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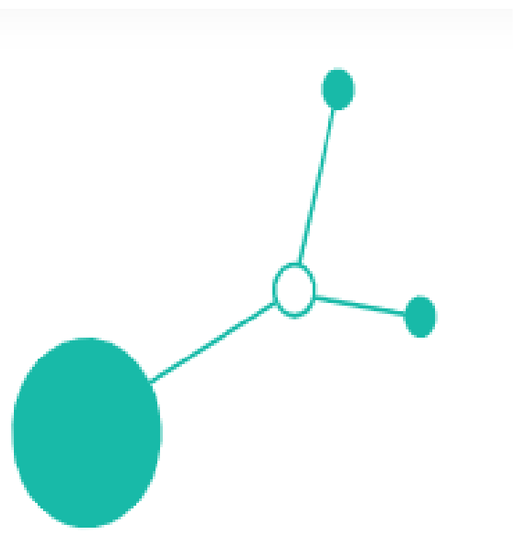
DIGIVITALITY

DIGITAL HEALTH INNOVATION

PLAYBOOK



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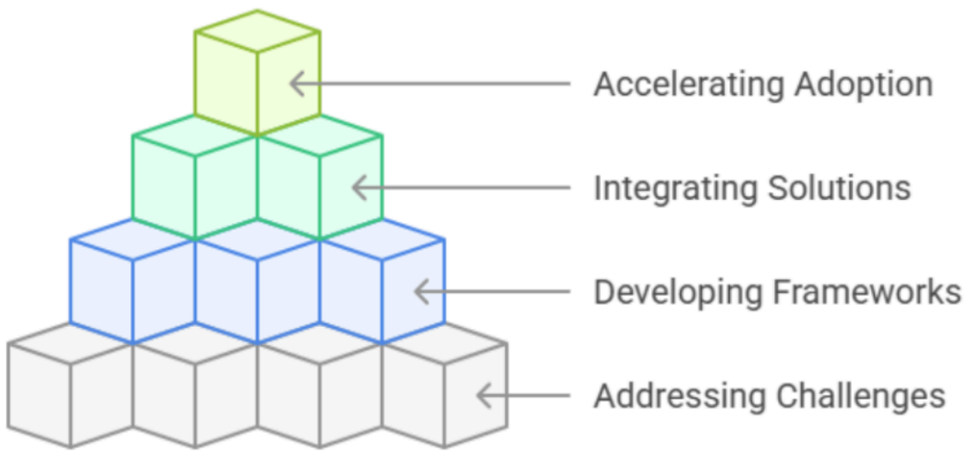
INTRODUCTION

The DIGIVITALITY Digital Health Innovation Playbook is a practical guide designed to support key stakeholders in building and scaling digital health ecosystems, particularly across Central and Eastern Europe (CEE).

This playbook presents clear, ready-to-use frameworks and tools for developing, validating, and integrating digital health solutions into healthcare systems. It is based on cross-border collaboration models and showcases actionable steps to accelerate the adoption of digital innovation.

Rooted in real-world experience from the DIGIVITALITY project, besides focusing on the essential aspects and milestones of setting up and developing a supporting framework to innovation, it offers strategies to overcome challenges such as regulatory barriers, limited funding, fragmented infrastructure, and difficulties in stakeholder collaboration.



After reading this chapter, you will understand why functioning innovation ecosystems and collaboration of stakeholders play a key role in the success of start-ups and you will know who this Playbook is for, how it is structured, and how to quickly find the sections and tools that match your role and level of experience.

Why Digital Health Matters in CEE

Despite growing interest in digital transformation, healthcare systems in CEE still face systemic limitations – efficient and focused collaboration of stakeholders in the ecosystems, —fragmented infrastructure, complex regulations, underfunded early-stage ventures, and slow clinical adoption.

The region holds strong potential, but coordinated, structured support is essential to unlock it. This playbook addresses these needs through scalable frameworks, inspired by successful models like DiGA, tailored to (A Digital Health Application Scheme first introduced in Germany), tailored to CEE realities.
In practical terms, this means helping stakeholders move from one-off pilots to repeatable, scalable pathways for validation, reimbursement, and long-term adoption.

Who is this Playbook for?

Startups

Startups can use this Playbook to successfully navigate medical and clinical validation processes across different maturity stages, from early feasibility to pilot execution and scale-up by engaging with hospitals and research institutions for need validation, feedback on idea and feasiblitity, pilot projects and evidence generation. It offers guidance on how to structure these collaborations to ensure real-world testing and data collection that support both medical, clinical and market validation.

Hospitals and clinicians

Healthcare providers are at the heart of addressing the challenges of the healthcare ecosystem, from everyday clinical procedures to gaps and inefficiencies in existing solutions, as well as testing and adopting digital innovations.

This Playbook supports them in:

- Identifying and clearly articulating unmet clinical needs, enabling the design of effective, challenge-based innovation programs.

- Creating procedures to engage effectively with startups, using structured collaboration models that minimize administrative burden.

- Implementing and validating digital solutions in real-world clinical settings, while ensuring patient safety, regulatory compliance, and seamless integration with existing hospital systems and workflows.

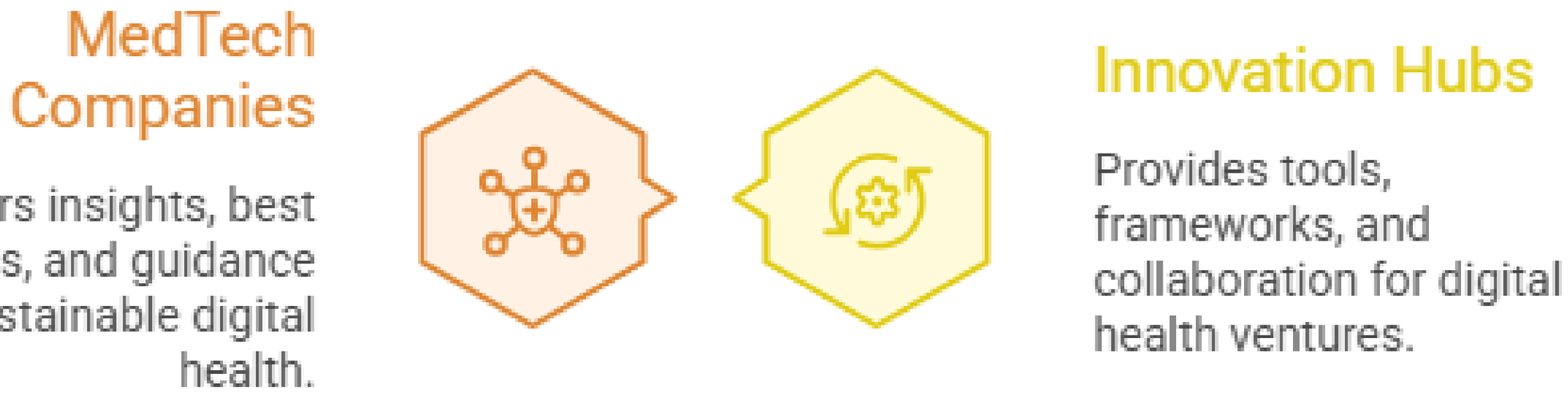
For hospitals, the Playbook also shows how to move from isolated pilots to institutionalized innovation structures such as innovation offices, living labs, or digital health committees.

Innovation Hubs, TTOs, and Accelerators

These ecosystem builders are responsible for bridging the gap between innovation and real-world implementation.
The Playbook supports them by providing ready-to-use tools and templates for:

- Scouting, mentoring, and supporting digital health ventures, enabling systematic identification and development of high-potential solutions.
- Designing structured support frameworks, including incubation programs, regulatory readiness training, and investor matchmaking.
- Facilitating multi-stakeholder collaboration, bringing together startups, clinicians, hospitals, and MedTech industry partners within a single, coherent innovation process.

It also offers guidance on how hubs can measure their own impact (e.g. number of pilots conducted, funds raised, adoption rates, or partnerships formed) and use these results to secure long-term funding and strategic partnerships.



MedTech Companies

MedTech companies are key enablers of sustainable digital health ecosystems.

The Playbook offers them:

- Evidence-based insights to support the design of interoperable digital products, compliant with regulatory frameworks such as the EU Medical Device Regulation (MDR) and the European Health Data Space (EHDS).

- Best practices for pricing and reimbursement strategies, including references to successful models such as Germany’s DiGA framework.

