TRANSFORMING ROMANIA'S HEALTH INNOVATION ECOSYSTEM: A STRATEGIC VISION FOR REGIONAL COMPETITIVENESS

WHITE PAPER

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Paper Summary

This advertorial synthesizes findings from the Policy Improvement Report (August 2025) and S3-Based Regional Action Plan and Roadmap (September 2025) developed under the I3HIES project framework. Both documents represent evidence-based strategic frameworks developed through comprehensive stakeholder consultation and international best practice analysis.

KEYWORDS

HealthTech; digital health; living labs; Smart Specialization Strategy; RIS3 NV; Northwest Regional Development Agency; Cluj IT Cluster; monitoring and evaluation; quadruple helix; cross-sector integration; GDP-weighted prioritization; export development; investment attraction; regulatory compliance (MDR); technology transfer.

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Introduction

Northwest Romania faces structural barriers constraining healthcare innovation while possessing regional capabilities that, if coordinated strategically, could enable measurable progress. The region operates in an unfavourable context 39% of the EU average GDP per capita, zero medical device notified bodies, and fragmented healthcare technology ecosystems. Yet the constellation of existing regional ingredients suggests potential for systematic improvement through targeted policy interventions and infrastructure integration.

This white paper examines how strategic policy enhancements, aligned with regional capabilities and concrete infrastructure opportunities, could create conditions for advancing healthcare innovation. The analysis draws from comprehensive stakeholder consultations conducted through the I3HIES project framework, policy analysis of Romania's National Recovery and Resilience Plan and Northwest Region Smart Specialization Strategy, and international benchmarking against peer regions.

Cluj IT hypothesis is that through coordinated policy action (notified body establishment + RIS3 enhancement), alignment of existing regional strengths (entrepreneurial activity, technology expertise, academic infrastructure, enabler organizations, local public sector support), and leverage of concrete opportunity (Regional Emergency Hospital 2027), Northwest Romania could enable healthcare innovation progress despite starting from an unfavourable position. Success depends on systematic policy coordination, not isolated initiatives.

National medical device market positioning

Romania's medical device market is projected to expand to US$2.02-2.62 billion by 2030 at a 5.4% compound annual growth rate. However, structural disadvantages constrain this opportunity. Romania generated €287.15 million in medical device production in 2021 while importing €427 million, primarily from Germany (€121 million), the Netherlands (€74.3 million), and China (€32 million). Healthcare spending per capita stands at €419 allocated specifically to pharmaceuticals and medical devices, approximately 60% of the EU average of €699.

Romania operates zero notified bodies under the EU Medical Device Regulation. This absence forces Romanian medical device companies that require third-party conformity assessment to employ expensive foreign certification services, resulting in 30-50% cost premiums and timeline delays. Small and medium enterprises face a disproportionate burden due to fixed translation and localization costs that cannot be distributed across large product portfolios. Poland and the Czech Republic established an adequate notified body infrastructure through EU partnership arrangements, enabling domestic certification capacity a competitive advantage unavailable to Romanian companies.

Northwest Region GDP per capita reaches only 39% of the EU average, below Romania's national average of 42.1%. Yet the healthcare sector demonstrates disproportionate regional concentration: 3,965 health sector firms representing 13.91% of the national total, and 14,527 healthcare employees representing 9.5% of the national employment. This concentration exceeds the regional share of the national population, suggesting that healthcare represents the region's most significant competitive advantage despite its overall economic position.

Regional academic infrastructure includes Babeș-Bolyai University, Iuliu Hațieganu University of Medicine and Pharmacy, and Technical University of Cluj-Napoca, with specialized medical engineering capabilities. IT employment concentration at 15% of the national total provides a foundation for healthcare technology development and digital health solution integration. Venture capital investment reached €16.2 million during the 2020-2024 period, indicating growing investor interest despite regional economic constraints.

Regulatory infrastructure deficit. Zero notified bodies creates a systematic competitive disadvantage. Wolf Theiss legal analysis identifies this gap as creating "limited possibilities for certification of medical devices resulting in long waiting times and higher certification costs for Romanian companies." Foreign certification scheduling delays, communication barriers, and premium fees accumulate into a systemic disadvantage affecting all Romanian companies that require third-party conformity assessment.

