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DIGIVITALITY

JOINT TRANSNATIONAL STRATEGY TO IMPROVE CEE HEALTHCARE FINANCING POLICIES

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Executive Summary

This document addresses the critical need to accelerate the adoption of digital health technologies in Central and Eastern European (CEE) healthcare systems through improved public financing mechanisms. It proposes concrete action steps to overcome the regulatory, financial, and institutional barriers that currently impede the systematic reimbursement of validated digital healthcare solutions.

The analysis, conclusions, and recommendations presented in this document stem predominantly from comprehensive gap analysis conducted across Czech Republic, Hungary, Poland, Slovakia, and Slovenia during the second half of the DIGIVITALITY project implementation period. The evidence base was developed through extensive stakeholder mapping and participatory processes including structured interviews and multi-stakeholder workshops with health insurers, hospital administrators, regulatory agencies, public health bodies, and digital health innovators during 2023-2024. These consultations identified common barriers affecting all CEE countries while recognizing country-specific contexts requiring tailored implementation approaches[1].

The strategy draws inspiration from established Western European financing models for digital health solutions, particularly Germany's Digital Health Applications (DiGA) fast-track process, Belgium's mHealth Pyramid, and France's PECAN program. However, rather than prescribing direct adoption of these frameworks, the strategy carefully analyzes their core principles, success factors, and implementation challenges to extract lessons applicable to CEE contexts while addressing the specific institutional capacities, healthcare system structures, and political economies characteristic of the region.

A fundamental premise underlying this document is that systematic digital health financing represents complex structural healthcare reform requiring multi-year commitment and sequenced implementation. International experience, particularly from France where achieving functioning reimbursement frameworks has proven challenging even with strong institutional capacity, demonstrates that establishing effective digital health financing systems demands careful preparation, stakeholder consensus-building, and institutional capacity development that cannot be rushed.

Given this reality, **this Joint Transnational Strategy deliberately focuses on foundational and preparatory steps rather than prescribing a specific financing model** for immediate implementation across the CEE region. The document recognizes that CEE countries are in early developmental stages regarding digital health ecosystems, with most activity currently limited to isolated pilot projects lacking systematic institutional frameworks or sustainable financing mechanisms.

Therefore, **this strategy does not advocate for a single, uniform financing model to be adopted immediately across all CEE countries**. Instead, it presents a carefully sequenced three-phase approach that builds essential foundations before countries make fundamental strategic commitments about permanent reimbursement frameworks:

1. **Phase 1 (0-12 months): Information Transparency and Accessibility** establish comprehensive online guidance, process maps, and support resources enabling innovators to understand regulatory requirements and financing pathways. These foundational actions require minimal financial investment while creating shared stakeholder understanding of requirements and processes.

[1] Workshop minutes, institutions and experts attending are the stand-alone output of the Digivitality project.

2. **Phase 2 (6-24 months): Financial Support and Testing Infrastructure** provide tangible mechanisms including CE certification vouchers and sandbox environments where digital health solutions can be validated safely. These interventions enable evidence generation through controlled pilot implementations while managing risks and building institutional experience.
3. **Phase 3 (6-36 months): Strategic Decision-Making on Reimbursement Frameworks** involve establishing multi-stakeholder working groups to develop comprehensive feasibility studies that critically assess international models against local contexts. Only after completing this rigorous analytical and deliberative process do countries make informed decisions about which systematic financing approaches best fit their specific healthcare system structures, institutional capacities, fiscal constraints, and policy priorities.

This flexible, phased framework acknowledges that no single solution fits all CEE countries while providing clear guidance on evidence-based approaches that have succeeded in comparable healthcare systems. It enables countries to progress at speeds appropriate to their institutional readiness, political circumstances, and resource availability, while learning from each other's experiences and maintaining opportunities for regional cooperation that leverages collective strengths to overcome individual country limitations.

1. Context and Rationale

1.1 The Digital Health Imperative

The global demographic transition presents unprecedented challenges for healthcare systems worldwide. The number of people aged 60 and older is projected to double to 2.1 billion by 2050, with the segment aged 80 and above growing even faster. This demographic shift is also pronounced in Central and Eastern Europe, where aging populations combined with physician shortages and constrained healthcare budgets create urgent pressure on healthcare systems to find new solutions for managing larger patient populations with existing resources.

Digital health technologies offer promising approaches to these challenges by enabling healthcare systems to manage larger patient loads with existing personnel while maintaining or enhancing patient safety and care quality. Telemedicine platforms have potential to reduce the burden on healthcare professionals by minimizing unnecessary in-person patient visits, shortening hospital stays, and decreasing costly rehospitalizations. Remote monitoring solutions enable opportunities for proactive intervention before medical conditions deteriorate, potentially preventing acute episodes requiring emergency care. Mental health applications provide scalable psychological and behavioral health support without requiring proportional increases in specialist availability—particularly critical given severe shortages in mental health workforce across the CEE region.

The COVID-19 pandemic accelerated awareness of digital health possibilities, demonstrating that remote care delivery can maintain continuity when traditional in-person models face disruption. However, the crisis also revealed the gap between ad hoc emergency responses and systematic integration of digital health solutions into standard care pathways supported by sustainable financing mechanisms.

1.2 Current State in CEE Region

Despite the potential benefits of digital health technologies, the CEE region significantly lags behind Western European countries in digital health adoption and systematic public financing. While isolated pilot projects occasionally demonstrate promising results, these initiatives typically operate as exceptions rather than integrated components of healthcare delivery. The transition from pilot projects to systematic financing and broader implementation faces multiple interconnected barriers spanning regulatory frameworks, financing mechanisms, technical infrastructure, and market economics.

These challenges cannot be overcome through technological solutions alone—they require active participation of public stakeholders and strong cooperation among health insurance companies, hospitals, digital health innovators, patient advocacy groups, regulatory authorities, and policy-makers. Successful digital health integration demands coordinated action across multiple institutions, each playing distinct but complementary roles in creating enabling environments for innovation adoption.

The DIGIVITALITY Project Approach:

The DIGIVITALITY project conducted extensive stakeholder mapping and gap analysis across Czech Republic, Hungary, Poland, Slovakia and Slovenia during 2023-2024. Innovation Hub[2] in every country performed multiple research methodologies to ensure comprehensive understanding of the status quo, barriers and opportunities through:

- **Document analysis** reviewing existing legislation, regulatory frameworks, reimbursement procedures, pilot program evaluations, and policy documents.
- **International benchmarking** examining digital health reimbursement frameworks in Western European countries to identify transferable best practices.
- **Multi-stakeholder workshops** bringing together diverse participants to identify common challenges, surface differing perspectives on priorities and solutions, build consensus on action priorities, and develop country-specific implementation roadmaps.

Through these consultations, the project identified common barriers affecting all CEE countries while recognizing important differences in healthcare system structures, institutional capacities, political contexts, and implementation readiness that necessitate country-specific approaches within a common strategic framework.

