precede deployment decisions.
- Define minimum system requirements for the first DMH services to be deployed: baseline interoperability expectations, accessibility requirements and cybersecurity controls.
- Establish a minimum dataset for monitoring service activity, safety and user experience from the first deployment.
- Prioritize modularity in early architectural choices so that infrastructure can evolve without requiring wholesale replacement as requirements change.

Phase two: developing interoperable and sustainable infrastructure

- Implement interoperability standards and integration workflows to connect DMH services with referral pathways, electronic health records and other care systems.
- Develop phased infrastructure investment plans, explicitly aligned with service models and care pathways, and designed to address the gaps identified in the short-term readiness assessment.
- Establish vendor management and lifecycle processes covering procurement, contract management, software updates and technology refreshment, so that infrastructure remains current and supported.
- Define business continuity, disaster recovery and contingency arrangements to protect service users from disruption.
- Incorporate environmental sustainability criteria into infrastructure procurement, including energy efficiency of data centres and device lifecycle considerations.

Phase three: building resilient infrastructure for a sustained and evolving ecosystem

- Establish infrastructure governance arrangements that actively manage technology lifecycles across the full portfolio of DMH services.

- Develop shared or federated infrastructure components – including common identity frameworks, interoperability layers and data exchange standards – that reduce duplication across services and enable coherent system-level responses to new technology generations.
- Build proactive relationships with research institutions, technology developers and international partners to ensure that infrastructure planning anticipates the next wave of DMH technologies, rather than always catching up with them.
- Ensure infrastructure planning explicitly supports service transformation and enables fundamentally different models of care that are only possible with mature digital foundations.

Short-term outcomes

In the short term, countries undertake a structured assessment of existing digital infrastructure. In parallel, countries define minimum system requirements for any DMH solution, including baseline interoperability expectations (e.g. with referral pathways and electronic health records where present), accessibility requirements and minimum cybersecurity controls. Early architectural choices prioritize modularity and adaptability so that services can evolve without requiring wholesale system replacement. This includes (but is not limited to) broadband availability, electronic health records, referral systems and access to appropriate hardware and software. These assessments are combined with demographic and geographical analyses to identify DMH initiatives that are feasible within current constraints and appropriate to population needs. Minimum datasets should be defined to enable consistent monitoring of service activity, outcomes and user experience.

For consideration

Establish a minimum dataset for DMH supports governance, accountability and system learning. Consistent data on service activity, outcomes and user experience enable informed decision-making, monitoring of equity and performance, comparison across contexts and decisions to scale, adapt or decommission services as appropriate.

Medium-term outcomes

As implementation advances, systems and processes are put in place to support interoperability, vendor and lifecycle management, data quality, cybersecurity and service continuity. Infrastructure development is explicitly aligned with service models and care pathways, ensuring that DMH supports integration rather than fragmentation within the wider mental health system.

Interoperability is implemented in practice through agreed technical standards, shared identifiers and integration workflows, enabling continuity across levels of care and reducing duplication, manual workarounds and siloed service delivery.

Long-term outcomes

In the long term, robust, interoperable and secure digital infrastructure underpins the routine delivery of DMH (in addition to service delivery, clinical and operational governance, and data and planning strategies being in place). Data are used ethically and effectively to support proactive care, service planning, performance monitoring and system-wide learning, contributing to improved efficiency, quality and outcomes.

Progress in technology and data infrastructure is shaped by system-wide enablers and constraints, including disparities in digital maturity, infrastructure gaps, data governance requirements and workforce readiness. These cross-cutting challenges, and approaches to addressing them through phased investment and adaptive service models, are described in the sections concerning enablers and barriers to implementation.

Infrastructure is resilient and adaptable, supporting iterative service improvement, technology refreshment and safe integration of new capabilities without disrupting continuity of care.

Action Domain 5: Engagement and capacity-building

Purpose

The purpose of this Action Domain is to build and sustain the skills, confidence, culture and partnerships required for effective and responsible use of DMH. Workforce capacity is addressed within this Action Domain rather than as a standalone item, reflecting the need to build skills, confidence, culture and leadership alongside service design and technological change. Workforce capacity includes clinical, digital, implementation and change leadership competencies, alongside protected time, supervision and support to embed digital approaches safely into routine care.

A skilled, supported and confident workforce is essential to the safe, effective and sustainable implementation of DMH *(81)*. This includes ensuring that clinicians, managers and support staff have the digital competencies required to select, use and integrate digital tools into routine practice while maintaining therapeutic relationships, professional judgement and quality of care. Workforce strategies should address digital literacy, role clarity, leadership capacity and change management, recognizing existing workforce shortages and pressures within mental health systems *(81,82)*. DMH should be positioned as an enabler of workforce sustainability. This is done through supporting efficiency, task-sharing, supervision and new models of care rather than as an additional burden. Ongoing training, access to practical guidance and communities of practice are critical to support adoption, build trust and ensure that DMH strengthens, rather than destabilizes, the mental health workforce. Key elements of workforce and population capacity-building are outlined in Box 6.