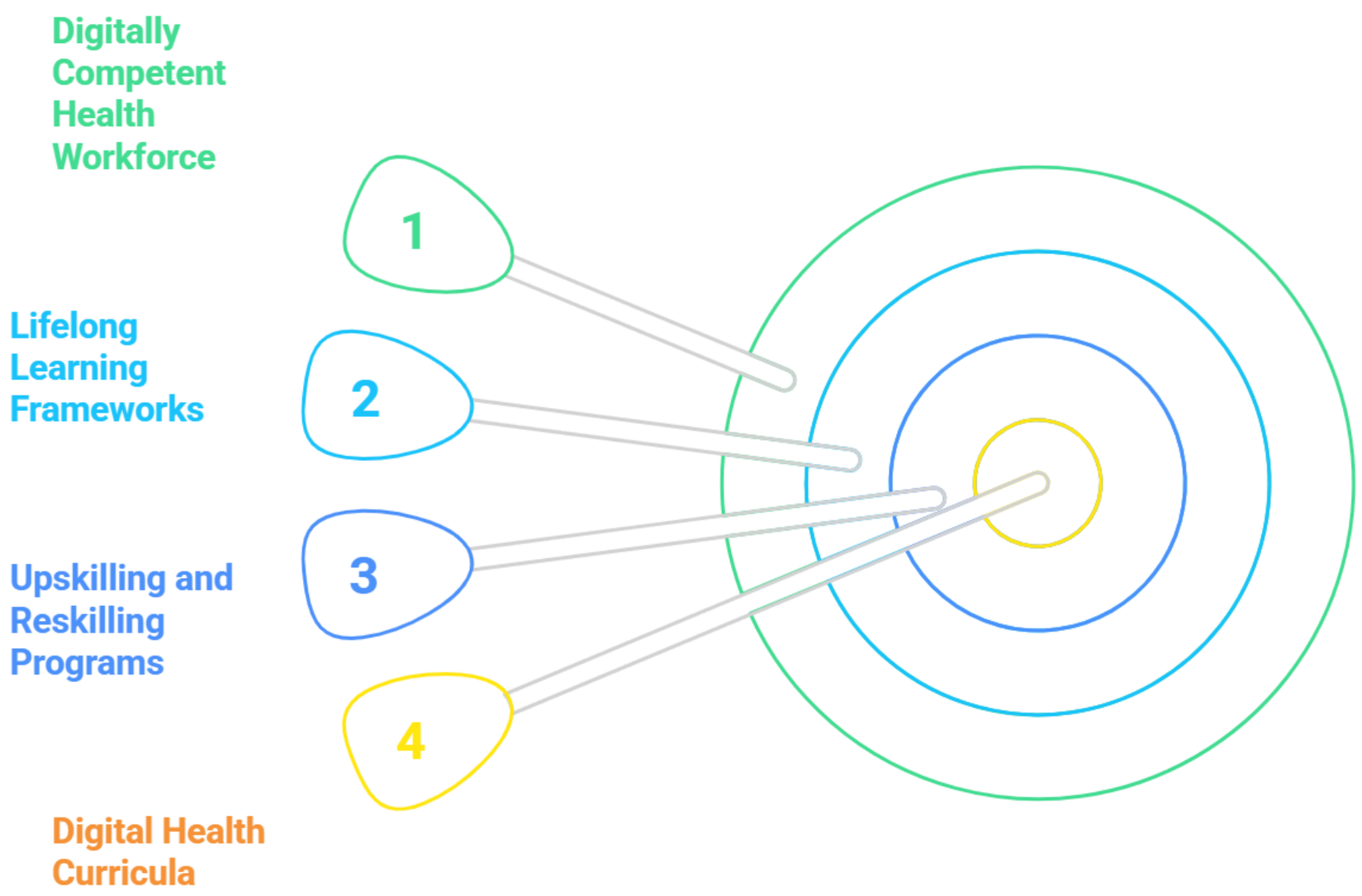
- Guidance for strategic partnerships and investment readiness, including how to demonstrate clinical relevance, scalability, and return on investment to attract key stakeholders.

In addition, it helps corporate teams align open innovation activities with internal product roadmaps, ensuring that startup collaborations lead to concrete portfolio integration rather than isolated pilot projects.

Other Key Stakeholders in the Ecosystem

While this Playbook primarily focuses on the core actors directly involved in startup validation and early-stage ecosystem building, we fully acknowledge that a broader range of stakeholders plays a critical role in enabling sustainable, inclusive, and scalable digital health transformation.

Although these groups are not the main users of the tools and frameworks presented here, their engagement remains essential to the long-term success of digital health adoption across Central and Eastern Europe (CEE).



Universities and Training Providers

The development of a digitally competent health workforce is recognized as a foundational enabler of system-wide transformation across the EU.

These actors contribute by:

- Integrating digital health curricula into medical, nursing, public health, and healthcare administration programs, preparing future professionals for the digital transition.
- Providing targeted upskilling and reskilling programs for clinicians, healthcare managers, administrators, and policymakers.
- Supporting lifelong learning frameworks aligned with the European Health Data Space (EHDS) and EU4Health digital workforce priorities.

Universities can also act as neutral conveners, hosting joint programs where startups, hospitals, and regulators co-design pilot projects and validation studies.

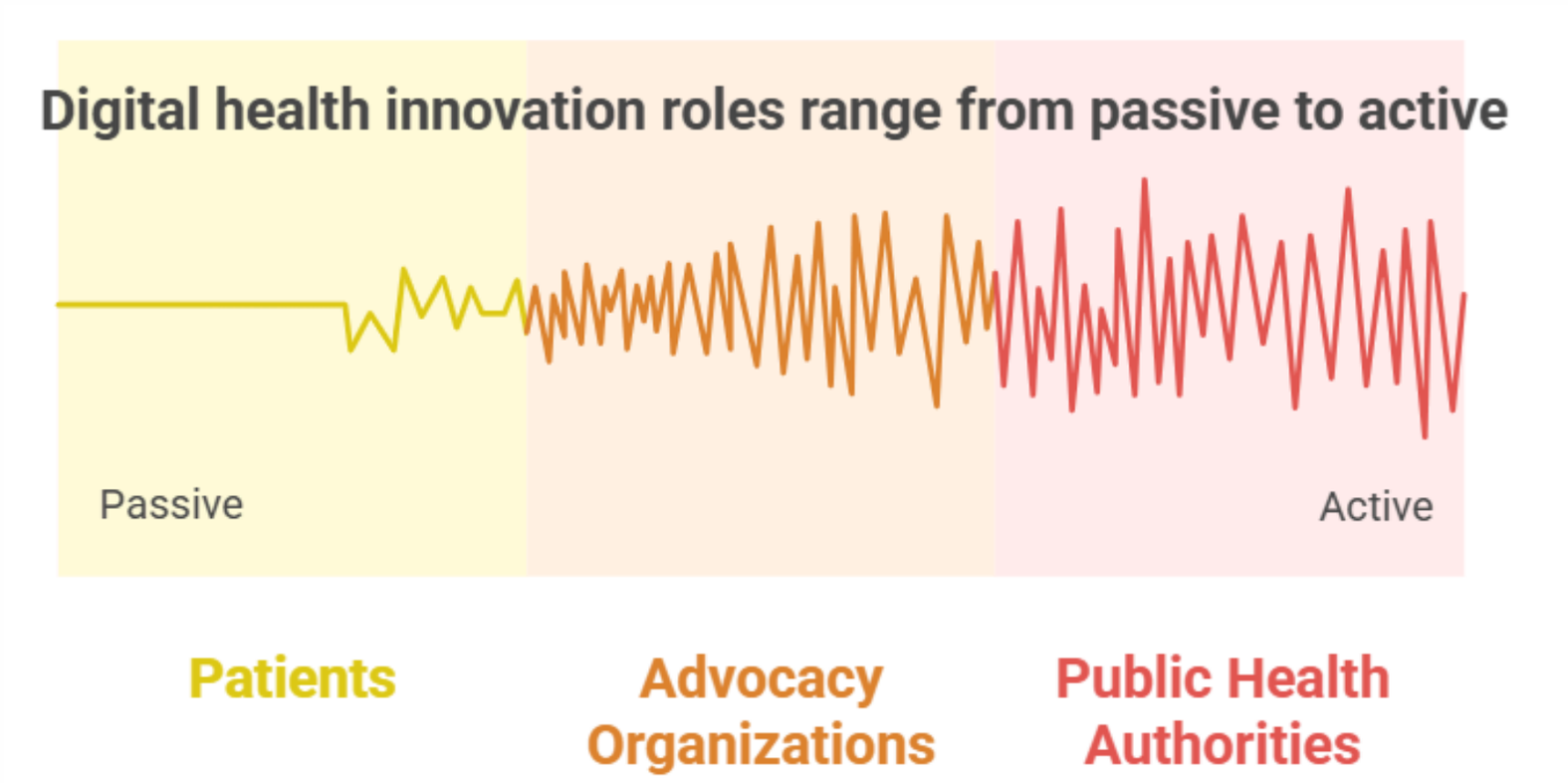
Patients and Advocacy Organizations

Patients and citizens are increasingly recognized as co-creators of digital health innovation rather than passive users. Their meaningful engagement ensures that digital tools are human-centered, trustworthy, and widely adopted.

Their roles include:

- Contributing to solution co-design through patient feedback, user testing, and participatory innovation models.
- Advocating for ethical data use, transparency, and privacy, including robust consent mechanisms aligned with GDPR and EHDS principles.
- Promoting digital health equity, ensuring that vulnerable and underserved populations have access to emerging technologies.
- Supporting system-wide integration of digital health solutions, acting as active participants in adoption across healthcare services.
- Addressing digital health literacy gaps, helping reduce barriers and enable equitable access to digital health-based services.

Involving patient organizations early in pilot design can prevent resistance at later stages and significantly increase acceptance and trust in new tools in routine clinical care.



Public Health Authorities & National Regulators

Public institutions and regulatory bodies shape the enabling environment that allows innovation to scale safely and effectively.

While this Playbook does not serve as a regulatory guide, these actors are responsible for:

- Harmonizing national legislation with evolving EU frameworks, such as the Medical Device Regulation (MDR), General Data Protection Regulation (GDPR), and the European Health Data Space (EHDS).
- Designing national-level regulatory sandboxes, fast-track pathways, and outcome-based reimbursement models, enabling controlled and evidence-driven innovation.
- Facilitating data interoperability and secure access, through national health data infrastructures aligned with EHDS principles for secondary use of health data.

Their early involvement in pilot planning is crucial to ensure that evidence generated by startups and hospitals can later be leveraged in reimbursement decisions and Health Technology Assessment (HTA) processes.

How to Use This Document

This Playbook is designed as a modular, role-based roadmap to help you navigate the complexity of validating and scaling digital health innovations in Central and Eastern Europe.
You do not need to read it from start to finish. Instead, begin with the core chapters that explain the ecosystem and the roles of key stakeholders, and then move directly to the sections that match your role, level of experience, and immediate goals.
The Playbook provides:

- Practical tools – including templates, legal checklists, stakeholder engagement plans, and regulatory navigation aids.
- Actionable frameworks – for collaboration models, pilot readiness, and ecosystem integration.
- Tailored pathways – for startups, hospitals, innovation hubs, and MedTech companies, aligned with their maturity level and specific innovation objectives.

Two Ways to Use This Playbook

Interactive Entry Point – Choose Your Role

You can navigate the Playbook interactively by answering three simple guiding questions:

1. Who are you?
2. What is your level of experience?
3. What do you want to achieve?

Based on your answers, you will be directed to the appropriate role-specific pathway:

- Startups – Feasibility Pathway
- Hospitals – Innovation Readiness Pathway
- MedTech Companies – Collaborate & Integrate Pathway
- Innovation Hubs – Challenge-to-Pilot Pathway

Comprehensive Reading
Alternatively, you can read the entire Playbook from start to finish.