Healthcare system capacity constraints. Romania's nursing density stands at 8.0 per 1,000 inhabitants compared to the Netherlands at 11.4, a 30% deficit affecting hospital capacity to implement and monitor medical devices. European Commission analysis documents that Romania allocates 44% of healthcare spending to hospitals versus the EU average of 28%, concentrating advanced medical technologies in urban teaching hospitals while rural facilities operate with limited clinical staff and outdated equipment. Understaffed healthcare institutions prioritize basic patient care over the evaluation and implementation of technology.

Strategic misalignment. RIS3 strategy, unchanged since 2020, emphasizes sectors demonstrating systematic decline. Automotive sector integration within manufacturing priorities persists despite the Romanian car market declining 9.6% in 2025 and 53,669 job losses announced across the EU automotive employment. Healthcare technology receives minimal strategic attention despite demonstrated capabilities and market opportunity. Current strategic frameworks provide generic rather than specialized support for ecosystem development, preventing systematic translation of academic research capabilities into commercial advantages.

Commercialization gap. Strong academic capabilities in medical research, engineering, and clinical expertise operate without systematic commercialization pathways. Technology transfer mechanisms remain underdeveloped, with limited intellectual property commercialization rates, industry partnerships, and successful product launches from academic research. Healthcare innovation export development remains minimal despite market potential and established IT sector export capabilities, reflecting fragmentation among academic research, technology companies, and healthcare providers.

Despite constraints, the Northwest Region demonstrates elements that enhance the contribute to healthcare innovation:

Entrepreneurial activity. Second-highest Startup Nation programme participation after Bucharest - Ilfov demonstrates business formation capability and entrepreneurial orientation exceeding comparable EU regions at a similar development stage.

Technology expertise. Established software development capabilities applicable to healthcare technology applications. The regional IT sector demonstrates proven export development success and a growing healthcare technology company presence, requiring systematic integration with healthcare sector opportunities.

- **Academic infrastructure.** Medical universities, engineering programs, and the Romanian preference for STEM education are reflected in graduate numbers, providing research capabilities and a human capital foundation.
- **Enabler organizations.** Freshblood, HIVE, and the Cluj IT Cluster provide existing ecosystem support structures that are already operating and engaged in innovation facilitation. These organizations demonstrate the capability to coordinate stakeholders, provide business mentoring, and facilitate market connections.
- **Local public sector support.** Cluj Municipality engagement through innovation initiatives, Botnar Foundation FIX programme providing direct business support, and local government involvement in ecosystem development create a policy-supportive environment.

Digital infrastructure shows 50% telemedicine and teleradiology penetration across regional healthcare providers, a dynamic startup ecosystem in Cluj-Napoca with interdisciplinary collaboration among universities, hospitals, and companies, and strong regional brand recognition with a robust IT professional network. Yet, bureaucratic complexity, insufficient inter-hospital connectivity, a shortage of specialized personnel, and inadequate public-private partnership mechanisms create systematic barriers that require policy intervention.

Policy recommendations

The strategic enhancement of Romania's National Recovery and Resilience Plan proposes establishing a domestic medical device regulatory infrastructure by allocating funds from existing health sector components. This intervention addresses the fundamental cost premium barrier affecting all Romanian medical device companies.

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Smart Specialization Strategy enhancement to address fundamental policy misalignment by implementing a systematic monitoring mechanism, market-responsive priority adjustment, and performance-based resource allocation.

Establish a Regional Innovation Council model on the existing Regional Programme Monitoring Committee, with rotating leadership among business, academic, healthcare, and government stakeholders. Council provides a binding recommendation authority for strategic priority modification and resource allocation adjustment. Quarterly business community consultation through a systematic survey methodology provides direct feedback on the effectiveness of the strategic framework, market opportunity identification, and competitive barrier assessment.

Implement market-responsive priority adjustment with automatic trigger mechanisms for strategic review. Declining sector performance below 70% of targets triggers mandatory reassessment; emerging sector growth exceeding 150% of the regional average triggers integration assessment for priority development. Healthcare sector indicators systematically exceed growth thresholds requiring strategic integration consideration.

Abandon declining sectors. Automotive and textile industries face systematic European decline requiring a managed transition rather than continued resource allocation. Concentrate resources on healthcare technology (€2.4 billion market, 3,965 firms, demonstrated capabilities) and digital transformation, leveraging regional IT employment concentration.