Engagement and capacity-building must address the diverse populations that use and deliver DMH services. Service users are not a homogeneous group. This Roadmap recognizes the distinct needs and contexts of young people, including considerations around co-design, digital literacy, prevention, early intervention and online safety. This is alongside the needs of older adults, people with severe mental illness, refugees and displaced populations, people living in rural and remote communities, people with low digital literacy and those experiencing poverty, exclusion or mistrust of services. Capacity-building strategies must be designed and evaluated with these populations in mind, including through dedicated approaches to digital inclusion within mental health services, rather than relying solely on broader national digital inclusion initiatives, ensuring that DMH does not replicate existing inequities in access and outcomes.

Box 6. Building DMH capacity in the workforce and the population

Capacity-building for DMH should include the following.

- Strengthening digital health literacy for both providers and service users, enabling safe, confident and informed engagement with DMH tools.
- Accessible learning resources for the public, supporting skills such as navigating digital platforms, understanding privacy and data use, and identifying reliable information.
- Training opportunities for providers that build competence in using digital systems, supporting service users in digital interventions, maintaining data security and integrating digital tools into clinical pathways.
- Structured capacity-building plans, as emphasized in WHO guidance, to support digital transitions across health systems and ensure approaches are coordinated and sustainable.
- Education and training that reflect diverse needs and contexts, ensuring that DMH is accessible and equitable for different populations.
- A coordinated, system-wide approach that establishes a common baseline of digital competence, reduces inequalities and supports the long-term adoption and effective use of DMH services.
- Protected time, supervision and change support for the workforce to adopt DMH safely, including reflective practice on risk, ethics and therapeutic relationships in digital and blended care.

Sources: (1,72,81,83,84).

Actions

Phase one: minimum engagement and capacity to begin

- Map stakeholders and establish at least one structured engagement mechanism before service deployment.
- Conduct initial digital literacy and readiness assessment among both service users and providers in settings where deployment is planned.
- Identify and address the most critical workforce capability gaps required for the first services being deployed. This does not require a comprehensive training programme at this stage because targeted support for the specific roles involved in early implementation is sufficient.
- Establish co-design as a minimum requirement for any new service entering development, with lived experience involvement from the outset of design.

Phase two: embedding capability and deepening engagement

- Embed DMH competencies within education, training and professional development pathways for the mental health workforce, informed by the capability gaps identified in the short-term phase.
- Establish communities of practice and structured peer-learning mechanisms, connecting early adopters with those beginning implementation, to accelerate learning and reduce duplication of effort across settings.
- Develop and sustain DMH literacy programmes for service users and the public, with accessible formats for diverse populations.
- Define new and evolving roles – such as digital navigators, implementation support specialists and clinical safety leads – with career pathways, supervision and multidisciplinary integration.
- Build implementation science capacity across teams, including skills in change management, service redesign and performance monitoring, recognizing that these are not one-off training needs but ongoing professional development requirements.

Phase three: sustaining a digitally confident workforce and population

- Develop sustained national frameworks for DMH literacy that treat confidence and competence as ongoing system assets to be maintained, not one-time achievements. As technologies change, the same cycle of capability assessment and development repeats.
- Build cross-sector partnerships to create a broader ecosystem of support for DMH capability that extends beyond the health system alone.
- Establish strong collaborative networks across Member States for shared workforce development resources, joint training initiatives and exchange of implementation expertise. No single country needs to develop all capabilities from scratch.
- Ensure capacity-building strategies continue to address the full diversity of populations using DMH services, revisiting equity assessments as the service landscape evolves and new groups are reached or excluded.
- Build workforce capacity to maintain clinical confidentiality in digital and blended care settings. This includes training on the specific confidentiality risks of video therapy, asynchronous messaging and AI-assisted clinical tools; guidance on supporting service users who access care from domestic or otherwise non-private environments; and particular attention to the confidentiality and safeguarding needs of young people, migrants and others in vulnerable situations.

Short-term outcomes

Initially, engagement, communication and capacity-building are established as core elements of DMH governance and implementation. Stakeholders are systematically mapped and engaged through consultation and co-design, including people with lived experience, clinicians, service providers and civil society. Early DMH literacy initiatives address identified gaps among both service users and providers, supporting informed use and risk awareness.

Medium-term outcomes

Over time, DMH competencies are embedded within education, training and professional development pathways for the mental health workforce. Co-design and co-production become standard practice in service development and evaluation. Communities of practice and knowledge-sharing mechanisms support peer learning, reinforce adoption and build cross-sector capability.

Over time, trust and confidence in DMH increase among service users, clinicians and the wider public. As DMH becomes more familiar, accessible and better integrated into routine care, greater numbers of

people choose to use services that are supported or enhanced through digital technologies. Workforce confidence, digital literacy and readiness for change also improve, enabling more consistent adoption and use across settings.

New and evolving roles (e.g. digital navigators, implementation support and clinical safety leadership) are defined and supported through career pathways, supervision arrangements and multidisciplinary team design.

Long-term outcomes

In the longer term, a digitally confident workforce and population support sustained, appropriate and equitable use of DMH. Cultural acceptance strengthens while preserving choice, person-centred care and the central role of human relationships in mental health support.

Engagement and capacity-building efforts may be influenced by levels of digital literacy, trust and readiness among service users, the workforce and the wider public. Common barriers and enabling strategies related to awareness, communication and cultural change are described in the sections concerning enablers and barriers to implementation.

Action Domain 6: Monitoring, evaluation and learning

Purpose

The purpose of this Action Domain is to ensure that evidence, data and lived experience inform decision-making, accountability and continuous improvement in DMH.