This approach is especially recommended if you:

- Work across multiple stakeholder roles.
- Design cross-functional programs or support systems.
- Want a holistic understanding of the ecosystem and the interactions between stakeholders.

Each section of the Playbook is modular, allowing you to move freely between chapters as needed.
Tools and templates are clearly labeled for easy reuse, and cross-references help you connect validation with regulation, adoption, and scale-up.

Each pathway provides a targeted sequence of steps and tools tailored to your needs, whether you are exploring innovation for the first time or running advanced pilots and scaling solutions.

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DIGIVITALITY

Start Your Journey Through the DIGIVITALITY Playbook

Digital health transformation is complex—but you don't have to navigate it alone. This Playbook is designed to meet you where you are, offering practical guidance, tools, and roadmaps tailored to your role and experience level.

Whether you're a startup preparing for clinical pilots, a hospital exploring new technologies, a MedTech company seeking partnerships, or an innovation hub building a pipeline—we've mapped out your next steps.

Choose Your Role to Begin

Innovation Hub

Innovation hubs, accelerators, and tech transfer offices.

Go to section

Startup

Individuals identifying as part of a startup company.

Go to section

MedTech Company

Companies specializing in medical technology solutions.

Go to section

Healthcare Provider

Hospitals and healthcare providers seeking identification.

Go to section

CHAPTER I
Roadmap to build the ecosystem

Digital health ecosystems do not emerge by accident. They are the result of intentional design, trust-building between stakeholders, and the creation of clear pathways that connect ideas with real clinical impact. Chapter 1 sets the foundation for the entire Playbook by showing how to move from fragmented, isolated innovation activities toward a structured, collaborative ecosystem that can continuously generate, test, and scale digital health solutions.

This chapter introduces the logic of ecosystem thinking. Instead of treating startups, hospitals, MedTech companies, and innovation hubs as separate actors, it frames them as interdependent parts of one system. Each group has a different role, but real impact only happens when their activities are aligned, coordinated, and mutually reinforcing.

You will find here a practical roadmap for:

- Understanding what a functional digital health ecosystem looks like in practice.
- Identifying the core building blocks needed before pilots and programs can succeed.
- Clarifying roles and responsibilities of key stakeholders.
- Designing collaboration models that reduce friction and increase trust.
- Moving from ad-hoc projects to repeatable, scalable innovation processes.

Chapter 1 acts as the “architecture layer” of the Playbook. It explains how all later chapters fit together and why topics such as regulation, funding, stakeholder engagement, early HTA, and scaling only work when embedded in a coherent ecosystem design.

By the end of this chapter, you will:

- Understand the essential components of a digital health innovation ecosystem.
- Be able to assess where your region or organization currently stands.
- Know which foundations must be built before launching pilots or accelerators.
- See how ecosystem design directly influences the success or failure of startups and hospital collaborations.

This chapter is especially valuable if you are:

- An innovation hub or public authority designing support programs,
- A hospital preparing to open up to systematic collaboration with startups,
- A MedTech company seeking long-term innovation partnerships,
- Or a startup trying to understand how to navigate complex healthcare environments.

Think of this chapter as your ecosystem blueprint. Everything that follows in the Playbook builds on the structure you define here.

For Startups: Choose Your Experience Level

This section is designed for startups and innovators developing digital health solutions and navigating the journey from concept to adoption in real healthcare settings.
To guide you to the most relevant tools and strategies, we use the Healthcare Innovation Cycle (HIC) — a maturity framework co-developed by EIT Health (European Institute of Innovation & Technology) and CIMIT (Consortia for Improving Medicine with Innovation and Technology). It defines the key stages that every healthcare innovation must go through, from an initial idea to real-world adoption.

A. Concept & Feasibility

You have a prototype or MVP (Minimum Viable Product) and want to validate the need and usability.

No clinical testing yet.

You need to:
- ✓ Confirm the problem
- ✓ Test technical and clinical feasibility
- ✓ Get early user feedback

➡ Go to: Section A – Early Validation

At this stage, progress is measured by learning, not by revenue.
Short feedback loops with clinicians and patients are more valuable than adding new features.

B. Proof of Value

You're planning or running your first pilot in a real-world setting.

You need to:
- ✓ Collect clinical and usability data
- ✓ Engage with hospitals and regulators
- ✓ Show early evidence of value

➡ Go to: Section B – Pilots & Evaluation

Your primary goal at this stage is to demonstrate that the solution delivers real, measurable value in practice, not just in a conceptual or controlled setting.

C. Adoption & Sustainability

Your solution is validated, and you're working on sales, scaling, or reimbursement.
You need to:
- ✓ Secure market access
- ✓ Build implementation plans
- ✓ Strengthen your business model

➡ Go to: Section C – Scale & Market Access

This level is about building a repeatable go-to-market strategy, aligning your regulatory, reimbursement, and commercial efforts across multiple sites or countries.

For Hospitals: Choose Your Experience Level

This section is for hospitals and healthcare providers looking to collaborate with startups to solve clinical, operational, or patient care challenges through digital innovation. To guide you to the most relevant tools and strategies, we use the Healthcare Innovation Cycle (HIC) — a maturity framework co-developed by EIT Health and CIMIT. It outlines the stages every healthcare organization may progress through — from initial exploration to strategic innovation leadership. Hospitals can use these levels to clarify where they currently stand and what internal capabilities they need to build next (e.g. innovation office, pilot processes, reimbursement know-how)

A. Exploring Startup Collaboration

You are just starting to explore working with startups to address internal challenges.

You have no prior collaboration or structured innovation program.

You need to:

✓ Identify internal problems that could be solved digitally
✓ Understand the innovation landscape
✓ Build readiness to engage with startups

➡ Go to: Section A – Needs Assessment & Opportunity Framing

The focus at this stage is on building readiness — understanding key challenges, identifying stakeholders, and establishing basic governance structures, rather than launching multiple pilots immediately.

B. Piloting Solutions

You have participated in pilots or testbeds with startups and want to improve impact and efficiency.

You need to:

✓ Set up structured pilot processes
✓ Define success criteria and measure results
✓ Align innovation with clinical and operational goals

➡ Go to: Section B – Pilot Design & Implementation

Hospitals at this level benefit most from standard templates for pilot agreements, ethics and IT approval, and KPI dashboards to track outcomes across projects.

C. Leading with Innovation

You are running living labs or innovation programs and want to lead in adopting digital health solutions.

You need to:

✓ Streamline procurement and scaling pathways
✓ Institutionalize startup collaboration
✓ Share best practices and outcomes

➡ Go to: Section C – Strategic Innovation & Ecosystem Leadership

At this stage, hospitals start to act as reference centers, influencing regional policy, reimbursement models, and cross-border collaborations.

For Innovation Hubs: Choose Your Experience Level

This section is for innovation hubs, accelerators, clusters, and tech transfer offices supporting collaboration between startups and healthcare stakeholders to drive digital health innovation. To help you access the most relevant tools and strategies, we use the Healthcare Innovation Cycle (HIC) — a maturity framework co-developed by EIT Health and CIMIT. It guides organizations through key stages of innovation support — from launching programs to scaling ecosystem-wide impact.

A. Starting Out

You are a new innovation hub launching your first programs or open calls.

You need to:

✓ Define your mission and target groups
✓ Set up governance and scouting mechanisms
✓ Align with regional healthcare needs

➡ Go to: Section A – Program Design & Stakeholder Engagement

Early traction is typically achieved through a small number of well-structured initiatives—such as thematic calls or focused mentorship programs—rather than through large, resource-intensive accelerator schemes.

B. Early-Stage Acceleration

You run early-stage accelerator programs and want to build more effective validation pipelines.

You need to:

✓ Connect startups with hospitals and mentors
✓ Support early clinical validation
✓ Structure calls to attract high-potential solutions

➡ Go to: Section B – Building Validation Pipelines

At this stage, hubs are most effective when they use clear selection criteria, structured validation methods, and defined success metrics.

C. Scaling Impact

You are experienced in scaling startups across regions or Europe and want to increase long-term success and systemic impact.

You need to:

✓ Co-create scaling strategies with partners
✓ Influence policy and funding frameworks
✓ Measure and communicate ecosystem outcomes

➡ Go to: Section C – Ecosystem Development & Scale

Mature hubs can position themselves as regional conveners, publishing impact reports and playbooks and shaping national or EU-level funding priorities.

For MedTechs: Choose Your Experience Level

This section is for corporate MedTech companies seeking early access to validated digital health innovations and collaboration with startups to enhance their innovation pipeline. To navigate the most relevant strategies, we apply the Healthcare Innovation Cycle (HIC) — a maturity framework co-developed by EIT Health and CIMIT. It supports MedTechs in identifying, integrating, and scaling breakthrough solutions from the startup ecosystem.

A. Startup Scouting

You're beginning to explore collaborations with startups and external innovators.

You need to:

✓ Define focus areas and scouting criteria
✓ Understand early-stage startup needs
✓ Set up internal processes for evaluating opportunities

➡ Go to: Section A – Startup Scouting & Landscape Mapping

B. Open Innovation

You're actively participating in open innovation calls, challenges, or co-development pilots.

You need to:

✓ Structure partnerships and engagement models
✓ Provide technical and regulatory support
✓ Align startup activities with internal R&D

➡ Go to: Section B – Open Innovation & Co-Development

C. Strategic Partnerships

You're managing strategic investments, long-term pilot projects, or ongoing collaborations with startups.

You need to:

✓ Identify acquisition or licensing opportunities
✓ Scale validated solutions within your product portfolio
✓ Position your company as an industry innovation leader

➡ Go to: Section C – Strategic Integration & Portfolio Expansion

Level A: Early-Stage Startup

Level A represents the earliest phase, when ideas are being shaped, assumptions are tested, and potential users are first engaged. You are likely at Level A if you are still exploring your concept, conducting initial clinical interviews, and assessing clinical relevance. Success at this stage is not just about building a product—it's about generating trust, evidence, and strong partnerships that will support future pilots and scaling. This phase focuses on transforming a concept into a validated prototype, preparing for clinical testing, planning funding strategies, and engaging the broader healthcare ecosystem.