1.3 Key Medical Areas with High Potential for Digital Health Solutions:

The stakeholder consultations identified four priority domains where clinical need, technical feasibility, and potential healthcare system impact align favorably for the broader adoption of digital innovations in the CEE regions:

Monitoring of chronic diseases: Continuous monitoring of chronic diseases such as diabetes, cardiovascular conditions, and respiratory issues represents a high-priority application area. Digital solutions enabling remote data collection, trend analysis, and early warning systems can facilitate proactive intervention before conditions deteriorate, potentially reducing emergency hospitalizations and improving long-term

[2] DEX Innovation Center (Czech Republic), Health Venture Lab (Hungary), Ljubljana University Incubator (Slovenia), Medical University of Lodz (Poland) and Slovak alliance for innovation economy (Slovakia).

disease management. Given the prevalence of chronic diseases in aging CEE populations and the burden these conditions place on healthcare systems, chronic disease management represents both significant need and substantial opportunity for efficiency gains through digital health adoption.

Mental health services: Mental health emerged as a domain with exceptionally high demand for digital tools including telepsychiatry, online therapy, digital therapeutics for conditions like depression and anxiety, and mental health support applications. The severe shortage of mental health specialists across EU countries[3]—creates an urgent need for scalable solutions that extend limited specialist capacity. This domain is particularly suitable for early implementation.

Rehabilitation and physiotherapy: Home-based digital rehabilitation and physiotherapy platforms represent another high-potential domain. These solutions can extend limited clinical capacity for rehabilitation services, improve patient convenience and adherence through home-based programs, provide objective monitoring of exercise completion and progress, and enable remote guidance and adjustment of treatment plans by clinicians. Particularly for post-surgical rehabilitation, stroke recovery, orthopedic conditions, and cardiac rehabilitation, digital platforms can maintain quality care while reducing facility-based visit requirements.

Remote health monitoring for the elderly: Remote monitoring solutions for elderly patients—especially in rural areas and retirement homes common throughout the CEE region—address critical access barriers. Geographic distance, limited mobility, and transportation challenges often prevent elderly patients from accessing specialist care regularly. Remote monitoring technologies can enable vital sign tracking, medication adherence monitoring, fall detection and emergency response, and ongoing connection with healthcare providers, improving both access to care and patient safety while reducing unnecessary facility visits.

These four domains share common characteristics making them suitable for initial digital health financing initiatives: they address significant clinical needs affecting substantial patient populations, they offer clear potential for healthcare system efficiency gains or improved access, technical solutions are relatively mature with several validated options available.

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2. Gap Analysis: Common Barriers Across CEE Countries

The DIGIVITALITY project's gap analysis revealed that barriers to digital health adoption in CEE countries are not primarily technological but rather systemic, spanning regulatory frameworks, financing mechanisms, technical infrastructure, and market economics. These interconnected challenges create a complex environment where even clinically validated and CE-marked digital health solutions struggle to access public reimbursement and achieve sustainable market adoption.

2.1 Regulatory and Legal Barriers

Regulatory frameworks across CEE countries were designed for medicinal products and medical devices, resulting in incompatibilities with software-based health solutions. Unlike physical medical devices that follow established pathways from manufacturing through distribution, digital health applications challenge existing definitions, distribution models and regulatory categorization processes. Three critical regulatory gaps emerged consistently across all five countries:

[3] Transforming mental health in Europe: from crisis to opportunity. The lancet Regional Health - Europe, Volume 57, 101492.

Lack of Clear Public Financing Pathways

The most fundamental barrier identified is the absence of clear and dedicated public financing pathways for digital health solutions to enter public health insurance systems. Existing legislation on public financing, typically designed for medicinal products and traditional medical devices, is often inadequate or outdated, failing to properly accommodate digital health tools like telemedicine platforms or mobile health applications.

Current reimbursement frameworks assume physical products with stable specifications, distributed through established channels, and prescribed in standardized units. Digital applications which may be continuously updated, distributed electronically, and utilized through variable engagement patterns, simply do not fit these existing paradigms. This creates regulatory uncertainty that discourages both innovators from pursuing public financing and payers from considering coverage.

Definitional Gaps in Legislation

Legal frameworks across CEE countries follow EU legislation. However, experience of Slovakia and the Czech Republic - further elaborated in the country-level action plans in the Annex - shows the need for additional explanation of legislation on the local level, so digital health solution providers understand regulatory requirements for concepts such as "telemedicine solution," "digital application," or "remote monitoring device" or which administrative bodies hold decision-making authority.

Distribution and Access Challenges

Current regulatory frameworks are focused on medical devices as physical components. This might be challenging with obvious practical barriers for digital-only solutions that have no physical component to dispense. For example in Slovakia, all medical devices have to be dispensed through physical pharmacies or designated medical device dispensaries.

The absence of virtual dispensing mechanisms means that even if a digital application achieved medical device status and reimbursement approval, the actual logistics of "prescribing" and "dispensing" it to patients remain unclear. Questions arise about who verifies patient eligibility, how usage is tracked for billing purposes, how prescription limits are enforced, and what entity assumes responsibility for adverse event reporting.

2.2 Systematic Financing Gaps

Beyond regulatory clarity, CEE countries lack the mechanisms necessary to include digital health solutions into public financing at scale. While isolated pilot projects occasionally receive ad hoc funding, no CEE country has yet established a dedicated, transparent, and sustainable pathway for digital health applications to transition from innovation to standard care. Two critical financing gaps emerged from the stakeholder consultations:

Limited Public Financing

The most significant financing barrier is the fundamental absence of systematic public financing for standalone digital health applications. Unlike in Germany, Belgium, or France—where dedicated reimbursement schemes for digital health have been established—CEE countries rely on ad hoc arrangements

where digital solutions are occasionally financed as time-limited pilot cases by health insurers from their discretionary operational budgets.

These pilot arrangements, while valuable for demonstrating proof-of-concept, suffer from several limitations: they typically cover only small, selected patient groups; they operate under exceptional rather than standard procedures; they provide no clear pathway from pilot to systematic coverage; and they create uncertainty for both innovators (who cannot predict revenue sustainability) and healthcare providers (who cannot confidently integrate pilots into standard care pathways).

The absence of systematic public financing mechanisms means that even when digital health solutions demonstrate clinical efficacy and cost-effectiveness in pilots, they often fail to achieve broader adoption because no institutional pathway exists to transition from exceptional funding to standard coverage.

Assessment Process Inadequacies

Even when digital health companies seek reimbursement through existing channels, they encounter assessment processes designed for medicinal products and traditional medical devices. Health Technology Assessment (HTA) frameworks across CEE countries typically prioritize evidence from randomized controlled trials, long-term outcome data, and comparative effectiveness studies—appropriate requirements for interventions with stable specifications and long development timelines. While HTA bodies increasingly accept real-world evidence when RCTs are impractical, traditional clinical trial evidence remains the gold standardHealth Technology Assessment (HTA) frameworks across several CEE countries require evidence from randomized controlled trials, long-term outcome data, and comparative effectiveness studies—all reasonable requirements for interventions with stable specifications and long development timelines.

However, digital health applications present unique assessment challenges. Software evolves continuously through iterative updates, making traditional "fixed version" assessment problematic. While clinical evidence for digital health technologies increasingly comes from real-world deployment given the impracticality of blinding and the importance of user experience factors, HTA bodies are still developing frameworks to systematically evaluate such evidence alongside or in place of controlled trials.However, digital health applications present unique assessment challenges. Software evolves continuously through iterative updates, making traditional "fixed version" assessment problematic. In case of digital health technologies clinical evidence often comes from real-world deployment rather than controlled trials, given the impracticality of blinding and the importance of user experience factors.