Monitoring and evaluation frameworks for DMH should be designed to be compatible with the regional AI monitoring architecture; this is beginning to be established through the *Roadmap for action on artificial intelligence in health in the WHO European Region 2026–2033 (9)*, which proposes a three-tier scoring framework for tracking progress across liability, AI literacy and monitoring and evaluation domains. Where possible, mental health-specific indicators should be designed to nest within this broader framework for regional learning infrastructure spanning DMH and broader AI-in-health monitoring.

Actions

Phase one: minimum monitoring to support learning from the start

- The definition of minimum indicators[7] covering access, utilization, safety events, user experience and basic equity disaggregation needs to be considered before the first service goes live.
- Establish data collection processes that are proportionate to the scale of initial implementation.
- Agree a process for reviewing monitoring data at regular intervals and feed findings back into implementation decisions.
- Use existing national and international evidence actively to inform early deployment decisions.

Phase two: embedding evaluation and evidence-informed decision-making

- Develop and implement a formal monitoring and evaluation framework, incorporating what has been learned about which indicators are most useful and feasible from early implementation.
- Integrate monitoring and evaluation into governance, commissioning, service delivery and performance management processes so that evidence use is institutionalized rather than ad hoc.
- Establish formal processes for using monitoring data to inform scaling, adaptation and decommissioning decisions.
- Develop processes for incorporating lived experience data like patient-reported outcomes, user experience and co-produced evaluation into improvement cycles, with service users engaged as active contributors to evidence generation.
- Build analytical capacity and specialist knowledge within health systems to use data effectively for service planning and learning, including investment in staff, tools and shared data infrastructure.

[7] A persistent challenge identified across the Region is the absence of standardized, comparable indicators for DMH, making it difficult to assess impact, benchmark progress or make the case for sustained investment.

Phase three: contributing to a learning ecosystem and sustaining the evidence base

- Develop governance frameworks for the secondary use of aggregate DMH service data for system planning, policy development and research, including data linkage arrangements across health, social care and education systems.
- Establish long-term research partnerships with academic institutions to sustain the evidence base for DMH across successive generations of technology.
- Develop population-level monitoring capacity that can track the contribution of DMH to mental health outcomes at system scale, disaggregated by age, geography, socioeconomic status and other equity dimensions.

Short-term outcomes

In the short term, countries establish expectations and mechanisms for the monitoring and evaluation of DMH initiatives. Early indicators focus on access, utilization, experience, safety and emerging outcomes. Existing national and international evidence is actively used to inform early implementation and stakeholder communication.

Medium-term outcomes

As data systems mature, monitoring and evaluation are routinely used to guide commissioning, scaling, adaptation and resource allocation. Research, service data and lived experience are integrated to strengthen the relevance, credibility and usefulness of evidence for decision-makers.

Long-term outcomes

In the long term, DMH operates within a learning mental health system. Continuous data collection, evaluation and research support adaptive policy, regulation and practice; sustain trust and accountability; and contribute directly to improved population mental health outcomes. This includes disaggregated monitoring data by population group – age, disability status, ethnicity, rurality, socioeconomic status and digital literacy – to enable equity monitoring and identify where DMH may be widening rather than narrowing access and outcome gaps. The learning system operates at regional as well as national scale: evaluation findings flow between Member States through structured knowledge exchange, so that successful approaches are rapidly shared and avoidable mistakes are not repeated across systems. This regional learning infrastructure sustains improvement over successive technology generations.

For consideration

Monitoring and evaluation should inform decisions to continue, adapt or discontinue DMH services in line with evidence and system needs.

The effective use of monitoring, evaluation and learning can be constrained by data availability, comparability and analytical capacity. Cross-cutting barriers and strategies to strengthen evidence generation and use are described in the sections concerning enablers and barriers to implementation.

Cumulative effects across Action Domains

Collectively, these Action Domains establish the system conditions required to move from short-term readiness, through medium-term embedding, to long-term sustainability and impact. Progress across Action Domains is interdependent and mutually reinforcing. Together, they enable the development of a digitally optimized and integrated mental health system that improves access, quality, equity and outcomes for people and populations.

Children and young people as a priority population for DMH

Children and young people have a distinctive relationship with both mental health need and digital technology, one that demands dedicated attention across all six Action Domains of this Roadmap *(85)*. The cross-domain implications set out below should be read alongside the relevant Action Domain sections, where each issue is addressed in greater operational depth.

Distinguishing digital harms and therapeutic digital uses

This Roadmap addresses digital technologies as therapeutic or support resources for young people with mental health needs. It does not address digital technologies as risk factors for youth mental health, nor the harms of problematic social media use, algorithmic exposure to self-harm content, cyberbullying and excessive screen time. That territory is covered by the WHO Regional Office for Europe document *Addressing the digital determinants of youth mental health and well-being: policy brief (86)* and other related guidance. The Roadmap's scope is bounded to avoid conflating these distinct policy questions, which require different governance responses.

Cross-domain implications for children and young people

The issues below are not unique to children and young people, but they are sharpened by the specific mental health vulnerabilities, developmental dynamics and digital exposure patterns of this age group. Each subsection identifies implications within the relevant Action Domain, and these should be read in conjunction with the full Action Domain content in the relevant sections.