Transform RIS3 from a static document into a dynamic policy instrument, enabling responsive regional competitive positioning. Performance metrics encompass economic impact measurement, including GDP contribution, employment creation, and investment attraction, with sector-specific analysis.

The Regional Innovation Council provides continuous strategic guidance, ensuring that smart specialization domains remain focused on market-responsive priorities, that emerging opportunities receive systematic attention, and that declining sectors receive managed transition.

The regional emergency hospital as a catalyst for innovation

The Regional Emergency Hospital represents a concrete opportunity to integrate policies, regional capabilities, and healthcare innovation focus through proven Living Labs methodology.

Healthcare Living Lab Catalonia provides comprehensive innovation support, including co-creation facilitation, prototyping assistance, usability studies coordination, and clinical validation support. Service integration demonstrates systematic innovation development from initial concept through market application with technical assistance, regulatory compliance support, and funding application coordination.

Medical Delta ResearchOR Netherlands operates a real-life operating room environment for the validation of surgical technology. The Medical Delta network operates seven specialized Living Labs, achieving 40% faster time-to-market, attracting €15 million in annual innovation investment, and completing 200 collaborative projects across specialized testing environments.

These international examples share common characteristics:

- Clinical infrastructure integration, enabling actual technology validation within operational environments;
- Systematic stakeholder coordination across healthcare providers and technology companies;
- Regulatory compliance support, reducing market barriers;
- Performance measurement enabling innovation pipeline tracking from development through commercialization;

A systematic gap exists between academic research capabilities and clinical validation environments. Medical device companies lack a domestic testing infrastructure capable of conducting rigorous clinical validation. Healthcare providers lack structured innovation adoption pathways, creating systematic barriers to the implementation of emerging technologies in healthcare delivery. The current situation forces innovative companies to conduct clinical validation abroad, increasing costs and timeline delays.

The hospital's completion in 2027 creates a unique opportunity to integrate innovative infrastructure during operational establishment rather than costly retrofitting. A substantial testing environment enables diverse medical device applications, from emergency care to surgical specialties to diagnostic support. Regional ingredients (D1-D5) provide a supporting ecosystem, while policy improvements (notified body establishment, RIS3 enhancement) remove structural barriers, enabling innovation to be translated into market applications.

Combined intervention creates conditions for systematic healthcare innovation advancement rather than isolated initiatives constrained by regulatory barriers and strategic misalignment. The Living Labs methodology provides a concrete integration point where policy coordination, regional capabilities, and infrastructure opportunities converge into an actionable framework.

Conclusions and call to action

Northwest Romania faces unfavourable starting conditions, but targeted policy improvements, combined with existing regional capabilities and concrete infrastructure opportunities, could enable measurable progress in healthcare innovation.

Coordinated action is required. Individual policy improvements alone prove insufficient. Notified body enhancement requires RIS3 alignment to direct healthcare technology focus. RIS3 enhancement requires policy coordination supporting implementation. A Living Lab opportunity requires both policy improvements and RIS3 alignment to deliver results. Success depends on coordinated policy action across institutional levels.

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Immediate action 1. Establish the Regional Innovation Council model on the Regional Programme Monitoring Committee governance structure. Update RIS3 strategy reflecting current market reality through explicit abandonment of declining sectors (automotive, textiles), strengthened healthcare technology priority with dedicated resource allocation, and performance-based monitoring enabling responsive adjustment. Coordinate policy implementation, ensuring systematic alignment between NRRP medical device notified body development and RIS3 strategic focus. Transform the Regional Innovation Council into a north star function, providing continuous strategic guidance, ensuring smart specialization domains remain focused on market-responsive priorities.

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Immediate action 2. The 2027 completion deadline for the Regional Emergency Hospital creates a window of opportunity for coordinated policy implementation before significant infrastructure investment. Implementation success depends on political commitment from regional development authorities, systematic stakeholder engagement that demonstrates collective ownership, and sustained coordination with international partners, thereby accelerating knowledge transfer and quality assurance.

Success depends on coordinated policy action across institutional levels. Individual policy improvements alone are insufficient; NRRP notified body enhancement requires RIS3 alignment to direct healthcare technology focus; RIS3 enhancement requires policy coordination to support implementation; Living Lab opportunities require both policy improvements and RIS3 alignment to generate results.

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