Experts interviewed during the DIGIVITALITY project implementation suggested that HTA processes increasingly recognize alternative evidence formats and assessment criteria specifically tailored for digital health innovations. Without such adaptations, digital health solutions face the paradox of being compared to evidence standards designed for different intervention types, creating barriers disproportionate to their risk profiles—particularly for low-risk applications focused on mental health or nervous system, heart monitoring or medication reminder.

2.3 Technical and Infrastructure Barriers

Another barrier stems from the fragmented nature of health information systems across CEE countries, which combined with limited institutional capacity for digital health evaluation, constrains the ability of healthcare systems to integrate and assess digital solutions effectively:

Data and Interoperability Challenges

CEE countries generally lack centralized, standardized digital repositories for patient health data that digital applications could access with appropriate authorization. Where electronic health records exist, data is often unstructured, siloed across institutional boundaries, and stored in proprietary formats that resist interoperability.

Digital health applications typically require access to patient medical history, laboratory results, medication records, or clinical imaging to function effectively. When such data is scattered across disconnected hospital information systems, primary care databases, and insurance claims repositories—each with different technical standards and access protocols—the cost and complexity of integration might become prohibitive, particularly for startup companies with limited technical resources.

The lack of unified data standards also impedes evidence generation, as real-world effectiveness studies require linkage between digital health application usage data and clinical outcomes recorded in healthcare systems. Without interoperability, such linkage remains manual, time-intensive, and often impossible at the scale necessary for robust evidence.

Capacity and Resource Limitations

CEE countries face limited HTA personal and budget capacities[4], with small teams responsible for evaluating all health technologies across medicinal products, medical devices and now digital health. Such capacity constraints frequently lead to substantial delays in evaluation processes, with some assessments extending over several months even for conventional non-digital applications. Slovak health insurance companies raised this as a particular concern, that the emergence of new digital health solutions add further pressure on HTA capacities that are already operating under significant resource limitations.

These resource limitations create a "chicken-and-egg" problem: digital health solutions need real-world deployment to generate evidence for reimbursement decisions, but healthcare institutions cannot afford to implement solutions that lack reimbursement, particularly when implementation requires upfront investment in integration, training, and workflow redesign.

2.4 Market and Economic Barriers

The economic realities of CEE healthcare markets create additional challenges for digital health innovation beyond regulatory, financing, and infrastructure barriers. Small population sizes, limited healthcare budgets relative to Western Europe, and regulatory burdens specific to the European context combine to create an environment where digital health companies often struggle to justify market entry:

Small Market Size

Small market size emerged as a significant concern for most CEE countries, with Poland being a potential exception due to its larger population of 38 million. For Slovakia (5.5 million), Slovenia (2.1 million) and even Czech Republic (10.5 million) or Hungary (9.7 million), the addressable patient population for any specific digital health indication remains limited.

This market size constraint affects both innovation incentives and reimbursement dynamics. From an innovation perspective, digital health companies—particularly those based in larger markets—often prioritize countries where successful launches can generate substantial revenue. The investment required

[4] (Garciáa-Mochón et al,. 2019) (Kaló et al., 2016)

to navigate country-specific regulatory requirements, secure public financing, integrate with local health IT systems, and translate interfaces may not be justifiable for smaller CEE markets.

From a reimbursement perspective, small markets make it attractive to pilot only those digital solutions requiring relatively low investment. Even when pilots succeed, scaling them remains uncertain.

Regulatory Burden

The requirement to obtain CE marking and comply with the Medical Device Regulation (MDR) in the European Union represents a substantial administrative and financial burden, particularly for early-stage health startups. Stakeholders consistently noted[5] that compared to other regulatory frameworks, particularly the Food and Drug Administration (FDA) pathway in the United States, the European MDR process represents a complex regulatory framework that lowers motivation for digital health solutions to prioritize European market entry.

The MDR's emphasis on clinical evidence, quality management systems, and post-market surveillance—while important for patient safety—creates barriers that may be disproportionate for low-risk digital health applications. A medication reminder app or patient education platform faces similar regulatory overhead as higher-risk medical devices, despite presenting minimal safety concerns.

For CEE-based digital health innovators, these regulatory burdens are compounded by limited access to support services, guidance, and funding compared to Western European counterparts. The resulting regulatory compliance costs consume scarce resources that could otherwise be directed toward product development and clinical validation.

3. Western European Financing Mechanisms

While CEE countries face significant barriers to digital health adoption, several Western European nations have experience with systematic reimbursement frameworks that integrate digital health solutions into public healthcare financing. These pioneering models demonstrate that with appropriate regulatory structures, evidence requirements, and financing mechanisms, digital health solutions can transition from innovation to standard care. Examining these models reveals key design principles and implementation strategies that are worth trying to be adapted to CEE contexts while respecting differences in healthcare system structure, institutional capacity, and political economy.

The following analysis focuses on three leading frameworks: Germany's Digital Health Applications (DiGA)scheme, Belgium's mHealth Pyramid, and France's PECAN program. While each reflects its national health care system's unique characteristics, all share common elements that enable systematic digital health integration.

[5] Stakeholders opinion is also supported by publicly available resources:
Available at: https://mdsdenmark.dk/fda-vs-eu-mdr-key-differences-in-medical-device-regulations/#:~:text=The%20FDA's%20regulatory%20framework%20may,when%20choosing%20a%20regulatory%20pathway.
Han et all. More than red tape: exploring complexity in medical device regulatory affairs. Frontiers in Medicine.
https://www.frontiersin.org/journals/medicine/articles/10.3389/fmed.2024.1415319/full

3.1 The German DiGA Model

Germany's Digital Health Applications (DiGA)[6] Fast-Track Process represents the most ambitious framework for digital health reimbursement in Europe. The DiGA program established a dedicated fast-track reimbursement pathway specifically for low-risk digital health solutions that address medical conditions, injuries or disabilities through recognition, monitoring, treatment, alleviation or compensation.

Core Design Elements:

The DiGA framework's defining feature is its two-tier approach: provisional listing for 12 months followed by final listing contingent on demonstrated benefits. During the provisional period, digital health applications are reimbursed by statutory health insurance while companies gather additional clinical evidence through real-world deployment. This "test-and-learn" approach solves the evidence paradox facing digital health innovators—the need for large-scale deployment data that cannot be generated without access to public financing.

To qualify for DiGA listing, applications must meet strict requirements: CE marking as a medical device, demonstration of positive healthcare effects (either medical benefits or patient-relevant procedural or structural improvements in care), compliance with data protection and information security standards, and evidence of usability and accessibility. Applications are reviewed by the Federal Institute for Drugs and Medical Devices (BfArM) through a streamlined process. The process is tailor made for digital solutions, facilitating their potential accelerated uptake, particularly in the case of provisional listing that enables the gathering of additional data, information and evidence required from the applicant.