Governance and policy (Action Domain 1)

National DMH policies should explicitly address children and young people as a priority group, with dedicated consideration of safeguarding obligations, consent and parental involvement requirements, and the specific vulnerabilities of young people in care, experiencing poverty or displacement, or living in unsafe home environments. Governance structures should include meaningful representation from young people with lived experience while governance frameworks should also respond to longstanding concerns about the lack of adequate clinical validation of many DMH tools. Many mental health apps are not subjected to professional evaluation or clinical validation studies, contributing to uncertain effectiveness and insufficient regulatory oversight *(87)*.

Standards and regulation (Action Domain 3)

Youth-facing digital interventions should be evaluated against a risk profile that encompasses algorithmic manipulation, age-appropriate platform design and data minimization *(88)*, dimensions that current regulatory frameworks are currently at different stages of integrating. The right to erasure is particularly salient for young people, whose DMH data may persist into adulthood and carry long-term social consequences. Clinical confidentiality standards must address the specific challenge of young people accessing care from home environments where privacy cannot be assumed. Privacy and data security are frequently cited ethical concerns, highlighting the risks of illicit third-party access, cybercrime and data leakage, and warning that confidentiality breaches may damage trust in mental health services and reduce treatment-seeking *(41)*.

Technology and infrastructure (Action Domain 4)

Infrastructure assessments should consider whether young people in rural, low-income or displaced communities have equitable access to the devices, connectivity and digital literacy needed to benefit from DMH services. The digital divide – whereby technology is not equally available to all social groups due to economic, social or cultural inequalities – represents a persistent structural barrier that risks exacerbating rather than reducing existing inequities in access to mental health care *(41)*. Engagement and retention are also material infrastructure concerns: a scoping review of DMH interventions for young people found a mean retention rate of 66% across studies, ranging from 16% to 100%, with even lower rates anticipated in real-world deployment outside controlled trial conditions *(89)*.

A related infrastructure challenge concerns service continuity and navigation. Young people who engage with DMH services at different stages of their mental health journey (or across multiple modalities) often lack transferable records between providers, meaning they must repeatedly recount their histories and restart onboarding processes. Ridout et al. argue that this fragmentation risks incomplete clinical histories, duplicate assessments and delayed or inappropriate care *(85)*. Addressing this requires interoperable electronic health record systems that span both digital and offline services, and that are designed with young people's non-linear mental health journeys in mind. Future-looking models of DMH care for young people must also be dynamic enough to incorporate emerging technologies, while ensuring that new modalities are evidence-tested before implementation and that user privacy remains the first priority *(34)*.

Engagement and capacity building (Action Domain 5)

Co-design with young people, carers and youth organizations should be standard practice for any youth-facing DMH service. Evidence suggests that young people prefer digital tools that are interactive, visually engaging, personalized and linked to peer support or social connection. Guided digital interventions – particularly CBT-based approaches supported by clinicians, peers or parents – tend to achieve higher effectiveness and better engagement than fully self-guided tools *(73,74)*. This pattern reflects the fact that the majority of DMH interventions for young people are largely concentrated on anxiety and depression, and dominated by CBT, which was used in 43% of included studies in a recent scoping review *(89)*. There is a need to expand the range of modalities and to design interventions that address the full spectrum of mental health conditions affecting young people. Evidence from the same study also indicates that blended approaches combining digital tools with human support tend to be more appropriate than digital-only solutions for young people with more complex presentations or confirmed mental health diagnoses, where clinician-led blended support was used in 74% of relevant studies. There is also growing evidence that young people want to use dynamic social media environments to seek information about mental health and receive peer support, and that counsellor-moderated peer-to-peer social networks can safely and effectively facilitate this, reducing stigma and increasing the likelihood of future formal help-seeking *(34)*. The role of DMH tools in facilitating patient autonomy and empowerment is also well supported in the literature, with young people reporting greater willingness to engage with digital tools due to their anonymity, accessibility and flexibility *(55)*.

Additionally, capacity-building in schools and youth services should include DMH literacy, online safety and critical engagement with digital tools. Workforce training should address the specific skills required to

deliver safe, effective DMH support to young people, including maintaining therapeutic relationships and clinical confidentiality in digital and blended care models.

Monitoring, evaluation and learning (Action Domain 6)

Monitoring and evaluation frameworks should include age-disaggregated indicators, and track both benefits and potential harms, for children and young people. Evaluation should consider the long-term sustainability of benefits and equity across different youth populations. Current evidence suggests that benefits for young people may diminish after the immediate post-intervention period, underscoring the importance of follow-up data collection *(89)*. Monitoring frameworks should also track potential harms within therapeutic digital contexts, including disengagement, privacy breaches and exposure to distressing content within platforms. Young people should be involved in defining what outcomes matter and in interpreting evaluation findings. Evidence gaps remain significant with fewer than one half of DMH studies for young people recording any follow-up data beyond the immediate post-intervention period, and marginalized groups including young people from low-income backgrounds, rural areas, those who are neurodivergent, migrants and those who are lesbian, gay, bisexual, transgender, queer/questioning, plus other sexual orientations and gender identities (also known as "LGBTQ+"). These groups are consistently underrepresented in the current evidence base, limiting what can be concluded about equity of benefit *(56)*.