Key Milestones at This Stage

- A Minimum Viable Product (MVP) is ready for pilot-level testing
- Initial clinical interviews with doctors, nurses, or patients are conducted to gather real-world feedback
- A Letter of Intent (LOI) or similar agreement is signed with a clinical partner

These milestones demonstrate early traction, ecosystem interest, and a commitment to user-centered design.

Related Playbook Chapters

Go to: Chapter 2: Enabling environment

Go to: Chapter 4: Mapping and engaging stakeholders

Best Practice from the Field

An early-stage startup validated their product by combining mock-up demonstrations with structured clinician interviews before seeking funding. This approach helped them identify usability issues and improve alignment with hospital workflows—boosting their chances of successful pilot funding.Early testing with simple mock-ups is often more valuable than building a sophisticated first version. It saves time, reduces costs, and exposes design flaws before they become expensive problems.

Pitfalls to Avoid

Avoid developing features in isolation without clinical input. Healthcare relies on established workflows, and without clinician involvement even strong ideas often fail in real-world practice. Engage clinicians and patients early and regularly to ensure your product addresses real needs. Do not underestimate regulatory complexity—seek guidance from regulatory experts early. Even at Level A, knowing your MDR classification can prevent costly delays and major redesigns later.

Level B: From Pilot to Proof of Value

At this stage, startups move from testing functionality to proving real-world value.
A successful pilot alone is not enough—investors, partners, and payers will ask:
Does it work? For whom? At what cost? Can it scale?

Level B focuses on collecting actionable evidence, refining the solution based on usability insights, and beginning to shape a compelling business case.
Your mission now is to show that your solution delivers measurable improvements — in outcomes, workflows, or cost savings — not just that it works in principle.

Key Milestones at This Stage

- Pilot project executed in a real clinical setting with target users
- Initial outcome and usability data analyzed, with visual summaries
- Draft health economic value proposition developed, with preliminary estimates of time savings, cost reduction, or improved outcomes

These milestones help transition the solution from a prototype into a validated, investment-ready opportunity.

Related Playbook Chapters

Go to: Chapter 5: From Local to International
Go to: Chapter 8: Bringing Stakeholders Together
Annexes & Tools → Pilot design toolkits, KPI frameworks

Best Practice from the Field

A digital intake form was piloted across two hospitals with clearly defined KPIs (Key Performance Indicator), including patient waiting time reduction. Real-time feedback from clinicians and patients helped refine the interface, while measurable improvements supported further funding applications.

Pitfalls to Avoid

Skipping structured usability feedback: Superficial testing can miss critical issues. → Use both qualitative (interviews) and quantitative (task completion) data.

Collecting data without a plan: Metrics only matter if they align with business and clinical goals. → Define clear KPIs before launching the pilot.

Delaying business model thinking: Value is not just clinical—start building cost-benefit logic early to convince decision-makers.

Level C: Market Entry & Scaling

Startups at this stage have validated their solution, secured early traction, and are ready to grow. The focus now shifts to regulatory compliance, first sales, and international expansion - turning a promising prototype into a sustainable, scalable business. This phase is where clinical validation meets commercial reality. Success depends on aligning clinical data, regulatory approvals, and business strategy across diverse health systems.

Key Milestones at This Stage

- Regulatory approval submitted or obtained (e.g., CE mark, FDA, DiGA)
- Expansion into 1–2 international markets with strategic localization plans
- Integrated evidence package compiled for investors, hospitals, and regulators

These achievements signal market readiness and position the startup for sustainable growth or acquisition.

Related Playbook Chapters

Go to: Chapter 5: From Local to International

Go to: Chapter 9: Roadmap for Implementation

Go to: Chapter 10: Conclusion & Recommendations

Best Practice from the Field

A diabetes monitoring solution used pilot data to demonstrate clinical value, supporting regulatory approval in Germany and informing strategies for adoption in other European healthcare settings. Careful alignment of clinical requirements and regulatory standards across countries helped accelerate its broader rollout.

Pitfalls to Avoid

Treating payers only as buyers → Instead, engage them early to shape reimbursement and implementation strategy
Fragmented evidence → Create a unified evidence base that meets the needs of investors, regulators, and healthcare providers
Scaling without adapting → Don’t assume success in one country guarantees adoption in another. Local health systems matter.

Level A: Early-Stage Hospital

Embarking on innovation in hospitals at an early stage is less about full-scale adoption and more about building readiness. At this level, hospitals are exploring digital health but often lack structured innovation pathways. The focus is on identifying unmet needs, initiating first collaborations with startups, and preparing the internal culture for pilot testing. Hospitals in this phase play a crucial role in shaping solutions early, ensuring they align with clinical workflows, patient safety, and compliance.Early-stage hospitals focus on laying the foundation for innovation—understanding their needs, building basic processes, and creating the conditions for successful pilot work later on.

Key Milestones at This Stage

- Establishment of a small internal innovation team or contact person for digital health.
- Participation in needs-assessment workshops with startups and MedTech partners.
- Signing first collaboration agreements (e.g., Letters of Intent) with early-stage startups.

These milestones show that the hospital is moving from ad hoc interest to structured engagement with innovators.

Related Playbook Chapters

Go to: Chapter 2 – Enabling Environment

Go to: Chapter 4 – Mapping and Engaging Stakeholders

Go to: Chapter 7 – Setting up an Ecosystem

Best Practice from the Field

Some regional hospitals have successfully created an “Innovation Contact Point” — appointing a single doctor to liaise with startups. This approach makes it easier to pilot solutions, without major disruption. When nurses and IT staff are involved early, pilots tend to address real workflow challenges more effectively. Keeping the scope small and involving frontline staff early dramatically increases the likelihood of successful pilots.

Pitfalls to Avoid

- Lack of staff buy-in – without clinician and nurse involvement, pilots risk failing due to resistance.

Create feedback loops with frontline staff from the very beginning.

- Overcommitment without capacity – Taking on too many pilot projects strains limited resources.

Focus on 1–2 high-priority pilots aligned with hospital strategy.

Level B: Mid-Stage Hospital

At the mid stage, hospitals are actively engaging in innovation rather than just exploring it. They already have some experience with pilots and collaborations, but the challenge shifts toward structuring innovation processes, integrating solutions into workflows, and ensuring sustainability. Hospitals at this level start to formalize their innovation management — moving from ad hoc pilots to coordinated projects that fit within broader clinical and organizational strategies. This is the phase where hospitals learn to run innovation systematically rather than experimentally. Processes, governance, and measurement become essential.

Key Milestones at This Stage

- Creation of a dedicated innovation office or digital health committee.
- Completion of 2–3 pilot projects with structured evaluation frameworks.
- Development of a clear process for onboarding startups/MedTech partners (legal, ethical, IT approval).
- First efforts to measure outcomes and cost-effectiveness of implemented pilots.
- Engagement with regional/national healthcare networks to share lessons.

These milestones show that the hospital is building internal capacity and becoming a reliable partner for startups.

Related Playbook Chapters

Go to: Chapter 3 – Strategic Goals of the Ecosystem

Go to: Chapter 4 – Mapping and Engaging Stakeholders

Go to: Chapter 8 – Bringing Stakeholders Together

Best Practice from the Field

Several hospitals have improved their innovation capacity by creating standardized pilot program frameworks with clear criteria for selection, ethics approval, and outcome measurement. This structured approach has been associated with higher pilot success rates, fewer administrative delays, and stronger trust with external partners.

Pitfalls to Avoid

- Fragmented communication channels – Pilots often fail because departments don’t coordinate.

Establish a central coordination team to streamline communication.

- Neglecting reimbursement pathways – Even promising pilots stall if there’s no financial model.

Engage payers early to discuss sustainability of digital solutions.

Level C: Late-Stage Hospital

Late-stage hospitals are leaders in digital health adoption. At this level, innovation is no longer a side activity but a strategic pillar of the hospital's identity. These hospitals act as regional or national reference centers, scaling validated pilots into routine care, co-developing solutions with MedTech partners, and influencing policy and reimbursement frameworks. The main challenge is to institutionalize innovation — making it sustainable, measurable, and replicable beyond individual departments or projects. The challenge at this stage is not to innovate, but to embed innovation into the organization so that it remains sustainable, measurable, and scalable.

Key Milestones at This Stage

- Establishment of an Innovation Hub / Living Lab within the hospital, attracting startups and MedTech.
- Scaling from pilot projects to routine adoption across multiple clinical units.
- Participation in international consortia and multicenter clinical trials.
- Demonstrated impact on patient outcomes, cost-effectiveness, and workforce efficiency.
- Ability to influence payers and regulators with evidence-based policy recommendations.

These milestones position the hospital as an anchor of the regional innovation ecosystem.

Related Playbook Chapters

Go to: Chapter 3: Strategic Goals of the Ecosystem

Go to: Chapter 8: Bringing Stakeholders Together

Go to: Chapter 9: Roadmap for Implementation

Best Practice from the Field

At large teaching hospitals, establishing a Hospital Innovation Hub can provide a structured testbed for startups. By standardizing evaluation metrics and involving payers, such hubs help integrate digital health solutions into routine care and develop models that can be replicated across other hospitals. This approach illustrates how structured innovation hubs can accelerate adoption, validate new health technologies in real clinical environments, and create scalable practices for broader healthcare systems.

Level A: Early-Stage MedTech

At the early stage, MedTech companies are in the conceptual or prototype phase, exploring how their technology can fit within healthcare. Their main challenge is to translate technical innovation into clinical value and demonstrate early feasibility. This requires close collaboration with clinicians, hospitals, and innovation hubs to ensure alignment with medical workflows, regulatory pathways, and market needs. Building trust and credibility is crucial at this level.

Key Milestones at This Stage

- Development of a functional prototype that demonstrates proof-of-concept.
- First clinical or user validation with healthcare professionals or small focus groups.
- Initial mapping of regulatory requirements (MDR/FDA classification).
- Securing a Letter of Intent (LOI) or preliminary collaboration agreement with a hospital.
- Beginning to explore intellectual property (IP) protection strategies.