Market Impact:

At the time of the preparation of this Joint Transnational Strategy document 57 digital health applications have achieved listing in the DiGA directory (48 in final listing and a further 9 under provisional status) out of 240 apps that applied for the reimbursement. Another, up to 12 apps are currently being processed. 28 apps received negative decisions and 127 withdrew from the process[7]. Digital solutions reimbursed under the DiGA Fast-Track scheme address a variety of indications, from diabetes management and mental health to chronic pain.

3.2 Alternative Models

Belgian mHealth Framework

Belgium's approach to digital health reimbursement takes a more graduated path through its mHealth Pyramid[8], which employs a three-tiered differentiation based on demonstrated value and integration into clinical care pathways.

[6] https://revolve.healthcare/blog/what-is-diga

[7] Available at: https://www.bfarm.de/EN/Medical-devices/Tasks/DiGA-and-DiPA/Digital-Health-Applications/Interesting-facts/_node.html

[8] https://mhealthbelgium.be/validation-pyramid

Three-Tier Structure:

Level 1 (Basic validation): Digital health applications demonstrate technical functionality, data security, and basic usability and safety in line with CE mark requirements. No reimbursement is provided.

Level 2 (Clinical integration): Applications demonstrate integration into clinical workflows and coordination with healthcare providers. Reimbursement request was submitted to National Institute for Health and Disability Insurance (NIHDI) that manages and supervises the compulsory health care and insurance benefits.

Level '3+' or '3-' (Socio-economic value): '3+' means full reimbursement granted only when applications demonstrate clear socio-economic benefit through rigorous health economic evaluation and clinical outcome data. Evidence must show either cost savings, improved health outcomes, or both relative to standard care. 3 light means temporary reimbursement while the app is in the process of proving social-economic value.

Market Impact[9]

Since launch, following the three-tier structure, 9 digital health applications (predominantly for telemonitoring at home), reached level three plus, therefore have fully proven social-economic value and are fully financed from public social security funds[10]. No app is currently in the status of '3-' (provisional admission) at the time of the preparation of this document. Three other digital apps reached level 2 and submitted a reimbursement request. In the first level, mHealth registers 18 digital health apps.

French PECAN

France's PECAN[11] (Forfait Innovation) program establishes a provisional reimbursement framework similar to Germany's DiGA but with more intensive evaluation processes and stronger emphasis on real-world evidence collection from academic medical centers. Similarly to other models, there is a strong focus on data security and GDPR compliance as well as system interoperability in terms of data generated by the digital solution.

Applications accepted into PECAN receive temporary reimbursement for up to one year while undergoing rigorous evaluation including comparative effectiveness studies, budget impact analyses, and outcomes research. The National Authority for Health (HAS) oversees evaluation protocols and makes final coverage recommendations based on comprehensive evidence reviews.

France's approach demonstrates how provisional reimbursement can be paired with academic research infrastructure to generate robust evidence for long-term coverage decisions. This model might be challenging for CEE countries if strong academic medical centers or substantial institutional capacity for evidence generation and evaluation is missing.

Market Impact

The initial feedback from the market suggests that qualifying for the PECAN pathway and to match its high-quality data criteria can be challenging for digital health innovators. While Digital Health Roadmap 2023-2027 aim to reach at least 50 applications in PECAN by the end of 2026, only 11 applications have been submitted with just 3 of them receiving favorable outcome[12]. Another view on challenges in PECAN stem

[9] Available at https://mhealthbelgium.be/apps

[10] In Belgium, National Institute for Health and Disability Insurance (NIHDI) manages and supervises the compulsory health care and insurance benefits.

[11] https://www.icthealth.org/news/pecan-frances-fast-track-scheme-for-digital-health-applications

[12] Available at: https://tinyurl.com/4up75d4e

from the experience of company HelloBetter that has six apps approved by DiGA in Germany received a negative decision for its digital therapeutic for patients with insomnia[13].

3.3 Key Characteristics

Analysis of the German DiGA, Belgian mHealth Pyramid, and French PECAN frameworks reveals common design elements that enable successful digital health integration, despite differences in national contexts and healthcare system structures. These success factors provide a blueprint for CEE countries developing their own frameworks.

CE Marking as Fundamental Prerequisite:

All described frameworks build on the foundation of CE marking, treating European medical device regulation as the baseline safety and quality assurance mechanism. This approach avoids duplicating technical assessment already performed for CE certification and focuses evaluation resources on effectiveness, value, and appropriate use—areas where national decision-makers must apply local priorities and cost-effectiveness thresholds. For CEE countries, this principle suggests that digital health reimbursement frameworks should leverage rather than replicate existing EU regulatory processes.

Provisional Reimbursement During Evidence Gathering:

Perhaps the most important common feature is provisional or conditional reimbursement that enables real-world deployment while additional evidence is collected. This design acknowledges the unique nature of digital health evidence generation—that robust real-world effectiveness data often cannot be obtained without significant patient populations using applications in routine care settings. Provisional reimbursement solves the "valley of death" where digital health companies have promising pilot data but cannot fund the large-scale deployments necessary to generate definitive evidence for permanent reimbursement decisions. However, in case such evidence is generated later, CEE countries should lead discussions whether the price of digital apps during the provisional period should reflect lower cost or threshold for quality adjusted life year (QALY) applied at the time of submission for provisional period and related health technology assessment.

Focus on Low-Risk Digital Solutions:

All existing reimbursement frameworks in Europe focus on low-risk digital health applications rather than attempting to create reimbursement pathways for all digital health technologies simultaneously. This risk-proportionate approach allows frameworks to establish processes, build institutional capacity, and demonstrate value before expanding to higher-risk applications like AI diagnostic tools or clinical decision support systems that require more intensive oversight. For CEE countries, such focus on low-risk digital health apps should be essential for sustainable implementation.

Strong Emphasis on Data Protection, Privacy, and Security:

Frameworks described above establish stringent requirements for data protection, privacy, and information security—often exceeding baseline legal requirements under GDPR. This emphasis reflects recognition that public trust is essential for digital health adoption and that healthcare applications handle particularly

[13] Available at https://www.icthealth.org/news/pecan-frances-fast-track-scheme-for-digital-health-applications

sensitive personal information. Requirements typically include encryption standards, access controls, transparent data usage policies, and mechanisms for patient consent and data deletion. CEE frameworks must similarly prioritize data protection both to ensure patient safety and to build the trust necessary for physician and patient adoption.

Clear Evaluation Criteria and Dedicated Regulatory Bodies:

Well-designed frameworks should provide transparent eligibility criteria, well-defined assessment processes, and designated institutional bodies with clear decision-making authority. Described frameworks attempt to provide transparent eligibility criteria, well-defined assessment processes, and designated institutional bodies with clear decision-making authority. This transparency reduces uncertainty for innovators, enables efficient processing, and ensures consistency in decision-making.

Iterative Learning and Adaptation:

Finally, all above-mentioned frameworks demonstrate willingness to learn from implementation experience and adapt policies accordingly. Germany has refined DiGA requirements and processes based on initial applications, Belgium continues to develop its tiered approach, and France adjusts PECAN protocols as evidence accumulates. This adaptive management approach acknowledges that digital health reimbursement remains a novel policy area where best practices continue to emerge. CEE countries should similarly build in mechanisms for regular review, stakeholder feedback, and policy refinement rather than treating initial frameworks as permanent structures.