Systematic monitoring of how young people engage with DMH services over time – including re-engagement patterns, dropout points and transitions between online and offline care – is essential to understand non-linear mental health journeys and to improve service design. This depends on transferable electronic health records across digital and face-to-face providers as a core infrastructure requirement to enable continuity of monitoring *(28)*. Routine screening and early intervention should, in turn, be informed by epidemiological evidence demonstrating that addressing mental disorders in childhood and adolescence yields long-term benefits for educational attainment, employment and broader societal outcomes *(90)*.

Barriers to implementation capacity

Transformative change in mental health systems inevitably encounters barriers. The guidance provided throughout this Roadmap is designed to address many of the common obstacles associated with the development and implementation of DMH. In particular, the principles underpinning the Roadmap act as core enablers, while the Action Domains set out the structural conditions required for change.

Effective governance, appropriate implementation methodologies and sustained engagement across stakeholders are especially critical in overcoming anticipated barriers.

Common barriers to DMH implementation capacity and corresponding strategies to address them are summarized in Table 1. The table draws together actions from multiple Action Domains and is intended to be read alongside, rather than in place of, the Action Domain-specific guidance.

Table 1. Barriers and proposed strategies and actions

Barriers	Proposed strategies and actions
Poor awareness or understanding amongst service users and the public	• Production of relevant evidence showcasing the benefits and impact of DMH. • General and targeted communications and promotion that stress the role DMH services and supports can play, and the benefits to service users. *Sources*: *(8,91–92)*
Mistrust and scepticism amongst service users and the public	• Promote the involvement of service users and the public in the design and development of DMH policies and services. • General and targeted communications and promotion that stress: the existing and growing evidence base for DMH; clinical safety and effectiveness; levels of service user acceptability; principle of co-production with service users and service providers; and opportunities to be involved in current and future DMH developments. • Visible enforcement of standards and regulations. • Use of service user champions. *Sources*: *(28,93,94)*
Poor awareness or understanding amongst service providers and clinicians	• Targeted communications that stress the role DMH services and support can play, the benefits to service providers and clinicians (e.g. assistance with administrative tasks), and that addresses concerns. *Sources*: *(95–97)*
Mistrust and scepticism amongst service providers and clinicians	• Targeted communications and promotion that stress: the existing and growing evidence base for DMH; clinical safety and effectiveness; levels of service user acceptability; principle of co-production with service users and service providers; and opportunities to be involved in current and future DMH developments. • Use of clinical champions. • Use of service user champions. • An identified governance structure at the right level of seniority, and with the required skills mix and representation. • Opportunities for involvement in DMH projects. • Visible enforcement of standards and regulations. *Sources*: *(28,56–58,94,98)*

Barriers	Proposed strategies and actions
Low levels of adoption	• Assess digital literacy and skills amongst service users and providers. Adopt strategies for upskilling where required. • Assess specific services and products for the following where adoption is low: accessibility, usability, integration and cost to end user. • Review how DMH services, supports and products are deployed to ensure they are integrated with, and complementary to, existing service delivery models. • Also ascertain whether digital solutions are being overutilized, e.g. as a "catch-all" intervention where not clinically appropriate or acceptable to the service user. • Consider whether there are key gatekeepers within the system, for example. general practitioners (who require targeted tailored engagement and communications on DMH). ***Sources:*** *(28,56–58,99)*
Poor basic technological infrastructure	• Further investment in digital infrastructure. • Consider innovative service delivery models that are interoperable and maximize the opportunities available through existing infrastructure. • Introduce innovations based on readily available technology at first (for example, back-office efficiencies for clinical teams utilizing existing software suites). • Maintain blended care (digital and human) as a default, so infrastructure gaps do not force full reliance on unreliable digital access. • Avoid assuming one-size-fits-all digital models will work universally across infrastructure contexts. ***Sources:*** *(100–102)*
Funding challenges	• Leverage policy mandate where available, otherwise seek to enshrine DMH in policy. • Review and strengthen engagement with key decision-makers. Consider stressing: evidence base, cost-saving opportunities, rigor of implementation methodologies and alignment with national priorities and other programmes of work. • Seek opportunities associated with wider digital transformation, if occurring. • Prioritize initiatives and projects with maximum impact for limited investment to showcase the potential of DMH. ***Source:*** *(28)*
Poor quality of DMH offerings	• Review standards and regulation for effectiveness and compliance. If regulations and standards are not in place, review international examples for guidance. • Review implementation methodologies for quality assurance. • Consider decommissioning services and supports if data and evidence show them to be ineffective. ***Source:*** *(28)*

Barriers	Proposed strategies and actions
Low levels of integration leading to siloed DMH development	• Consolidated coordination and commissioning at a national level • Standardize governance, evidence and procurement requirements where possible. • Emphasize interoperability to ensure new and existing systems can work together where possible. *Source*: *(102)*

Despite the rapid expansion of digital technologies within mental health care, persistent barriers continue to limit their full contribution to system improvement. Addressing these barriers requires coordinated action across policy, governance, standards, technology, engagement and capacity-building, and monitoring and learning, reinforcing the need for a system-level approach to DMH transformation.