Related Playbook Chapters

Go to: Chapter 2: Enabling Environment

Go to: Chapter 4: Mapping and Engaging Stakeholders

Go to: Annexes & Tools → Templates for evaluating

Best Practice from the Field

Leading MedTech organizations often establish innovation fast-track units with dedicated budgets and streamlined approval processes. These units allow project teams to bypass layers of bureaucracy and test the feasibility of solutions with hospitals in a matter of months. By combining the agility of a startup with the resources of an established company, such teams can accelerate go/no-go decisions, rapidly prototype and pilot new solutions, and expand collaborations with healthcare providers across regions.

Pitfalls to Avoid

- Over-bureaucratization – Corporate procedures can delay validation and decision-making.
- Create dedicated “fast-track” teams with autonomy for early projects.

Level B: Mid-Stage MedTech

At the mid stage, large MedTech companies have already secured internal approval and funding for a new project. The focus shifts from feasibility to clinical validation, market testing, and preparing for regulatory approval. This stage is critical for demonstrating real-world clinical benefits and health-economic value, which will determine whether the project can move forward into late-stage development and scaling.

Key Milestones at This Stage

- Execution of clinical pilots or multicenter feasibility studies.
- Generation of clinical evidence to support MDR/FDA pathways.
- Refinement of the business model and reimbursement strategy.
- Establishment of strategic partnerships with hospitals and payers.
- Internal preparation for manufacturing scale-up and compliance audits.
- Alignment of sales and distribution channels for market entry.

Related Playbook Chapters

Go to: Chapter 5: From Local to International

Go to: Chapter 6: Designing the Supporting Framework

Go to: Chapter 10: Conclusion & Recommendations

Best Practice from the Field

A mid-stage MedTech project leveraged structured clinical pilots to generate both clinical and health-economic evidence. By integrating feedback from multiple hospital sites and engaging payers early, the team was able to refine the solution, streamline regulatory submissions, and build a compelling case for broader adoption. This approach demonstrates how coordinated clinical validation and stakeholder engagement can accelerate regulatory approval and prepare the product for successful scaling across different markets.

Pitfalls to Avoid

- Regulatory missteps

Engage early with EMA/FDA and invest in regulatory expertise.

- Insufficient post-market evidence

Implement real-world evidence (RWE) programs and share outcomes.

- Global rollout without local adaptation

Tailor value propositions to each country’s health system and culture.

Level C: Late-Stage MedTech

At the late stage, large MedTech companies focus on full regulatory approval, market entry, and large-scale adoption. The project has moved past feasibility and clinical validation, and now the priority is to secure reimbursement, integrate into healthcare systems, and scale globally. At this level, credibility is high, but so are the stakes: global competition, complex regulatory pathways, and diverse healthcare markets demand careful strategy. Success depends on leveraging the company's global footprint while ensuring local adaptation to hospital workflows, payer systems, and cultural contexts.

Key Milestones at This Stage

- Execution of clinical pilots or multicenter feasibility studies.
- Generation of clinical evidence to support MDR/FDA pathways.
- Refinement of the business model and reimbursement strategy.
- Establishment of strategic partnerships with hospitals and payers.
- Internal preparation for manufacturing scale-up and compliance audits.
- Alignment of sales and distribution channels for market entry.

Related Playbook Chapters

Go to: Chapter 5: From Local to International

Go to: Chapter 9: Roadmap for Implementation

Go to: Chapter 8: Bringing Stakeholders Together

Best Practice from the Field

A late-stage MedTech project successfully leveraged multicenter clinical trials and early engagement with payers to secure both regulatory approval and reimbursement. By tailoring the solution to local hospital workflows and health system requirements while coordinating global rollout efforts, the team was able to achieve rapid adoption across multiple markets. This example demonstrates how integrating clinical validation, regulatory strategy, and local adaptation is critical for scaling health technologies internationally.

Pitfalls to Avoid

Avoid evidence gaps by conducting robust multicenter clinical trials and publishing results. Ensure reimbursement readiness by developing payer dossiers alongside clinical studies.

Level A: Early-Stage Innovation Hub

For early-stage innovation hubs, the priority is to establish credibility, build networks, and create the first structured support programs for startups and healthcare innovators. At this level, hubs are usually newly formed, with limited staff and resources, but strong ambition. Their main challenge is to attract both startups and external stakeholders (hospitals, MedTech companies, investors) while proving their own value in the ecosystem. The focus should be on ecosystem mapping, pilot activities, and partnerships, rather than large-scale programs. The hub's early wins will define its long-term positioning and reputation.

Key Milestones at This Stage

Rather than narrowing down to a single identity or sector focus (e.g., MedTech, digital health, biotech), which can be unsustainable over time, innovation programs should remain flexible and adaptive. Building cross-sectoral capacity allows hubs to adjust to emerging trends, diversify opportunities, and avoid dependence on one niche area.

Related Playbook Chapters

Go to: Chapter 2: Enabling Environment

Go to: Chapter 4: Mapping and Engaging Stakeholders

Go to: Chapter 7: Setting up an Ecosystem

Best Practice from the Field

Early-stage innovation hubs have successfully established credibility by focusing on small, well-structured pilot programs and building strong networks with startups, hospitals, and industry partners. By remaining flexible across sectors and aligning initial activities with real ecosystem needs—such as mentorship programs, workshops, and pitching events—these hubs demonstrated early value, attracted partners, and created a foundation for sustainable growth.

Pitfalls to Avoid

Avoid relying only on public grants by developing hybrid funding models, such as corporate sponsorships or paid services. Start with small, realistic pilot programs to deliver value without overpromising resources to startups.

Level B: Mid-Stage Innovation Hub

At the mid stage, innovation hubs move from initial credibility-building to consolidation and scaling. The hub is no longer "new," but it must prove that it can deliver consistent value to startups, hospitals, and MedTech partners. At this point, credibility depends on measurable results – number of startups supported, pilot projects launched, funding attracted, and partnerships built.

Key Milestones at This Stage

- Run structured acceleration/incubation programs (beyond ad-hoc events).
- Build a portfolio of validated startups with measurable outcomes (funding raised, pilots in hospitals).
- Strengthen hospital partnerships with active pilot projects or testbeds.
- Develop corporate engagement models for MedTech and pharma (e.g., open innovation challenges).
- Secure funding streams (mix of public grants, industry partnerships, service revenues).
- Expand visibility regionally or nationally through branding, publications, and thought leadership.

Related Playbook Chapters

Go to: Chapter 6: Designing the Supporting Framework

Go to: Chapter 7: Setting up an Ecosystem

Go to: Chapter 8: Bringing Stakeholders Together

Best Practice from the Field

Mid-stage innovation hubs have successfully scaled by running structured acceleration programs and building a portfolio of validated startups with measurable outcomes. By engaging hospitals through active pilot projects and collaborating with corporate partners via open innovation challenges, these hubs demonstrate consistent value to the ecosystem. Clear metrics, published impact reports, and regional visibility help strengthen credibility and attract further support.

Pitfalls to Avoid

Ensure hospitals are actively involved by formalizing clinical validation programs with clinician champions. Avoid over-reliance on public funding by building sustainable revenue models, such as corporate sponsorships or premium services. Maintain stakeholder trust by publishing clear KPIs and annual impact reports.

Level C: Late-Stage Innovation Hub

At this stage, the innovation hub is a recognized ecosystem leader with established credibility, proven results, and international partnerships. It manages structured, large-scale programs, attracts top-tier startups, and is integrated into both the hospital system and corporate MedTech pipelines. The hub's biggest challenge is sustaining leadership while continuously innovating. Mature hubs risk becoming bureaucratic, losing agility, or being outpaced by smaller, more flexible newcomers. To maintain their position, late-stage hubs must focus on global expansion, continuous renewal, and ecosystem thought leadership.

Key Milestones at This Stage

- Operate flagship accelerator/scale-up programs with international reach.
- Maintain a strong portfolio of success stories (startups that scaled globally, successful MedTech collaborations, impactful hospital pilots).
- Formalize strategic partnerships with large MedTech corporates and top hospitals.
- Develop international scouting and soft-landing programs for startups.
- Secure long-term financial sustainability through diversified income streams (corporates, equity funds, government partnerships).
- Position hub as a global thought leader in health innovation (policy influence, publishing playbooks, hosting global summits).