4. Strategic Vision and Objectives

4.1 Vision Statement

This vision acknowledges that CEE countries face common challenges—aging populations, physician shortages, constrained budgets, and fragmented digital infrastructure—that require innovative solutions but also present opportunities for coordinated regional action. By developing compatible regulatory frameworks, sharing evaluation resources, and learning from each other's implementation experiences, CEE countries can overcome the market size limitations that would make isolated national approaches less efficient.

The vision emphasizes creating environments for where digital health solutions that demonstrate clinical value and cost-effectiveness can transition from (currently exist, especially as pilot projects) providing them with a systematic framework on how to get into standard care, while maintaining appropriate oversight to protect patients and ensure responsible use of public resources.

4.2 Strategic Objectives

The following five strategic objectives translate the vision into concrete action domains, providing a framework for the implementation strategies detailed in subsequent sections:

1. Eliminate Legislative Barriers

Provide additional explanation to existing local legislation that follows EU legislation. Establish clear legal frameworks and definitions for digital health solutions across all CEE countries, Supporting creating legislative certainty that enables innovators to navigate financing processes efficiently and healthcare stakeholders to adopt solutions confidently. This includes additional explanation of regulatory requirements for concepts such as "telemedicine solution," "digital application," or "remote monitoring device" or which administrative bodies hold decision-making authority.updating medical device legislation to explicitly encompass digital applications and remote monitoring, creating virtual distribution mechanisms appropriate for software-based solutions, as well as and providing accessible guidance and roadmap of the whole regulatory process that demystifies requirements for small companies and startups.

2. Create Systematic Financing Pathways

Develop dedicated public financing schemes tailored to digital health innovations. This requires moving beyond ad hoc arrangements to establish transparent, predictable pathways where digital health solutions meeting defined criteria can access public financing. Financing pathways must balance enabling innovation with fiscal responsibility, ensuring that reimbursement flows to solutions demonstrating meaningful value for patients and healthcare systems.

3. Build Institutional Capacity

Strengthen Health Technology Assessment capabilities and create specialized assessment frameworks adapted to digital health evidence and evaluation requirements. This includes expanding HTA agency capacity to handle digital health applications without creating unsustainable delays or adopting assessment methodologies that appropriately evaluate software-based interventions and building expertise in digital health evaluation across regulatory bodies, health insurers, and healthcare institutions.

4. Enhance Technical Infrastructure

Improve data interoperability and digital health system integration capabilities to enable practical deployment of reimbursed digital health solutions at scale. This requires adopting common technical standards for digital health integration with hospital information systems and electronic health records, establishing data governance frameworks that enable appropriate access while protecting privacy, and creating the digital infrastructure necessary for virtual prescribing, distribution, and utilization monitoring of digital health applications.

5. Foster Regional Cooperation

Leverage collective market size and share best practices across CEE countries to overcome the limitations that individual national approaches would face. Regional cooperation can take multiple forms: coordinated pilot programs that generate evidence applicable across countries, and shared technical infrastructure for interoperability standards, harmonisation of HTA guidelines on digital health applications.

5. Implementation Framework Overview

The transition to systematic digital health financing requires a carefully sequenced approach that builds foundational elements before attempting more complex institutional reforms. This three-phase implementation framework reflects the reality that CEE countries are in the early stages of developing environments for digital solutions, with most activity currently limited to isolated pilot projects without systematic institutional frameworks.

Each action phase reflects similarities in barriers identified across Czech Republic, Slovakia, Poland, Hungary, and Slovenia through structured interviews with health insurers, hospital administrators, regulatory agencies, public health bodies, and digital health innovators conducted during 2023-2024. These phases are further developed by individual country-level action plans tailored to partner countries' needs and priorities.

Phase 1: Immediate Actions (0-12 months) focus on creating transparency and information accessibility—the most fundamental prerequisites currently absent across CEE countries. These foundational actions address regulatory uncertainty and information gaps that prevent innovators from even understanding pathways to market. Critically, these actions require minimal financial investment and can be accomplished through existing administrative procedures, making them politically feasible "quick wins" that demonstrate commitment and create momentum. By establishing clear information resources, Phase 1 enables all stakeholders—innovators, healthcare providers, as well as regulators—to operate with shared understanding of requirements and processes. Those actions create the necessary conditions for any subsequent financing scheme and demonstrate tangible progress to build stakeholder confidence.

Phase 2: Medium Term Actions (6-24 months) build on the information foundation by addressing financial and infrastructure barriers that prevent practical implementation. This phase provides tangible support mechanisms—financial assistance for regulatory compliance and safe testing environments for validation—that enable digital health solutions to progress from concept to evidence generation. Unlike Phase 1's information-focused interventions, Phase 2 requires dedicated funding and institutional coordination but is far less complex compared to permanent reimbursement frameworks. These actions create the conditions for generating real-world evidence while managing risk through controlled pilot implementations.

Phase 3: Long-Term Strategic Development (12-36 months) requires countries to make fundamental policy decisions about systematic public financing frameworks based on evidence generated during Phase 2 and comprehensive evaluation of international models. This phase involves establishing multi-stakeholder working groups to guide strategic decisions and ultimately implementing chosen public financing models based on the feasibility study that critically assess existing financing schemes from countries within the EU or beyond against local context. Rather than prescribing a single implementation approach, Phase 3 acknowledges that successful models will vary across CEE countries based on healthcare system organization (single-payer vs. multi-payer), HTA capacity, digital infrastructure maturity, fiscal constraints, and policy priorities regarding innovation incentives versus cost control.

Key Design Principles:

Sequential Dependencies: Each phase creates prerequisites for the next. Information transparency (Phase 1) enables innovators to pursue CE certification and access support programs (Phase 2). Testing environments (Phase 2) generate evidence needed for reimbursement decisions (Phase 3). This sequencing prevents premature commitment to reimbursement frameworks before adequate information, support infrastructure, and evidence exist.

Risk Management: The phased approach manages political and fiscal risk by starting with low-cost, low-barrier actions that build stakeholder confidence before advancing to more significant commitments. Early phases demonstrate tangible progress without requiring major institutional restructuring or budget allocations, creating political momentum for subsequent phases.

Incremental Commitment: Countries need not commit to all phases simultaneously. Phase 1 creates value independently by improving transparency. Phase 2 generates evidence and builds capacity regardless of Phase 3 decisions. This structure accommodates political realities where long-term commitments face uncertainty while enabling progressive advancement when conditions permit.

The ultimate objective is establishing systematic public financing pathways, but the phased approach recognizes that achieving this goal requires building foundational elements methodically rather than attempting comprehensive reform without adequate preparation. Countries may spend different durations in each phase based on institutional readiness, political windows, and resource availability.

6. Immediate Actions (0-12 months)

6.1 Regulatory Harmonization

Based on comprehensive gap analysis and country-specific stakeholder consultations conducted through the Digivitality project, the most fundamental barrier preventing digital health adoption across CEE countries is the profound lack of basic information accessibility about requirements, processes, and pathways. Importantly, these interventions are characterized as "low-hanging fruit"—they can be implemented without politically costly structural reforms, require minimal budgetary commitments, and can be accomplished through existing administrative and legislative procedures.