Final points for the Roadmap journey

3

Successful implementation of this Roadmap is characterized by DMH being routinely and safely integrated within mental health systems; by service users experiencing improved access, choice, quality and continuity of care; and by policy-makers and service leaders having confidence that digital approaches are governed, evidence-informed and sustainable. Over time, these conditions support measurable improvements in population mental health outcomes.

Countries may be at different stages of development across Action Domains. It is expected that systems will operate at different time horizons simultaneously, with some domains focused on foundational actions while others advance toward embedding or sustainability. The Roadmap is intended to be used flexibly to reflect this variation. Countries may also benefit from structured mechanisms for networking, peer learning and knowledge exchange to support ongoing implementation and continuous improvement (Box 7).

Effective implementation requires clarity about who is expected to do what. Annex 3 offers a suggested framing of roles and responsibilities across key actors. This is indicative rather than prescriptive and is intended to support planning and accountability discussions at national and regional level.

Box 7. Good practice networking and knowledge exchange

Countries may benefit from establishing or joining regional and national mechanisms for knowledge exchange on DMH. This can accelerate learning, reduce duplication and strengthen consistency across standards and implementation approaches.

Options include:

- communities of practice for policy-makers, implementers, clinicians and lived experience partners;
- shared repositories of standards, procurement templates, evaluation frameworks and minimum dataset specifications; and
- peer learning across countries on governance models, integration approaches and decommissioning decisions.

Conclusion 4

The Roadmap is designed to produce measurable and lasting change across the WHO European Region, working through two closely linked impact pathways.

The evidence base for DMH continues to grow and is, in important respects, more developed than for digital health broadly. There is now a substantial body of evidence supporting the effectiveness of digital interventions – particularly iCBT – for depression, anxiety disorders and related conditions. Research has reliably demonstrated clinically meaningful symptom reduction across guided and unguided formats, with effects maintained at follow-up. Evidence for blended care models, digital therapeutics and crisis support platforms is accumulating. The evidence base for generative AI, digital phenotyping and virtual reality-based interventions is at an earlier stage, although it is expanding rapidly. Key outstanding challenges include limited evidence of effectiveness in under-represented populations, insufficient attention to long-term outcomes and real-world implementation contexts, and the need for stronger equity-focused evaluation. The Roadmap's emphasis on evidence standards, phased adoption and monitoring is designed to build this evidence base systematically over time, while enabling countries to make use of what is already known.

This Roadmap should be read alongside a set of companion publications that the WHO Regional Office for Europe will release in the coming period. These include: the findings from the Knowledge Community Platform on Digital Mental Health Regulations, which documents Member State regulatory approaches and identifies opportunities for harmonization, and a scoping review of DMH interventions, which provides a more granular synthesis of the evidence base for specific interventions and conditions. Together, these documents form a coherent suite of resources designed to support Member States at different stages of DMH development, from strategic planning and governance to the selection and evaluation of specific tools and approaches.

Progress will be uneven across countries and domains, and that is expected. The Roadmap is designed to accommodate different starting points and different trajectories. In the near term, impact is expected primarily at the system level. Member States will be better equipped to make coherent, evidence-informed decisions about DMH, supported by shared normative frameworks, governance guidance and mechanisms for regional peer learning. Policy fragmentation will reduce as countries align DMH development with wider mental health and digital transformation agendas. Governance and accountability arrangements will strengthen, and the meaningful involvement of people with lived experience in design and oversight will become standard practice rather than an exception.

Over time, these system-level changes should translate into tangible improvements in the lives of people across the Region. Better-governed, more equitably deployed DMH will mean improved access to timely support. Particularly for those currently underserved by conventional services, it will mean higher-quality and more-consistent care, with digital tools that complement rather than replace therapeutic relationships. It will mean that systems are better able to learn from data, adapt to emerging evidence and respond to technological change without compromising safety or rights.

The Roadmap will be most impactful where it is used as a living resource, revisited as national contexts evolve, digital technologies advance and the evidence base grows. Member States are encouraged to return to it at key planning junctures: when developing or updating digital health or mental health strategies; when making infrastructure or procurement decisions; when reviewing governance arrangements; or when making the case for sustained financing. Its value lies not in prescription but in providing a coherent, principled framework within which nationally appropriate choices can be made and defended.

Most importantly, this Roadmap is an invitation to act. Digital technologies will continue to reshape mental health care whether or not systems are ready for them. The question is not whether to engage with DMH, but how to do so safely, equitably and in ways that strengthen rather than fragment the systems people depend on.

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Annexes 6

Annex 1: How the digital mental health (DMR) Roadmap was developed

The development of the *Digital Mental Health Roadmap for the WHO European Region (2027–2035)* represents a collaborative and inclusive process jointly led by Ireland's Department of Health and Health Services Executive and the WHO Regional Office for Europe. The process was informed by relevant evidence, existing literature and the lived experiences of stakeholders from across the Region, ensuring that the Roadmap is both grounded in research and responsive to real-world needs.

Initial phase: identifying gaps in the strategic areas

The development of the Roadmap was initiated in response to growing recognition that while digital technologies present transformative opportunities for mental health services, their integration requires careful consideration of regulation, ethical standards and quality assurance. Strong interest in developing common quality standards for the safe use of digital technologies in mental health was expressed during:

- The first meeting of the working group on Mental Health Data in Copenhagen (December 2022); and
- The Porto meeting "Towards a Roadmap on Digitalization in Mental Health for Transforming Mental Health Systems in the WHO European Region" (September 2023).