Related Playbook Chapters

Go to: Chapter 6: Designing the Supporting Framework

Go to: Chapter 9: Roadmap for Implementation

Go to: Chapter 10: Conclusion & Recommendations

Best Practice from the Field

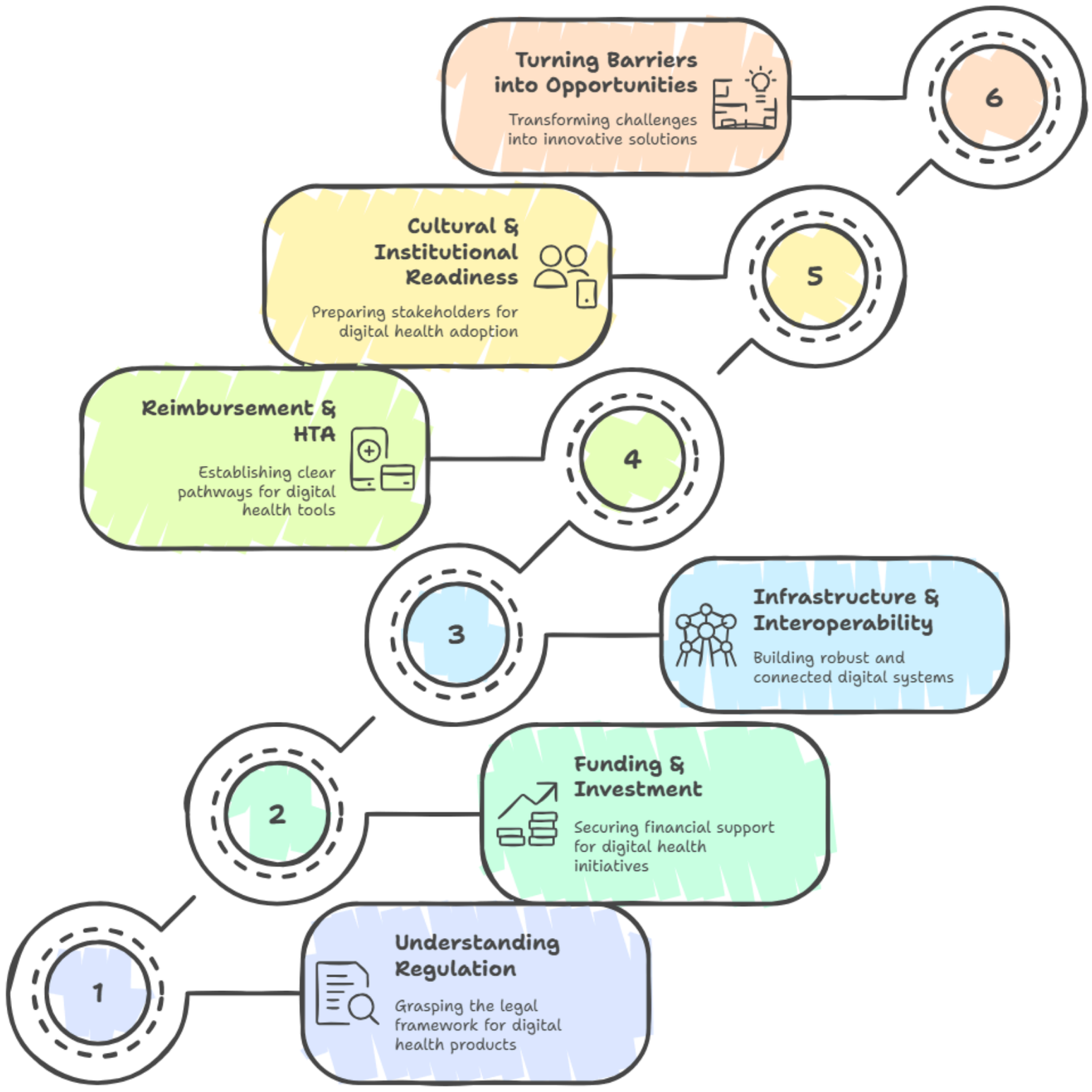
Late-stage innovation hubs maintain leadership by combining global reach with continuous renewal. They run flagship accelerator programs with international startups, build strategic partnerships with top hospitals. By publishing insights, sharing playbooks, and hosting global events, these hubs reinforce their thought leadership while staying agile and responsive to emerging trends.

Pitfalls to Avoid

Avoid complacency by continuously scanning for emerging trends and disruptive technologies. Reduce dependence on a few large partners by diversifying collaborations across corporates, hospitals, and payers. Expand beyond
regional reach through global partnerships and cross-continental programs.

CHAPTER II
Enabling environment for Digital Health Innovation

Entering digital health in Central and Eastern Europe (CEE) can feel complex due to varying infrastructure, regulatory requirements, and fragmented funding. Yet every barrier also creates an opportunity for innovators ready to collaborate with healthcare systems. This chapter provides orientation and first actionable steps for startups, hospitals, MedTech companies, and innovation hubs entering digital health in CEE. It helps especially hospitals and startups understand what they need to have in place before launching pilots, so that projects do not stall on regulation, IT capacity, or missing evidence

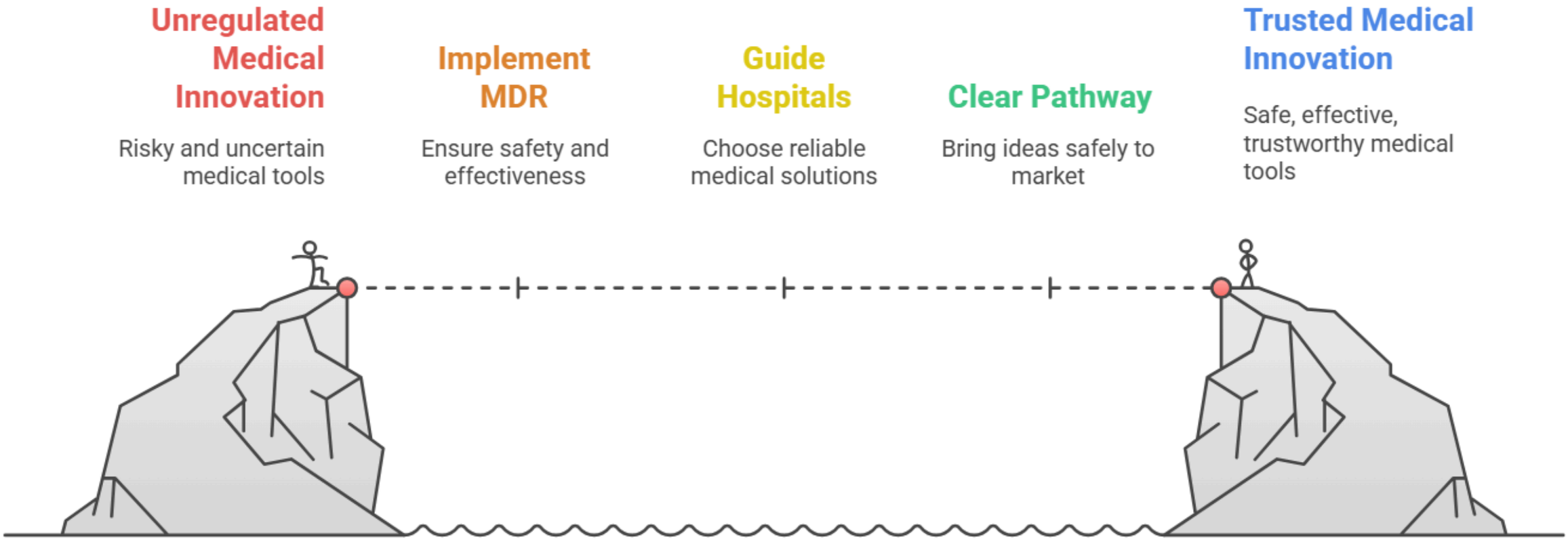


Why This Chapter Matters

The enabling environment shows newcomers the rules of the game. By understanding regulation, funding, infrastructure, reimbursement, and cultural factors, stakeholders can avoid wasted effort and start collaborating productively. For those at entry level (A), this chapter provides the orientation needed to take the first step into digital health innovation in CEE — with confidence and awareness of both risks and opportunities.

2.1 Regulation & Compliance — Getting the basics right

Almost every digital solution touching patient care must follow the EU Medical Device Regulation (MDR 2017/745) to ensure safety, performance, and clinical evaluation. This includes many digital tools such as mobile health apps, connected sensors, and AI-based software. CE marking should be planned early to avoid delays and rework.



At the same time, the European Health Data Space (EHDS) is being developed to allow citizens to securely access and share health data across EU countries. For hospitals, this enables smoother transfer of records, lab results, and imaging data. For startups and MedTech companies, EHDS provides standardized, interoperable data that can accelerate product development, support CE marking evidence, generate real-world clinical insights, and enable faster cross-border scaling—while maintaining compliance with strict privacy, security, and interoperability rules. In practice, this means that both hospitals and startups need at least a basic shared understanding of MDR and EHDS terminology before they start working together.

First steps for new stakeholders:

Check it out

Startups

Startups should prepare a simple readiness package covering regulatory, clinical, and technical basics, as unprepared teams slow pilots and increase risk.
It should include: intended purpose, MDR class, clinical approach, workflow fit, data needs, risks, and integration options.
Early preparation builds trust, speeds approvals, and avoids redesigns.

Hospitals

Understand MDR compliance when evaluating tools to avoid legal and reputational risks. Nominate at least one contact person (e.g. a digital lead or innovation officer) who can coordinate with startups on regulatory issues and liaise with the national competent authority where needed.

MedTechs

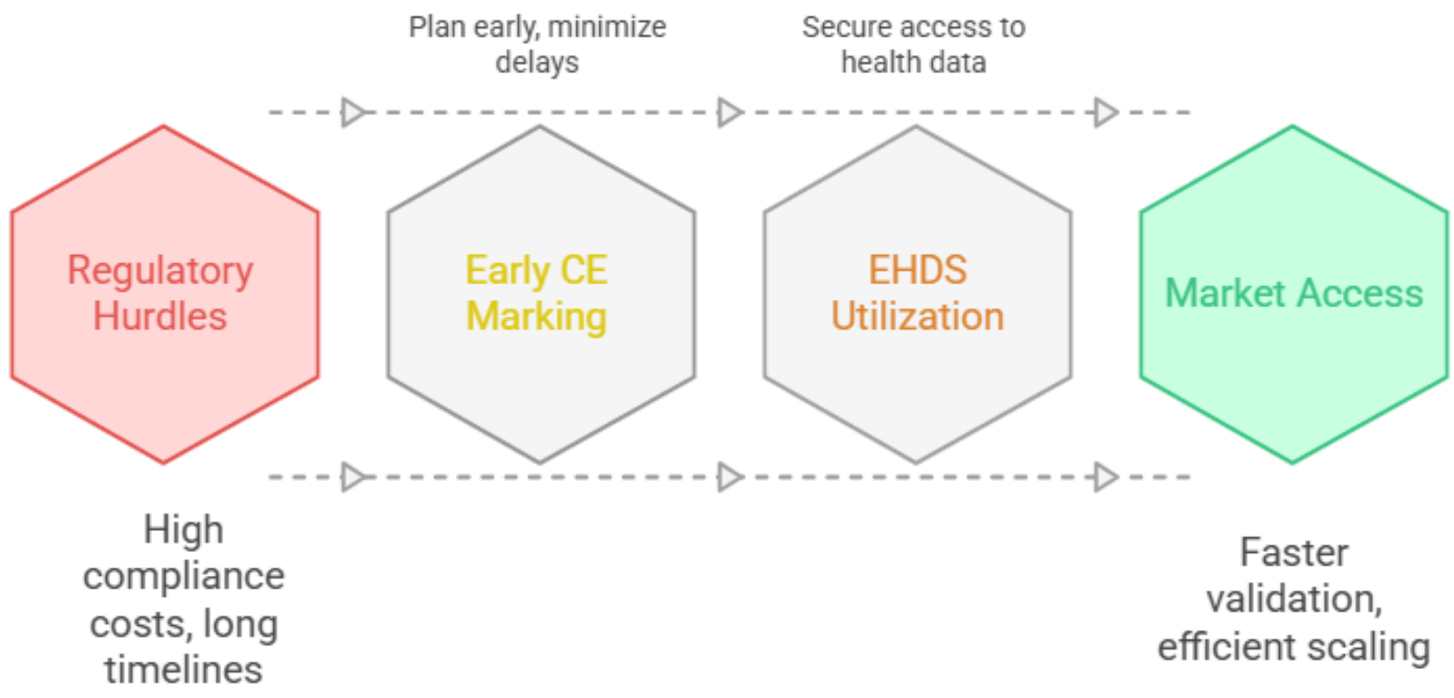
Identify your national regulatory authority and how its processes align or differ from EU-wide rules.

