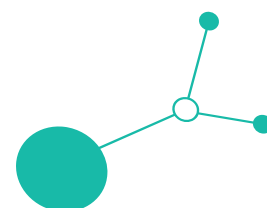


Country-level Action plan on public financing of digital Healthcare solutions

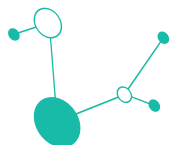
Slovenia



Version 1

12 2025





ACCELERATION OF DIGITAL SOLUTIONS IN SLOVENIA

Summary

This action plan focuses on three achievable steps that directly respond to Slovenia's identified challenges.

1. Supporting CE and evidence readiness through vouchers and guidance.
2. Testing provisional reimbursement via pilot hospitals and defined domains.
3. Aligning evaluation standards with EU harmonization efforts.

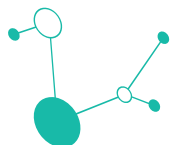
These actions require predominantly coordination efforts, not legislation. Therefore, they can be initiated immediately through collaboration among the Ministry of Health, AKAZ, Medical Chamber, hospitals, and innovation hubs such as LUI. Together, they create the foundation for a trusted, evidence-based, and scalable digital health ecosystem in Slovenia.

Rationale for the proposal

Slovenia is experiencing fast-growing innovation activity in digital health, yet the pathway for such solutions to achieve certification, validation, and reimbursement remains fragmented. Startups and hospitals often lack clear guidance, structured support, and predictable processes. As a result, promising solutions frequently stall before reaching patients or clinical practice.

At the same time, European harmonization efforts—such as EDiHTA and the EU Task Force for Digital Medical Device Evaluation—are rapidly establishing common frameworks for evidence, safety, and assessment. Slovenia must position itself within these developments to avoid duplicating efforts, strengthen cross-border interoperability, and open opportunities for local innovators.

The proposed action plan focuses on **practical, low-barrier interventions** that can be implemented without complex legislative change. Instead, they rely on stronger coordination among key national actors (MoH, AKAZ, ZZZS, LUI, hospitals, and the Medical Chamber). By supporting early evidence generation, enabling structured real-world testing, and aligning national



criteria with EU frameworks, Slovenia can accelerate the adoption of trustworthy digital health solutions while ensuring patient safety and system sustainability.

These targeted actions collectively create the foundational infrastructure needed for a **credible, evidence-based, and scalable digital health ecosystem**—one that supports innovators, clinicians, and decision-makers.

Curret state:

Slovenia's digital health environment includes active innovation hubs, emerging startups, and strong clinical institutions, yet the national system does not have a fully defined pathway for digital medical devices to reach routine care or reimbursement. Currently:

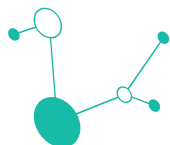
- Little dedicated support for **early evidence or CE-readiness support** exists. Startups must independently fund regulatory consulting, quality system development, and evidence planning—resulting in delays and inconsistent quality.
- **Hospitals lack structured mechanisms to test digital solutions in real-world conditions.** While individual pilots occur, they are typically ad hoc, without standardized evaluation plans, shared methodologies, or a link to future reimbursement.
- **Evaluation criteria are fragmented and not fully aligned with EU initiatives.** Slovenia lacks a unified national framework for clinical, technical, economic, and patient-centric assessment of digital medical solutions. Current criteria differ from emerging European standards, which limits cross-border recognition and increases administrative burden for innovators.
- **Stakeholders recognize the importance of digital transformation**, but coordination across institutions remains limited. Innovation efforts (e.g., LUI and Digivitality partners) are active and producing tools, templates, and training, yet these resources are not systematically embedded into national processes.

Overall, Slovenia has **high innovation potential** but an **underdeveloped support and evaluation infrastructure**, creating barriers for solutions to progress from prototype to certified, validated, and reimbursed digital health

Identified barriers and proposed action steps:

ACTION 1: Establish a “CE Readiness & Evidence Support Scheme”

- **Barrier:** early-stage Slovenian startup face significant challenges that stems from CE certification and clinical validation - key prerequisites for digital health solutions to enter reimbursement framework.
- **Action:** Slovenia should launch a small-scale CE Readiness and Evidence Support Scheme coordinated by innovation actors. Such scheme would provide expert vouchers or mini grants (up to €10,000) for regulatory consulting, notified body documentation, and quality system setup. There will be also access to a national support team for study design and evidence planning (based on templates developed in the Digivitality project as well as



shared technical resources (training materials, regulatory FAQs, document templates) hosted on LUI's website.

■ **Responsibility:**

- ☐ Ministry of Health - endorsement and alignment with funding programs.
- ☐ AKAZ - guidance on quality and evaluation standards.
- ☐ Ljubljana University Incubator (LUI) - coordination and applicant support.
- ☐ Medical Chamber of Slovenia - advisory input through its Digital Health Department.

ACTION 2: Launch a “Provisional Reimbursement Sandbox” with Pilot Hospitals

- **Barrier:** Digital health solutions providers struggle with sufficient real-world evidence data and early validation.
- **Action:** Slovenia should implement 12 to 18 month provisional reimbursement sandbox. Solutions with CE certification and basic safety documentation can receive temporary reimbursement (e.g., through hospitals' innovation budgets). Three to five pilot domains (mental health, chronic diseases, rehabilitation) will be prioritized. Each pilot will include a standardized evaluation plan, assessing both clinical outcomes and patient-relevant process benefits (e.g., improved workflow, time savings).
- **Responsibility:**
 - ☐ Ministry of Health and Health Insurance Institute (ZZZS) - sandbox endorsement and monitoring.
 - ☐ Selected hospitals and primary care centers - pilot sites and data collection.
 - ☐ AKAZ - evidence supervision and evaluation methodology.
 - ☐ LUI / Digivitality partners - coordination and project management.

ACTION 3: Align Slovenian Evaluation Framework with EU Standards (EDiHTA, Task force)

- **Barrier:** current Slovenia's digital health evaluation and reimbursement criteria suffers with miss-alignment in comparison to European standards.
- **Action:** At the EU level, Slovenia should formally engage in the European Task Force for Harmonized Evaluation of Digital Medical Devices (led by France with EIT Health) and explore participation in EDiHTA and similar Horizon Europe projects. At the national level, translate and adapt harmonized taxonomies and assessment criteria (clinical, technical, economic, and patient-centric). Use them as a reference framework for all future national or hospital-level evaluations. In addition, organize a national alignment workshop (MoH, AKAZ, Medical Chamber, LUI, EIT Health) to validate adoption and discuss interoperability.
- **Responsibility:**
 - ☐ Harmonized Slovenian evaluation criteria by 2026.
 - ☐ Reduced duplication and faster acceptance of EU-validated solutions.
 - ☐ Strengthened links between Slovenian and EU digital health ecosystems.