These consultations identified key gaps and priorities that informed the strategic direction of the Roadmap, which was aligned with the four main themes of the European Digital Health Strategy *(1)*:

- governance, norms and standards: promoting political commitment, legal clarity, ethical correctness, data safety, financing strategies and integrating digital into established health services;
- capacity: promoting and funding research and enhancing digital health literacy and skills;
- infrastructure, horizon scanning and scale-up: promoting the highest standards of development and interoperability, and ensuring high-quality digital products and services; and
- networking and knowledge exchange: as a cross-cutting theme.

A concept note was developed (February–March 2025) to establish the scope, purpose, objectives and methodology for the Roadmap development process.

DMH Subgroup participants and contributors to the Roadmap

To ensure the Roadmap reflects diverse perspectives and practical realities, a multistage consultation process was established involving key stakeholders from across the WHO European Region. Core stakeholder groups were represented by:

- key Member State representatives leading DMH initiatives in their respective countries
- WHO Regional Office for Europe actors and technical experts
- organizations led by people with lived experience
- WHO collaborating centres
- clinical experts and mental health professionals
- digital health technology specialists
- policy and implementation leaders.

Extended consultations

The consultation process followed a phased approach to ensure iterative development and refinement.

Phase one: initial consultation with key stakeholders (April 2025). An online consultation was convened by the WHO Regional Office for Europe, led by Ireland, to:

- present and discuss the concept note and proposed approach
- agree on drafting principles and strategic areas
- identify priority themes and potential challenges
- establish the framework for the theory of change approach.

Phase two: first draft review (May 2025). Following the development of a preliminary draft synthesizing feedback from the initial consultation, the stakeholder group reconvened to:

- review the draft structure and content
- provide detailed feedback on the Action Domains
- ensure alignment with national contexts and priorities
- refine the short-, medium-, and long-term outcomes framework.

Phase three: follow-up consultation with key stakeholders (May 2025). A second round of consultation allowed for:

- review of the revied draft incorporating earlier feedback
- deeper engagement with specific technical areas
- validation of the "Enablers and barriers to implementation" section
- testing of the practical applicability of the guidance.

Phase four: refined draft development (June and July 2025). Feedback from earlier consultations was synthesized into a more complete draft, with particular attention to:

- strengthening the theory of change framework
- enhancing clarity and usability of Action Domain guidance
- ensuring comprehensive coverage of cross-cutting themes
- integrating implementation and financing considerations.

Phase five: Pan-European Mental Health Coalition consultation and WHO Health Information Network and its Subgroup on Digitalization and Innovation (July 2025). A regional consultation was held with broader stakeholder representation, including:

- members of the Pan-European Mental Health Coalition
- the WHO Health Information Network and its Subgroup on Digitalization and Innovation.

This consultation provided:

- regional validation of the Roadmap's relevance and applicability
- insights on diverse implementation contexts
- feedback on alignment with regional priorities and global standards
- input on dissemination and implementation support mechanisms.

Phase six: integration of consultation feedback (September–December 2025), including:

- incorporating feedback from all consultation phases
- incorporating references and supportive resources.

Phase seven: final consultation and structure validation with WHO Regional Office for Europe Technical Focal Points in Mental Health and members of the Working Group on Digital Health and AI (May 2026). A regional consultation was held with broader stakeholder representation, including:

- Technical Focal Points in Mental Health nominated by WHO European Region Member States; and
- members of the Working Group on Digital Health and AI.

This consultation provided:

- final technical validation of the Roadmap's structure, coherence and feasibility;
- Targeted feedback on the proposed actions, including their clarity, prioritization and operational relevance;
- Assessment of alignment with ongoing national, regional and global digital health and mental health strategies;
- Refinement of the theory of change, including confirmation of outcomes, outputs and enabling conditions;
- Strengthening of the call to action, ensuring it is actionable, context-sensitive and adaptable across diverse country settings; and
- Identification of entry points for implementation, including opportunities for integration into existing national plans and programmes.

Phase eight: finalization and preparation for publication. The final phase focused on consolidating all inputs and preparing the Roadmap for formal publication and dissemination. This included:

- final integration of feedback from all consultation phases, ensuring consistency and coherence across all sections;
- refinement of key messages, including the Executive summary and call to action, to enhance clarity, impact and usability;
- technical editing and quality assurance, including standardization of terminology, formatting and alignment with WHO publication guidelines;
- validation of references and supporting resources, ensuring accuracy and relevance; and
- design and layout preparation, to facilitate accessibility and user-friendly navigation of the document.

This phase ensured that the Roadmap is a high-quality, policy-relevant and actionable document, ready to support Member States in advancing the safe, effective and equitable use of digital technologies in mental health.

Throughout the consultation process, the WHO Regional Office for Europe provided secretariat support, convened engagement activities and coordinated communication among stakeholders.

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Annex 2:
Principles that underpin our approach to digital mental health (DMH)

Collaboration, co-design and co-production with stakeholders

Effective DMH depends on genuine collaboration across stakeholders including people with lived experience, carers, clinicians, researchers, community organisations, technologists, and policy makers. Evidence shows that co-designed tools are more relevant, acceptable, and sustainable *(1–5)*. Meaningful partnership throughout the DMH lifecycle must be supported by shared accountability, transparent governance, and attention to data protection and ethics *(6,7)*.

