

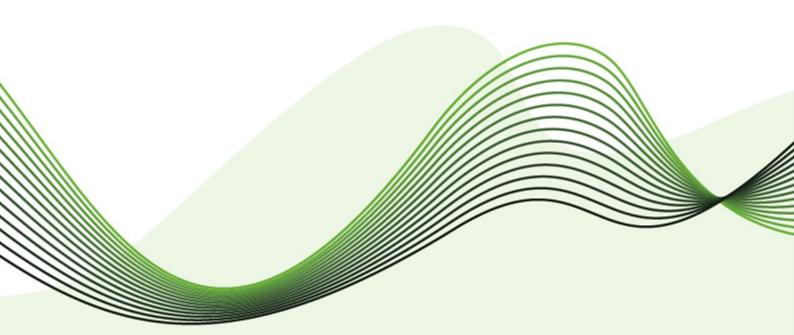
Policy Brief

BRIDGING GAPS FOR SMART HEALTH: STRENGTHENING REGIONAL INNOVATION ECOSYSTEMS IN EUROPE

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1. Summary

Smart health ecosystems are vital to Europe's digital health transition, driving innovation that improves patient care, system efficiency, and competitiveness. Yet regional ecosystems face common challenges, including funding gaps, regulatory hurdles, and fragmented infrastructures.

This policy brief draws on insights from three workshops carried out by SHIFT-HUB, an EUfunded project, in regional smart health ecosystems: Central Macedonia (Greece)¹,Northern Portugal (Portugal)², and Baden-Württemberg (Germany)³, covering three distinct and representative parts of Europe, namely Eastern, Western and Northern. The policy brief compares regional strengths and needs, and provides evidence-based recommendations to guide more targeted and effective policymaking at regional, national, and EU level facilitating smart health innovations.

Highlights

- All three regions show promising smart health ecosystems, but yet face persistent funding and regulatory hurdles.
- Funding gaps at various stages, especially for clinical trials and validation phases, limit the ability of start-ups to scale successfully.
- > Networking opportunities and cross-sector collaboration remain uneven, with calls for stronger investor education and government facilitation.
- > Data infrastructure and interoperability are missing links for innovation, particularly in Baden-Württemberg and Central Macedonia.
- Internationalisation and visibility vary: Baden-Württemberg is well-connected but under-promoted, while Northern Portugal and Central Macedonia seek stronger integration into global ecosystems.







Bridging Gaps for Smart Health:

A Policy Brief on Strengthening Regional Innovation Ecosystems in Europe





Key Challenges

- Fragmented ecosystems
- Funding bottlenecks
- Regulatory hurdles
- Data infrastructure gaps
- · Uneven visibility and branding



Policy Recommendations

- Close funding gaps for validation phases
- Develop interoperable health data infrastructures
- Promote investor education & incentives
- Strengthen networking & mentoring
- Enhance visibility & cross-border collaboration



Regional Snapshots

Central Macedonia (Greece):

- Emerging ecosystem, promising start-ups.
- · Needs networking, pre-seed funding, unified strategy.

Northern Portugal (Portugal):

- · Strong research base, but fragmented.
- Struggles with mentorship & mid-stage funding gaps.

Baden-Württemberg (Germany):

- Mature ecosystem, strong accelerators & support.
- Needs more visibility, data infrastructure & early-stage funding.



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Figure 1. Infographic







2. Context of the issue

Smart health ecosystems represent a crucial building block in Europe's ambition to modernise healthcare, strengthen resilience, and foster sustainable growth. They encompass digital health solutions, connected medical devices, artificial intelligence (AI) in diagnostics and treatment, data-driven research, and patient-centric services. These innovations can transform healthcare delivery by improving accessibility, efficiency, and personalisation of care while simultaneously stimulating Europe's competitiveness in health technologies.

The European Union has made digital health transformation a central policy priority. The EU's Digital Health Strategy⁴ and the planned European Health Data Space (EHDS)⁵ aim to unlock the value of health data, enable secure cross-border data flows, and empower

citizens with greater control over their health information. The EHDS particularly will provide the regulatory and infrastructural framework to foster interoperability of health data, creating new opportunities for Al-driven applications and evidence-based healthcare policy.