Action 1.1: User-Friendly Process Guidance and Information Access about regulatory requirements

Objective: develop practical and publicly available online guide to help with the classification of digital applications, remote monitoring solutions or telemedicine platforms, eliminating ambiguity about their regulatory status and how to ensure compliance with AI governance requirements such as transparency, human oversight and risk management, as well as with the options for different financing schemes, related criteria and roadmap to navigate technology developers to get public funding.

Rationale: Digital health innovators, especially early-stage companies and startups without extensive regulatory affairs departments, face extreme difficulty navigating complex MDR regulatory and country-specific public financing processes. The categorization process is very complex for companies emerging outside traditional healthcare systems, and current practice shows they can navigate it only with significant external help. The absence of basic information in user-accessible formats creates unnecessary friction, discourages market entry, and disproportionately disadvantages smaller innovators who lack resources for extensive regulatory consulting. For CEE-based digital health innovators, these regulatory burdens are compounded by limited access to support services, guidance compared to Germany, Belgium or France as their financing mechanisms provide a roadmap and key information about the requirements in the process. The resulting regulatory compliance costs consume scarce resources that could otherwise be directed toward product development and clinical validation.

Specific Implementation:

Interactive Process Maps:

- Create interactive online process maps on dedicated websites showing step-by-step pathways for financing digital health solutions.
- Include regulatory requirements at each stage, necessary documentation with templates, timelines and expected processing durations, and contact information for responsible institutions.
- Provide clickable elements that expand to describe specific processes, including institutions involved and their roles.
- Offer process maps in both national languages and english language to accommodate international developers.

Comprehensive Guidance Materials:

- Develop practical MDR-AI-evidence guidelines specific to digital medical devices.
- Create evidence and metrics packs containing baseline clinical, process, and technical indicators; minimum real-world evidence requirements; and guidance for proof-of-concept studies.
- Provide regulatory FAQs addressing common questions about software classification, CE marking requirements, and evidence standards.
- Offer document templates for common submissions (categorization applications, clinical evaluation reports, evidence summaries).

Support Infrastructure:

- Create catalogs of ongoing digital health projects to improve visibility and enable collaboration.
- Develop training resources covering regulatory compliance, evidence generation, and reimbursement pathways.
- Publish best-practice case studies illustrating successful navigation of regulatory and public financing processes.

Expected Outcome: Digital health companies and healthcare providers gain clear understanding of regulatory requirements related to software-based interventions. This legal certainty is prerequisite for both financing discussions and confident clinical adoption. Improved understanding of regulatory requirements reduces delays and improves documentation quality.

Responsible Bodies: Ministries of Health (methodological leadership); National medical device regulatory authorities (implementation guidance).

7. Medium-term Actions (6-24 months)

7.1 Financial support and safe testing environments

Having established comprehensive information resources in Phase 1, Phase 2 addresses the two other critical practical barriers preventing digital health solutions from progressing toward reimbursement. Financial constraints on achieving regulatory compliance and absence of safe environments for generating real-world evidence. Phase 2 interventions provide tangible support mechanisms that enable progression from concept to evidence generation while managing risk through structured, supported processes. Unlike Phase 1's information-focused approach requiring minimal investment, Phase 2 demands dedicated funding for financial support programs and institutional coordination for testing environments. However, these investments remain substantially lower than committing to permanent reimbursement frameworks (Phase 3) while creating the evidence base necessary for informed reimbursement decisions.

Action 1.2: Support for CE Certification and Regulatory Compliance

Objective: Provide targeted financial support to help early-stage digital health companies achieve CE certification compliance and navigate MDR requirements, addressing the regulatory burden that disproportionately affects startups and small companies.

Rationale: The requirement to obtain CE marking and comply with Medical Device Regulation (MDR) in the European Union represents a substantial financial burden that can, according to interviews with experts and various web sources can reach 10 to 50 thousand euros. Compared to other regulatory frameworks, especially FDA in the United States, those barriers may be disproportionate for low-risk digital health applications. The resulting regulatory compliance costs consume scarce resources that could otherwise be directed toward product development, clinical validation, and market preparation. Many promising solutions never reach patients because companies cannot afford regulatory compliance, not because solutions lack clinical value.

Specific Implementation:

Financial Support Mechanisms:

- Establish vouchers schemes (€20,000-€50,000) subsidizing regulatory compliance costs for eligible digital health startups.
- Structure vouchers to cover specific certification components: notified body conformity assessment fees, quality management system (QMS) development and ISO 13485 certification, clinical evaluation report preparation by qualified experts, technical documentation development support, regulatory consulting for classification and pathway determination.

Expected Outcome: Early-stage CEE digital health companies can achieve CE marking despite limited resources, leveling the playing field with larger companies and competitors from more developed digital health ecosystems. Reduced financial and expertise barriers to CE compliance increase the likelihood that innovative solutions developed in CEE countries reach patients rather than failing due to regulatory burdens.

Responsible Bodies: National innovation agencies and development banks (funding mechanisms); Ministry of Health (program coordination and strategic oversight); Digital health innovation hubs (dissemination of information about financial support).

Action 1.3: Establish Safe Testing Environments

Objective: Create safe environments for testing digital health solutions before full-scale deployment, reducing integration risks and costs for both healthcare institutions and innovators and addressing interoperability challenges.

Rationale: CEE countries' health IT landscapes are highly fragmented, with hospital information systems, primary care electronic health records, and insurance databases operating on incompatible technical standards. Digital health applications requiring integration face prohibitively expensive custom development for each institution. Hospitals must protect integrity of their certified HIS environments, making integration of new digital tools risky, technically demanding, and costly. This creates a critical bottleneck preventing even approved and reimbursed solutions from reaching practical deployment.

Specific Implementation:

Safe Testing and Regulatory Sandbox:

- Establish dedicated "technology or digital sandboxes"—structured testing environments operating under special regulatory frameworks that enable innovation testing with appropriate safeguards (2-3 priority use cases per year initially).
- Create structured evaluation protocols for pilot implementations with predefined metrics and transparent assessment criteria.
- Define clear processes for transitioning from sandbox testing to production deployment.
- Establish risk management frameworks ensuring patient safety during pilot phases.
- Focus initially on low-to-medium risk applications (Class I/IIa devices) to build experience before addressing higher-risk solutions.

Minimum Interoperability Standards:

- Establish minimum data exchange standards mandatory for all publicly funded healthcare institutions in compliance with European Health Data Space provisions.
- Define technical requirements for digital health application integration capabilities.

Expected Outcome: Digital health solutions can be safely tested in real clinical environments without risking certified hospital information system integrity. Clear technical standards reduce custom integration costs making solutions more affordable for smaller healthcare institutions. Structured pilot frameworks generate credible evidence for reimbursement decisions while providing innovators with early market feedback. Reduced technical barriers accelerate time from regulatory approval to clinical deployment.

Responsible Bodies: Ministries of Health (coordination and regulatory oversight); National medical device regulatory authorities.