Integration and comprehensiveness

Digital mental health should be embedded within existing health systems and care pathways, supporting smooth transitions between levels of care and ensuring emergency responsiveness. Integration extends across technologies, service tiers, and user needs, from prevention to crisis care. Sustainable DMH requires alignment across policies, service models, and user journeys to achieve connected, coherent systems *(8)*.

Alignment

DMH development must align with national and local mental health strategies, wider digital transformation agendas, and budgetary and policy cycles. Ensuring that mental health is represented in broader health system reforms which, often has focused on physical health, is vital to avoid exclusion and maximise investment *(9)*.

Accessibility and equity

Digital innovation should expand access and reduce inequality, not replicate existing barriers. Each country should assess and address the digital divide, tackling issues such as connectivity, literacy, language, disability access, and affordability. An intersectional approach considers gender, age, ethnicity, disability, and socioeconomic status and is essential to achieve equitable benefit across populations.

Equity in digital mental health is not merely an aspiration but a structural requirement. Equity considerations should be built into procurement criteria, dataset curation standards, and post-market surveillance protocols for all digital mental health tools receiving public funding or recommended for use within national health systems. In particular, training datasets for mental health AI applications must be audited for representativeness across language, ethnicity, socioeconomic status, age, gender identity, and neurological diversity. The consequences of inaction in this area are acute: AI-enabled mental health tools deployed at scale without adequate governance are already in use across the Region, and in the absence of ethical frameworks, liability standards, or post-market surveillance, harm in mental health contexts, manifesting as clinical deterioration, crisis escalation, or reinforcement of suicidal ideation, is likely to be underreported and slow to surface *(10–12)*.

Person-centred choice and personal preference

Digital tools should enhance and extend care options while preserving choice. Service users should be able to decide how and when to use digital technology, supported by informed guidance from clinicians. Over time, increasing trust and familiarity should encourage broader voluntary uptake *(13,14)*.

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Annex 3:
Roles and responsibilities

Effective implementation of the Roadmap requires active contribution from a range of actors. The responsibilities outlined below are intended to be indicative rather than prescriptive, recognizing that roles will vary according to national contexts, governance arrangements and stages of digital maturity. They are designed to support accountability discussions at national and regional levels, and to clarify how effort and leadership should be distributed across the system.

These roles apply across all Action Domains and time horizons. No single actor can implement this Roadmap alone: the Roadmap's ambitions are achievable only through sustained collaboration, mutual accountability and a shared commitment to equity and person-centred values.

WHO Regional Office for Europe

The WHO Regional Office for Europe provides normative leadership and technical support across the Roadmap's full scope. This includes developing and disseminating policy guidance, standards frameworks and implementation tools; convening and facilitating peer learning across Member States; supporting governance capacity development; and advocating for the political prioritization of digital mental health (DMH) and the financing needed to sustain it. The WHO Regional Office for Europe maintains regional monitoring frameworks, synthesizes evidence and facilitates cross-country data sharing and benchmarking. It coordinates collaboration with the European Commission and other institutional partners, and ensures that Roadmap dissemination reaches decision-makers through its established regional networks.

Member States

Member States are the primary agents of implementation. Their responsibilities span the full policy and delivery cycle: developing, adopting and periodically reviewing national DMH policies and strategies; establishing and resourcing governance and accountability structures; enacting and enforcing regulatory and standards frameworks; investing in workforce digital competency and in digital infrastructure that supports equitable access; and financing DMH services in ways that ensure they remain free at the point of use. Member States are also responsible for reporting on progress against agreed regional indicators and for using monitoring and evaluation evidence systematically to guide adaptation, commissioning and decommissioning decisions.

Partners and civil society

Partners and civil society – including technology developers, nongovernmental organizations, professional associations and advocacy organisations – contribute to the Roadmap's implementation through innovation, accountability and engagement. They participate in governance, standards development and regulatory advisory processes; support co-design and delivery of DMH services; provide training and capacity building; and advocate for equitable, rights-based approaches. Civil society organizations play a distinctive role in connecting underserved and marginalized communities to DMH, and in providing independent accountability on equity, quality and safety.

Service users and people with lived experience

People with lived experience of mental health conditions hold a central and non-negotiable role in this Roadmap. They are not merely recipients of DMH services but active agents in their design, governance and evaluation. Their responsibilities include participating formally in policy co-design and consultation processes; holding representation in governance structures and standards development bodies; co-designing and co-producing digital tools and services; providing accountability feedback on quality, safety and impact; and contributing to the design and interpretation of monitoring and evaluation activities. Peer support and community engagement by people with lived experience also build trust and improve relevance, particularly for populations who are hard to reach through conventional service pathways.

Academia and research

Academia and research institutions underpin the Roadmap's commitment to evidence-informed practice. Their responsibilities include generating and synthesizing evidence to inform policy, governance and standards; independently evaluating the implementation, effectiveness, equity and impact of DMH initiatives; developing and evaluating training curricula and workforce competency frameworks; contributing implementation science expertise to support scaling and sustainability; and providing independent accountability through research and audit functions. Research institutions also play a role in international knowledge exchange, ensuring that learning from the WHO European Region contributes to and benefits from global evidence.

The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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