Information on the workshop series approach is provided in Section 4. Evidence and Analysis

Smart health ecosystems at regional level are key to realising these ambitions, yet they face structural barriers. These barriers represent key challenges that have been identified based on a workshop series

carried out within the scope of SHIFT-HUB, an project funded by the European Union, in three regional European smart health ecosystems:

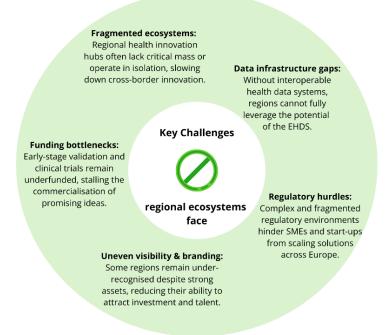


Figure 2. Key challenges and barriers regional smart health ecosystems face.

At the same time, these challenges open up opportunities for European alignment. By strengthening regional ecosystems and connecting them more effectively across borders, the EU can accelerate the translation of research into market-ready solutions, enhance citizen trust in digital health, and ensure that European innovators can compete globally.









This policy brief contributes to the broader EU health and digital agenda by providing evidence from three regional workshops (Central Macedonia¹, Northern Portugal², and Baden-Württemberg³), identifying gaps, and offering recommendations on how to design more targeted, needs-oriented policies that enable smart health ecosystems to thrive.

3. Policy Recommendations

Based on the insights gathered from the three SHIFT-HUB regional workshops in Central Macedonia¹, Northern Portugal², and Baden-Württemberg³, the following recommendations aim to address the identified challenges and support the development of stronger, more interconnected smart health ecosystems across Europe. Structured around key objectives and actions, they address the most pressing barriers—funding gaps, regulatory hurdles, data infrastructure, networking, and visibility—while creating feasible, evidence-based pathways for policymakers and stakeholders.

1. Objective: Close the funding gap for clinical validation and early-stage growth

Action: Establish targeted EU and regional instruments to finance critical validation stages (clinical trials, regulatory approval, and market pilots). Use blended finance combining grants with equity schemes to de-risk private investment.



Evidence: All three regions reported severe funding shortages, especially in early validation and clinical trials. In Northern Portugal, start-ups highlighted the difficulty of financing clinical trials, while Baden-Württemberg stakeholders identified the "vicious cycle" between funding and regulatory compliance.

Impact: Greater access to validation funding will accelerate time-to-market for health innovations, strengthen Europe's competitiveness, and improve patient access to digital health solutions.

Ethical dimension: Enables smaller start-ups and university spin-offs to bring patient-oriented solutions to market, increasing equity of access to innovation.

2. Objective: Develop interoperable health data infrastructures

Action: Support the creation of regional and cross-border health data platforms aligned with the European Health Data Space (EHDS), including clear guidelines for SMEs and start-ups on secure access to anonymised datasets.



Evidence: Both Baden-Württemberg and Central Macedonia highlighted missing or fragmented data infrastructures as a barrier to Al-driven solutions.

Impact: Interoperable infrastructures will facilitate cross-border research and enhance Europe's capacity to deliver personalised healthcare.

Ethical dimension: Governance frameworks must ensure GDPR compliance, transparency, and trust to guarantee fair and safe use of health data.







3. Objective: Promote investor education and incentivise long-term engagement



Action: Develop EU-supported training programmes and risk-assessment tools for investors in the health sector. Complement these with tax incentives or co-investment schemes to stimulate private capital.

Evidence: Central Macedonia stakeholders stressed the lack of informed pre-seed investors, while Northern Portugal pointed to over-reliance on grants.

Impact: Improved investor literacy and incentives will diversify financing, reduce reliance on public funds, and strengthen sustainability.

Ethical dimension: Reduces information asymmetries and broadens access to capital for innovators across regions.

4. Objective: Strengthen networking, mentoring, and cross-sector collaboration



Action: Create structured mentoring schemes and pan-European networks linking researchers, start-ups, hospitals, and investors. Expand accelerator models, such as LinkHealth@BW, into cross-regional clusters.