Innovation hubs

Offer educational sessions on MDR, CE marking, and EHDS so all ecosystem actors share the same baseline knowledge.

How MDR Implementation Affects Market Entry for Digital Health Startups in CEE?

The EU Medical Device Regulation (MDR, 2017/745) defines how medical devices—from simple bandages to apps, wearables, and AI tools—are classified, tested, and approved. For digital health innovators, even a mobile app that monitors health may require CE marking, certifying compliance with EU safety, health, and performance standards before marketing or patient use. MDR has increased the regulatory requirements for medical devices, creating longer approval timelines and higher compliance costs for startups compared to previous frameworks.



Startups entering CEE markets must navigate these regulatory requirements while considering national procedures for CE-marked devices. Even though the MDR is EU-wide, local authorities may differ in administrative processes, timelines, or guidance documents, which can influence how quickly a product can enter a specific market. Planning for CE marking early in the development process, including clinical evaluation and documentation, is essential to minimize delays and avoid costly rework.

Hospitals also need to understand that hosting a pilot with a non-compliant tool can expose them to legal and reputational risks; therefore, many will expect startups to have at least a clear MDR strategy before signing collaboration agreements.

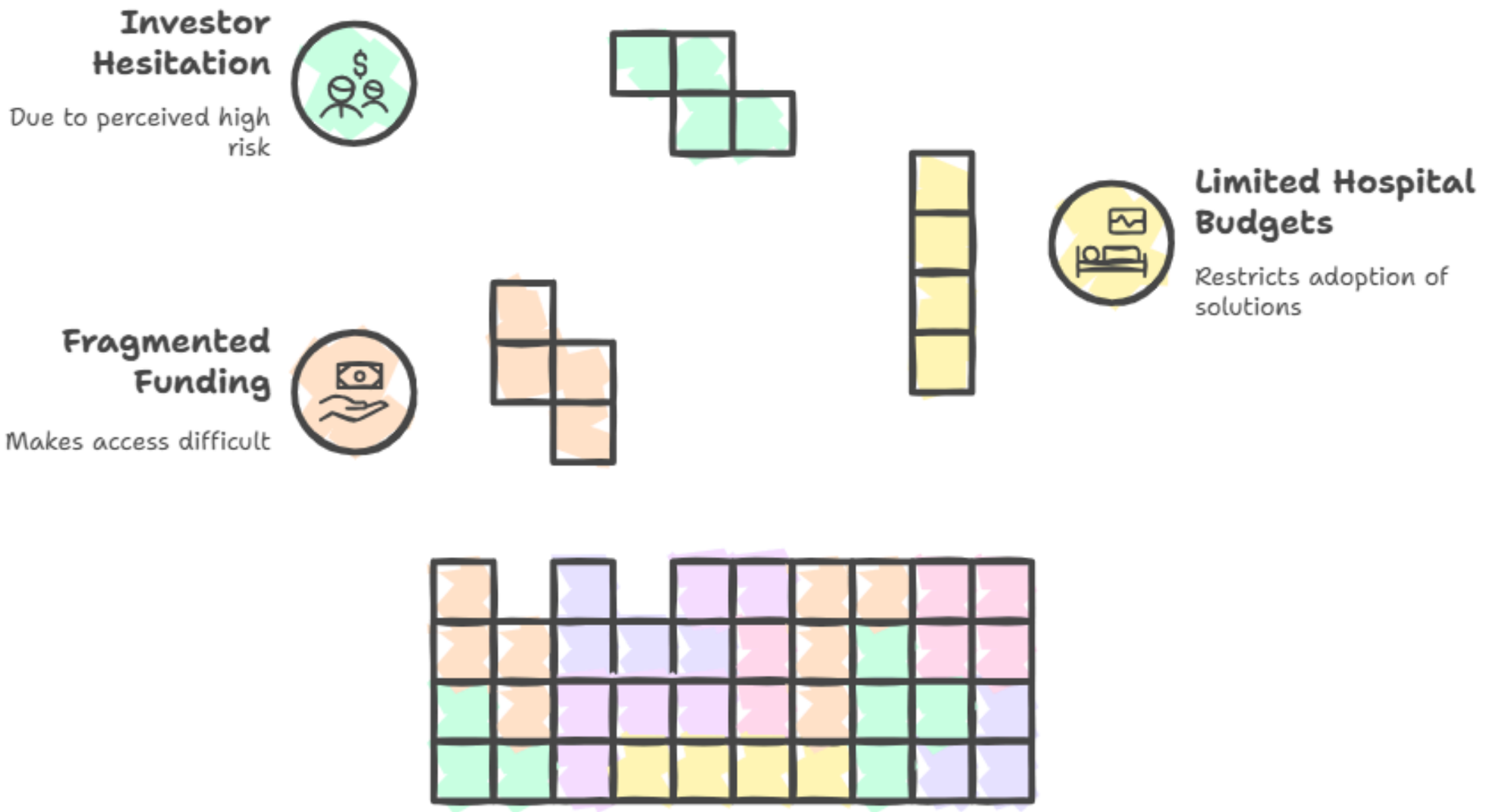
The European Health Data Space (EHDS) presents an additional opportunity for startups and MedTech companies. By enabling secure, cross-border access to standardized health data, EHDS allows innovators to generate real-world evidence, validate solutions in larger patient populations, and scale products across multiple countries more efficiently. Compliance with privacy, security, and interoperability requirements remains critical, but EHDS can accelerate both clinical validation and market expansion.

Key Takeaways for Startups:

- Map CE marking requirements early and integrate them into development and clinical evaluation plans.
- Understand local procedures for device registration and market access in each target CEE country.
- Leverage EHDS to collect standardized, interoperable data to support clinical validation and scaling.
- Prepare a concise regulatory briefing (2–3 pages) that you can share with hospitals
- and hubs to build trust and transparency around your MDR and EHDS strategy.

2.2 Funding & Investment: Starting Small but Strategic

Access to capital is one of the main barriers to digital health in CEE. While funding is available, it is often fragmented. Hospitals struggle with limited budgets, and investors may be hesitant because digital health is still considered high-risk. At the same time, EU-level programs like Horizon Europe, EU4Health, and Digital Europe provide grants that do not require giving up equity. These programs can help startups and hospitals run their first pilots, build credibility, and attract private investors later on.



Venture capital activity in the region is slowly growing, but usually concentrated in major hubs like Warsaw, Prague, or Budapest. Public–private partnerships and corporate innovation arms (for example, pharmaceutical companies or MedTech giants) are becoming more active and may co-finance pilots.

Startups

Apply for small grants or join accelerator programs to build
your first proof of concept including both envisaged medical impact as well as market access. When planning pilots with hospitals, include a realistic budget for staff time, integration, and evaluation to avoid assuming that hospitals can provide these resources for free.

Check it out

Hospitals

Explore whether EU or national schemes can help
co-finance pilot projects with innovators.
Appoint an internal project owner who can combine hospital resources with external grants and clearly communicate what the hospital can and cannot fund.

Check it out

MedTechs

Partner with startups to co-develop and test solutions using external funding.

Innovation hubs

Act as connectors, guiding applicants toward funding opportunities and
helping build consortia for EU proposals.

Funding Sources in CEE

EU Grants (Horizon Europe, EU4Health, Digital Europe)
These are non-dilutive funding programs at the European level. They support research, development, pilot projects, and scaling, while also providing prestige and visibility. Although competitive, winning such grants signals credibility to investors and partners. Beneficiaries include startups, hospitals, MedTech companies, and innovation hubs.

National Grants
Each CEE country has its own schemes, usually smaller in scale compared to EU grants but easier to access. They often require co-financing and are tailored to national priorities. These are particularly useful for startups and hospitals at the early stages of innovation.

Structural and Cohesion Funds
These EU regional funds are designed to support infrastructure and digitalization in member states. They are often used to finance hospital IT systems, electronic health records, or broader digital upgrades. Hospitals and innovation hubs are the main beneficiaries of these funds.

Venture Capital (VC)
Equity investment is available in CEE but tends to concentrate in hubs such as Warsaw, Prague, and Budapest. Venture capital comes with high expectations for rapid growth and scalability, making it most relevant for startups and MedTech companies looking to expand quickly.

Corporate Venture and Public–Private Partnerships (PPPs)
Pharmaceutical and MedTech corporations increasingly invest in or partner with startups and hospitals to co-develop solutions. These partnerships bring both funding and strategic expertise. Startups and MedTechs benefit most, gaining access to markets and credibility.

Accelerators and Incubators
These programs provide early-stage support through small grants, mentorship, training, and investor connections. They are designed to help startups develop their proof of concept while also strengthening the role of hubs in guiding innovators. Startups and innovation hubs are the key beneficiaries.

Hospital Budgets
Traditional hospital budgets are limited and rarely cover innovation fully. However, they can play a role in co-financing pilots, especially when combined with external grants. Hospitals are the primary beneficiaries, though startups and MedTechs also benefit indirectly through pilot projects.

2.3 Infrastructure & Interoperability: Building Connections

Not all hospitals in CEE are equally digitalized (European Commission, Digital Decade 2024: eHealth Indicator Study (July 2024)). Some have advanced electronic health records (EHRs), telemedicine platforms, or secure data exchange systems. Others still rely heavily on paper records or outdated IT solutions. This fragmentation slows down innovation, but it also creates opportunities for new actors to build bridges between disconnected systems.