8. Long-Term Strategic Development (6-36 months)

8.1 Rationale for Multi-Stakeholder Working-Group and Country-Specific Feasibility Study

Having established information resources (Phase 1) and generated real-world evidence through supported certification and pilot programs (Phase 2), countries now face the critical strategic decision: **which systematic public financing framework best fits their specific context, priorities, and capabilities?**

Attempting to prescribe a single "best" model for all CEE countries would ignore these fundamental contextual differences in local context and priorities. Instead, **Phase 3 establishes a structured decision-making process** where countries systematically evaluate options, build stakeholder consensus, and make evidence-informed strategic choices appropriate to their specific contexts. This approach respects national sovereignty and institutional diversity while providing structured guidance that prevents countries from "reinventing the wheel" or making uninformed choices based on incomplete analysis.

The two-component approach—multi-stakeholder working groups providing governance and deliberation mechanisms, combined with independent feasibility studies providing rigorous analytical foundations—ensures that strategic decisions reflect both technical analysis and stakeholder consensus. Working groups without rigorous analytical support risk opinion-based debates lacking empirical grounding; feasibility studies without stakeholder engagement risk technically sound but politically infeasible recommendations. The combination creates conditions for evidence-informed decisions with broad stakeholder buy-in necessary for successful implementation.

1. **Conducts comprehensive feasibility study** critically assessing existing international models against local context.
2. **Engages multi-stakeholder working groups** building consensus on priorities and acceptable trade-offs about reimbursement models based on feasibility analysis and stakeholder input to implement chosen financing framework with appropriate adaptation to local circumstances.

Action 1.4: Commission Country-Specific Feasibility Studies on Reimbursement Models

Objective: Create formal multi-stakeholder working groups that provide governance for Phase 3 strategic decision-making, commission and oversee feasibility studies, deliberate on reimbursement model options, and build broad consensus on chosen approaches—ensuring strategic choices reflect diverse perspectives, address practical implementation realities, and secure stakeholder commitment necessary for successful framework implementation.

Rationale: The choice of financing model fundamentally shapes the digital health market, determining which types of solutions become financially viable, how quickly innovations reach patients, the administrative burden on both payers and providers, and the alignment of incentives between digital health companies and healthcare system objectives. No single model is universally optimal—each represents different trade offs between innovation incentives, cost control, implementation complexity, and fit with existing healthcare financing structures. Before making strategic decisions on financing models, countries must establish broad stakeholder consensus on objectives, priorities, and implementation approaches delivered through feasibility study. Multi-stakeholder working groups provide the essential forum in terms of experts to develop the feasibility study as well as for this consensus-building while ensuring that policy decisions reflect diverse perspectives and practical implementation realities.

Specific Implementation:

Working Group Structure and Composition

The DIGIVITALITY project demonstrated the value of this approach through successful working group processes in all five countries. Multi-stakeholder forums brought together previously disconnected institutions and individuals, created spaces for productive dialogue despite initial divergent views, generated actionable recommendations with broad support, and built relationships enabling ongoing collaboration beyond project completion.

Core Participants:

Effective working groups should follow DIGIVITALITY approach where working groups included representatives from:

Government and Regulatory Institutions:

- Ministries of Health and relevant departments providing policy leadership, legislative authority, and help with coordination across government.
- Medical Device Regulatory Authorities: Regulatory frameworks, CE certification interfaces, compliance oversight, safety monitoring, understanding of European regulatory developments.
- Health Technology Assessment Agencies: Evidence evaluation methodologies, assessment capacity constraints, quality assurance approaches, international HTA collaboration.

Healthcare Financing and Delivery:

- Health Insurance Companies and Public Payers: Financing perspectives, budget implications, administrative feasibility, claims processing capabilities, payment mechanism design, utilization management approaches.
- Hospital Representatives (Chief Executives, Medical Directors, IT Directors): Frontline clinical perspectives, implementation experiences, workflow integration challenges, resource implications, provider adoption factors.
- Primary Care Physician Representatives: Outpatient care perspectives, prescription practicalities, patient management approaches, integration with ambulatory care.

Innovation Ecosystem:

- Digital Health Innovators, startups, SMEs and large corporations: Industry perspectives, development processes and timelines, technical capabilities and constraints, market dynamics, innovation incentives and disincentives, international competitive factors.
- Industry Associations: Collective industry views, common concerns across companies, international experiences, advocacy positions.
- Digital Health Innovation Hubs and Accelerators: Early-stage company needs, support service perspectives, ecosystem development priorities, startup challenges.

Research and Expertise:

- Academic Researchers or Health Economists: Scientific expertise, evaluation methodology, evidence generation approaches as well as economic modeling, budget impact analysis, value frameworks, pricing considerations, cost-effectiveness methodologies.

- International Experts: Comparative perspectives from countries operating mature frameworks, implementation experiences and lessons learned, international best practices.

Expected Outcomes: Functioning governance structures overseeing Phase 3 strategic decision-making and development of feasibility study (Action 3.2). This portfolio of experts is a group to discuss important areas such as HTA requirements, infrastructure priorities, and the final recommendation about reimbursement model selection. Such working group also provides room to develop broad consensus among key stakeholders on strategic direction and chosen approaches, shared understanding of trade-offs, rationale for decisions, and implementation requirements that should lead to stakeholder commitment to supporting implementation and addressing challenges collaboratively with direct impact on reduced resistance and conflict during implementation through inclusive decision processes.

Responsible bodies: Ministries of Health (Overall working group coordination, secretariat support, policy integration, resource provision, high-level oversight). Digital Health Innovation Hubs given their expertise from Digivitality, under the appropriate invitation or relevant mandate from Ministries of Health (Facilitation, logistics, stakeholder engagement, documentation, communication support).

Action 3.2: Commission Country-Specific Feasibility Studies on Reimbursement Models

Objective: Sponsor comprehensive, independent feasibility study that critically evaluate existing digital health financing schemes from international examples against each country's specific healthcare system context, institutional capacity, fiscal constraints, and political priorities—providing evidence-based foundation for strategic reimbursement framework decisions.

Rationale: Strategic decisions about systematic public financing frameworks represent major policy commitments with long-term consequences for innovation incentives, healthcare budgets, administrative processes, and patient access. These decisions merit rigorous analysis rather than ad hoc adoption of models developed in different contexts.

Feasibility studies provide countries with analytical foundations because it will evaluate multiple areas: systematically assess which international models align with local healthcare system structure; identify implementation prerequisites and capacity requirements; estimate costs, resource needs, and budget implications; surface potential implementation barriers and mitigation strategies; provide evidence base for stakeholder discussions and political decision-making; prevent costly mistakes from adopting incompatible frameworks.

Specific Implementation:

Study should systematically evaluate relevant EU and might be even open to evaluate other international reimbursement frameworks outside EU. For each model, feasibility study should attempt to evaluate:

Core Design Elements:

- Eligibility criteria (CE certification requirements, evidence standards, risk classification).
- Application and review processes (responsible bodies, timelines, documentation requirements).
- Evidence requirements (types of evidence accepted, validation standards, real-world data vs. RCTs).
- Public financing mechanisms (provisional vs. permanent, pricing determination, payment structures).

- Monitoring and reassessment processes (ongoing surveillance, evidence generation requirements, delisting criteria).