Evidence: All regions identified weak networking as a barrier, especially Central Macedonia, where stakeholders called for more government-facilitated matchmaking.

Impact: A stronger collaborative culture will accelerate knowledge transfer, improve alignment between research and market needs, and reduce duplication.

Ethical dimension: Ensures inclusive ecosystems where emerging regions gain access to networks often concentrated in metropolitan hubs.

5. Objective: Enhance visibility and internationalisation of regional ecosystems





Evidence: Baden-Württemberg was recognised as strong but under-promoted; Northern Portugal emphasised the need for internationalisation to retain entrepreneurs; Central Macedonia called for a unified Greek ecosystem to reach "critical mass."

Impact: Greater visibility will attract investment, talent, and partnerships, embedding regional ecosystems in Europe's and the global innovation landscape.

Ethical dimension: Promotes a more balanced European innovation landscape, reducing inequalities between high-profile and less visible regions.







4. Evidence and Analysis

The following section summarises the most relevant evidence gathered through the three regional SHIFT-HUB Entrepreneurial Discovery workshops in Central Macedonia¹, Northern

Portugal², and Baden-Württemberg³. It presents key findings from stakeholder discussions, expert insights, and concrete examples that directly support the proposed policy recommendations highlighting common challenges and region-specific dynamics. methodology was based on a moderated, structured panel discussion approach covering the three topics (1) challenges/barriers/needs, (2) opportunities and (3) comparison to other ecosystems. Answers and discussions between regions were compared,



conclusions and recommendations formulated and revised by the panellists. For each panel discussion, the panellists featured representatives of regional stakeholders across the smart health ecosystem – including University/Research representatives supporting Innovation or Technology Transfer, regional initiatives and Innovation Hubs, Venture Capital organisations, Innovators and Entrepreneurs (Start-Ups, Solution Providers, Technology Developers), regional Policymakers - enabling a comparative understanding of barriers and enablers across different European contexts. Limitations remain, as the workshops provide qualitative perspectives rather than comprehensive data, yet they offer a robust and balanced reflection of ecosystem needs and opportunities.

Central Macedonia (Greece)¹

Central Macedonia's smart health ecosystem is in a maturing phase, centred around Thessaloniki's innovation zone and the Aristotle University of Thessaloniki. Key challenges include limited networking opportunities, lack of pre-seed funding, weak government support, and insufficient critical mass. Stakeholders called for a unified national ecosystem and stronger European integration to enhance visibility and investment attractiveness.



Northern Portugal (Portugal)²



Northern Portugal's ecosystem is dynamic but still evolving. While strong in research and early innovation, it struggles with gaps between early-stage and late-stage funding, regulatory burdens, insufficient mentorship structures, and actors operating in isolation. The ecosystem relies heavily on grants, leading to sustainability challenges, and many entrepreneurs relocate abroad due to lack of support. Internationalisation and reduction of fragmentation is seen as crucial for attracting investment and building market-ready solutions.







Baden-Württemberg (Germany)³

Baden-Württemberg has a well-developed life sciences and smart health ecosystem, with accelerators such as 4C, arise, and Life Science Accelerator BW. The region benefits from strong networks and political support facilitated by the well-connected state agency BIOPRO, but faces regulatory complexity, early-stage funding gaps, and insufficient visibility. Also, data infrastructure limitations hinder the scaling of Al-driven solutions.





Across all three regions, common issues include funding gaps in validation phases, regulatory hurdles, and the need for better networking and collaboration structures. Differences lie in maturity: Baden-Württemberg is well-established but under-promoted, Portugal is research-strong but fragmented, and Central Macedonia is still building foundational ecosystem structures.

5. Sources

- 1 Report SHIFT-HUB Entrepreneurial Discovery Workshop, Thessaloniki (Greece), 2024: Exploring Central Macedonia's Opportunities for Smart Health
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- 5 Commission Communication 2022 (Year) 196/2: "Communication from the Commission A European Health Data Space: harnessing the power of health data for people, patients and innovation". Document 52022DC0196

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