Institutional Requirements:

- Regulatory body capacities and expertise needed.
- HTA agency capabilities and methodological approach.
- Administrative infrastructure and processing systems.
- Staff expertise and training needs.

Financial Implications:

Budget requirements for public financing (based on anticipated application volumes and solution costs).

- Administrative costs for framework operation.
- Infrastructure investments needed.
- Revenue implications for health insurance budgets.

Implementation Complexity:

- Legislative amendments required.
- Technical system developments (prescription, billing, monitoring).
- Training and capacity building requirements.
- Timeline to operational implementation.

Compatibility Assessment:

- Alignment with existing healthcare system structure (single-payer vs. multi-payer).
- Fit with current or emerging HTA processes and evaluation frameworks.
- Compatibility with existing financing mechanisms (for traditional medical devices, pharmaceuticals).
- Synergies or conflicts with current eHealth strategies.
- Political feasibility given current policy priorities.

Expected Outcome: Comprehensive feasibility study report (approximately 100 pages) providing systematic analysis of financing models, their comparison with clear recommendations. Recommendations about the financing options will be supported with the roadmap, cost estimates and resources requirements as well as risk analysis and mitigation strategies. In such a format, feasibility study will provide objective, rigorous analysis informing strategic choices with country-specific adaptation guidance.

Responsible Bodies: Ministries of Health (Primary responsibility for commissioning studies, defining scope, securing funding, overseeing execution) Working group (developing feasibility study).

9. Success factors and recommendations for the implementation of this strategy

9.1 Critical success factors

Successful implementation of systematic digital health financing across CEE countries depends on several critical success factors that extend beyond the specific actions outlined in previous sections. These success factors address the political, organizational, and cultural dimensions of healthcare system transformation that technical solutions alone cannot solve.

Strong leadership and commitment

Political will: Sustained political support and leadership commitment at national and regional levels is likely the most critical factor determining success or failure. Leadership must extend beyond single ministers or agencies to include parliamentary support for necessary legislation, insurance company leadership embracing new assessment and payment approaches, and medical professional leadership encouraging provider adoption. Building broad coalitions of support increases resilience to personnel changes and political transitions.

Accountability structures: Clear designation of responsible institutions for each implementation component prevents diffusion of responsibility where everyone assumes someone else will act. Each action item should have named institutions with authority, resources, and explicit accountability for delivery. Regular high-level monitoring by Ministries of Health or Prime Minister's offices signals priority and enables rapid problem-solving when implementation stalls.

Stakeholder Alignment

Broad consensus: Achieving broad consensus requires inclusive processes where stakeholders believe their concerns are heard and addressed. The multi-stakeholder working groups outlined in Section 7.1 provide essential forums for this consensus-building, but only if conducted authentically with genuine willingness to incorporate feedback rather than pro forma consultations with predetermined conclusions.

Effective and transparent communication: Communication strategies should segment messaging: clinical evidence and workflow integration for physicians, cost-effectiveness and utilization control for payers, quality and accessibility for patients, and clear pathways and timelines for digital health companies. One-size-fits-all messaging fails to address specific concerns driving resistance.

Evidence-Based Approach

Rigorous evaluation: Pilot programs and early implementations must include robust evaluation processes generating credible evidence about effectiveness, cost impacts, implementation requirements, and unintended consequences. Without rigorous evaluation, policy decisions devolve into opinion-based debates where stakeholders selectively cite anecdotes supporting their preferences.

10. Conclusion

The systematic integration of digital health solutions into CEE healthcare systems through improved public financing mechanisms represents both an urgent necessity and a realistic opportunity. The convergence of demographic pressures—aging populations requiring more care with fewer healthcare workers—with constrained budgets and mature digital health technologies creates compelling rationale for transformative action. Digital health solutions offer promising pathways to managing larger patient populations with existing resources while maintaining or enhancing care quality, but realizing this potential requires systematic financing frameworks enabling transition from isolated pilots to standard care.

This joint transnational strategy provides CEE countries with a comprehensive roadmap for overcoming the interconnected barriers—regulatory uncertainty, information gaps, financial constraints, infrastructure limitations, and institutional capacity challenges—currently impeding digital health adoption. Based on extensive stakeholder consultations conducted through the DIGIVITALITY project during 2023-2024, the strategy reflects real barriers identified by health insurers, hospital administrators, regulatory agencies, digital health innovators, and patient advocates across Czech Republic, Hungary, Poland, Slovakia, and Slovenia.

The Three-Phase Implementation Framework

The strategy carefully sequenced three-phase approach manages political and fiscal risk while building foundational elements necessary for successful public financing framework implementation:

Phase 1 (0-12 months) establishes information transparency through comprehensive online guidance, interactive process maps, regulatory FAQs, and support resources.

Phase 2 (6-24 months) addresses financial and infrastructure barriers through tangible support mechanisms including voucher schemes (€20,000-€50,000) subsidizing CE certification costs and regulatory sandbox environments enabling safe testing of digital health solutions.

Phase 3 (6-36 months) involves fundamental strategic decisions about systematic public financing frameworks based on comprehensive feasibility studies developed by multi-stakeholder working group.

Learning from International Experience While Respecting Local Contexts

The strategy draws extensively on Western European experiences—particularly Germany's DiGA Fast-Track process with provisional listing enabling evidence generation during market access, Belgium's mHealth Pyramid with tiered progression based on demonstrated value, and France's PECAN with intensive academic evaluation—extracting common success factors while recognizing these models reflect their origin countries' unique characteristics. Key transferable principles include: building on CE marking as fundamental prerequisite rather than duplicating technical assessments, employing provisional reimbursement during evidence gathering solving the "valley of death" facing innovators, focusing initially on low-risk applications building capacity before expanding to higher-risk solutions, emphasizing data protection and security building patient and provider trust, providing transparent evaluation criteria and dedicated institutional responsibilities, and maintaining adaptive management approaches enabling learning and refinement.

However, direct adoption of these models without adaptation to CEE contexts would likely fail. Feasibility studies and working group processes enable countries to extract relevant principles while adapting implementation to local realities of healthcare system organization, institutional capacities, market sizes, fiscal constraints, and stakeholder preferences.

The Path Forward: Incremental Progress Toward Transformation

The ultimate objective—systematic public financing enabling validated digital health solutions to access patients as standard care—requires building foundational elements methodically rather than attempting comprehensive reform without preparation. Countries may progress through phases at different speeds based on institutional readiness, political windows, resource availability, and Phase 2 pilot results. Some may move rapidly through all three phases in 36 months; others may spend longer in early phases building consensus and capacity before advancing.

This flexibility is strategic, not a weakness. Digital health financing remains novel policy territory where even mature European frameworks continue learning and adapting. Forcing premature commitment to permanent frameworks before adequate information, evidence, and stakeholder alignment exist risks implementation failures undermining future efforts. The phased approach enables countries to demonstrate value, build confidence, and develop capacity progressively creating sustainable transformations rather than failed attempts.

The convergence of demographic necessity, technological maturity, and growing stakeholder recognition of digital health potential creates favorable conditions for action. CEE countries implementing this strategy systematically will position themselves as digital health leaders, attract innovation investment, improve healthcare system sustainability, and most importantly, cater to the health needs of patients.