The biggest challenge is interoperability — making sure different IT systems can "talk to each other." Without it, data is locked in silos, making it hard for clinicians, patients, and innovators to benefit from digital tools. EHDS aims to standardize this at the European level, but local adoption will take time.

First steps for new stakeholders:

Startups

Design flexible solutions with modular architecture so they can integrate with multiple hospital IT systems.

Hospitals

Map your current digital infrastructure to understand strengths and gaps in your digitalization journey.

EXAMPLE

A regional hospital in Poland conducts a digital audit of its infrastructure: it identifies that radiology is already digitized (PACS system), but lab results are still paper-based and EHR access is limited to certain departments. With this map, the hospital can prioritize which areas are "ready for pilots" and which need upgrading first before adopting digital health solutions.

MedTechs

Position yourself as an integration partner — don't just deliver a product, help it connect with existing systems.

Innovation hubs

Create "neutral zones" such as living labs where vendors, hospitals, and startups can experiment with interoperability, or mapping of hospital infrastructures to connect startups with environments already equipped for pilot implementation.

2.4 Reimbursement & HTA: Building the Case for Value

One of the most confusing parts of digital health in CEE is reimbursement — the way health systems pay for new technologies. Unlike drugs, which usually have clear reimbursement pathways, most digital tools don't. In practice, this means many pilots rely on temporary funding or out-of-pocket payments from patients.

A related concept is Health Technology Assessment (HTA). HTA is a process by which authorities (most importantly, payers) evaluate whether a new solution provides enough value — in terms of clinical benefit, cost-effectiveness, and safety — to justify reimbursement. In CEE, HTA systems are still evolving, but they are gaining importance. A well-known example abroad is Germany's DiGA fast-track, which allows digital therapeutics to be reimbursed within the national system if they prove safety and effectiveness.

First steps for new stakeholders:

Startups

Start collecting data early, even from small pilots. Evidence of cost savings and better patient outcomes is powerful.

Hospitals

Document the impact of pilot projects — this data can support reimbursement discussions with payers.

MedTechs

Learn how to prepare dossiers that speak not only to regulators but also to payers.

Innovation hubs

Share international good practices like DiGA to inspire local policymakers and partners.

What is DiGA?

DiGA stands for Digitale Gesundheitsanwendungen, or digital health applications, and refers to a special category of apps and software-based medical devices in Germany. These are low-risk medical devices (Class I or IIa under MDR) that patients can use independently — for example, apps for managing diabetes, supporting mental health, or tracking chronic conditions. What makes DiGA unique is the "fast-track" pathway: once approved by the German Federal Institute for Drugs and Medical Devices (BfArM), a DiGA can be prescribed by doctors and reimbursed by statutory health insurance. To qualify, companies must prove that their app is safe, protects patient data, and shows a positive healthcare effect, such as improving outcomes or making care more efficient. DiGA has become a model for how reimbursement of digital health tools could work across Europe, inspiring discussions in many CEE countries.

What is earlyHTA?

Early HTA (early Health Technology Assessment, eHTA) is a structured process for evaluating a health technology—such as a medical device, digital health solution, or pharmaceutical product—at an early stage of its development, before market entry. Unlike traditional HTA, which is conducted after regulatory approval and is mainly used to inform reimbursement decisions, eHTA serves a different purpose and is applied during the development phase. Its main role is to support strategic and operational decision-making, including:

- assessing the level of innovation,
- making go/no-go decisions,
- selecting target indications and patient groups,
- prioritizing market segments and payment models,
- supporting strategic pricing of the investigational technology.

This approach has been part of the development processes of innovative pharmaceutical companies for decades (Bodrogi and Kaló, 2010). eHTA integrates clinical, economic, and organizational perspectives to answer key questions such as:

- Does the technology address an unmet clinical need?
- What type of clinical evidence will be required to demonstrate its value?
- Is the technology likely to be cost-effective compared to existing solutions?
- Which healthcare systems or markets are most likely to adopt and reimburse it?

By applying early HTA, startups and MedTech companies can reduce development and investment risks, avoid pursuing products that may later fail reimbursement, and design studies that generate the right type of evidence from the outset. For hospitals and policymakers, eHTA helps identify promising innovations that are worth piloting and supporting.

EXAMPLE

In practice: early HTA often includes literature reviews, expert interviews, economic modeling, and scenario analysis.

Before launching a new AI imaging tool, a company might use early HTA to compare its expected costs and benefits against standard radiology workflows, helping shape both its product design and market-entry strategy.

In practice, eHTA typically includes:

- literature reviews,
- expert interviews,
- early economic modeling,
- scenario and sensitivity analyses.

For example, before launching a new AI-based imaging tool, a company might use eHTA to compare its expected costs and benefits against standard radiology workflows, helping to shape both product design and market-entry strategy.

Practical guidance through case studies

A practical understanding of eHTA can be gained by reviewing the case studies conducted within this project:

- UCare – a hospital SaaS platform for detecting Acute Kidney Injury using AI-powered prediction.
- VR Vitalis – a hospital SaaS platform using Virtual Reality for post-stroke rehabilitation.

Early HTA therefore functions not only as an evaluation tool, but as a strategic compass that guides innovation toward clinical relevance, economic viability, and real-world adoption.

Early HTA should be understood not as a one-time analysis, but as a continuous and iterative process that evolves together with the technology. As the innovation matures, assumptions made in the early phases can be refined, validated, or corrected. This makes eHTA a dynamic decision-support tool rather than a static report. Each iteration brings the technology closer to a solution that is not only clinically meaningful, but also economically viable and organizationally feasible.

From an innovation management perspective, eHTA helps align scientific ambition with real-world constraints. Many promising technologies fail not because they are ineffective, but because they do not fit existing reimbursement pathways, exceed available budgets, disrupt clinical workflows too strongly, or lack a clear value proposition for decision-makers. Early HTA allows these barriers to be identified when changes are still possible and relatively inexpensive.

Importantly, eHTA forces innovators to shift their thinking from “Does my technology work?” to “Does my technology create value in a healthcare system?” This includes value for:

- patients (better outcomes, safety, quality of life),
- clinicians (efficiency, usability, workflow integration),
- hospitals (cost containment, performance indicators, capacity management),
- payers (cost-effectiveness, budget impact, long-term savings),
- policymakers (public health impact, equity, scalability).

This systemic perspective is what differentiates eHTA from purely technical or clinical feasibility studies.

The eHTA exercises performed for these innovations generated several important lessons that can guide future assessments and be shared with the broader innovation community:

1. Gradual and structured approach is essential
2. A step-by-step process is needed:
   - initial training,
   - structured discussions with innovators based on standardized questionnaires (scoping reviews),
   - translation of results into a structured health economic model (e.g., Excel-based).
3. Future improvements could include:
   - recruiting a larger pool of startups,
   - grouping them by Technology Readiness Levels (TRLs),
   - tailoring evaluation questions to each TRL group.
4. Training is critical
5. More extensive initial training significantly improves results. Key concepts and terminology must be clearly understood and consistently used by all stakeholders.
6. Dual validation: clinical and market
7. Validation should be both:
   - clinical – confirming medical relevance and effectiveness, and
   - market-based – assessing real willingness and ability to pay.
8. In healthcare, “market demand” means not only interest, but also:
   - existence of a payer,
   - affordability within healthcare budgets,
   - the value of the technology exceeding its price,
   - feasibility of integration into clinical workflows.
9. Timing is critical
10. Timely recruitment, early discussions, rapid feedback, and multiple iterations with innovators strongly improve outcomes and the overall quality of the assessment.

Early HTA therefore functions not only as an evaluation tool, but as a strategic compass that guides innovation toward clinical relevance, economic viability, and real-world adoption.

Early HTA is closely linked to business model development. It supports:

- defining the customer (hospital, payer, insurer, patient, public authority),
- selecting the most realistic payment mechanism (DRG add-on, subscription, licensing, bundled payment, value-based contract),
- testing price sensitivity,
- estimating budget impact for different stakeholders.

This allows innovators to move beyond abstract pricing strategies and toward pricing that is anchored in real healthcare economics. In this way, eHTA becomes a bridge between innovation, market access, and financial sustainability.

2.5 Cultural & Institutional Readiness: Building Trust

Technology alone cannot transform healthcare. Adoption depends on mindset, trust, and readiness. In many CEE countries, clinicians remain cautious about digital tools. Their concerns are often linked to workload, legal liability, or fear of losing direct patient contact. Patients, however, especially after the COVID-19 pandemic, are increasingly open to digital consultations and monitoring. (Nature)

Institutional readiness also varies. Some hospitals are creating innovation offices or appointing “digital champions” to lead transformation. Others remain resistant, focusing on short-term pressures rather than long-term innovation.

First steps for new stakeholders:

Startups

Spend time with clinicians. Understand their pain points before suggesting solutions. This builds trust.

Hospitals

Nominate a digital champion — a doctor, nurse, or manager who can advocate for innovation internally.

MedTechs

Offer training and ongoing support alongside technology. This reduces fear and increases adoption.

Innovation hubs

Organize multi-stakeholder workshops where patients, clinicians, and innovators can openly exchange views.

2.6 Turning Barriers into Opportunities

The barriers of CEE's health systems may seem daunting, but each one also creates opportunities. Lack of reimbursement opens space for direct-to-consumer models or pilots financed by insurers. Fragmented IT systems create demand for integration platforms. Skepticism from clinicians can be overcome through co-creation and training, while small hospital budgets encourage the adoption of value-based healthcare models where payments are tied to patient outcomes.

First steps for new stakeholders:

Startups

Use agility to your advantage. Focus on niches where large players may struggle to adapt.

Hospitals

Turn barriers into arguments for joining EU- or grant-funded projects that cover innovation costs.

MedTechs

Adapt global solutions to local gaps. CEE-specific tailoring can be a strong competitive advantage.

Innovation hubs

Treat every barrier as a chance to connect needs with innovators and attract support from EU initiatives.

The real opportunities in overcoming barriers lie not only in technology but in people and the networks they create. Collaboration, trust, and shared learning are what turn challenges into progress (JMIR).

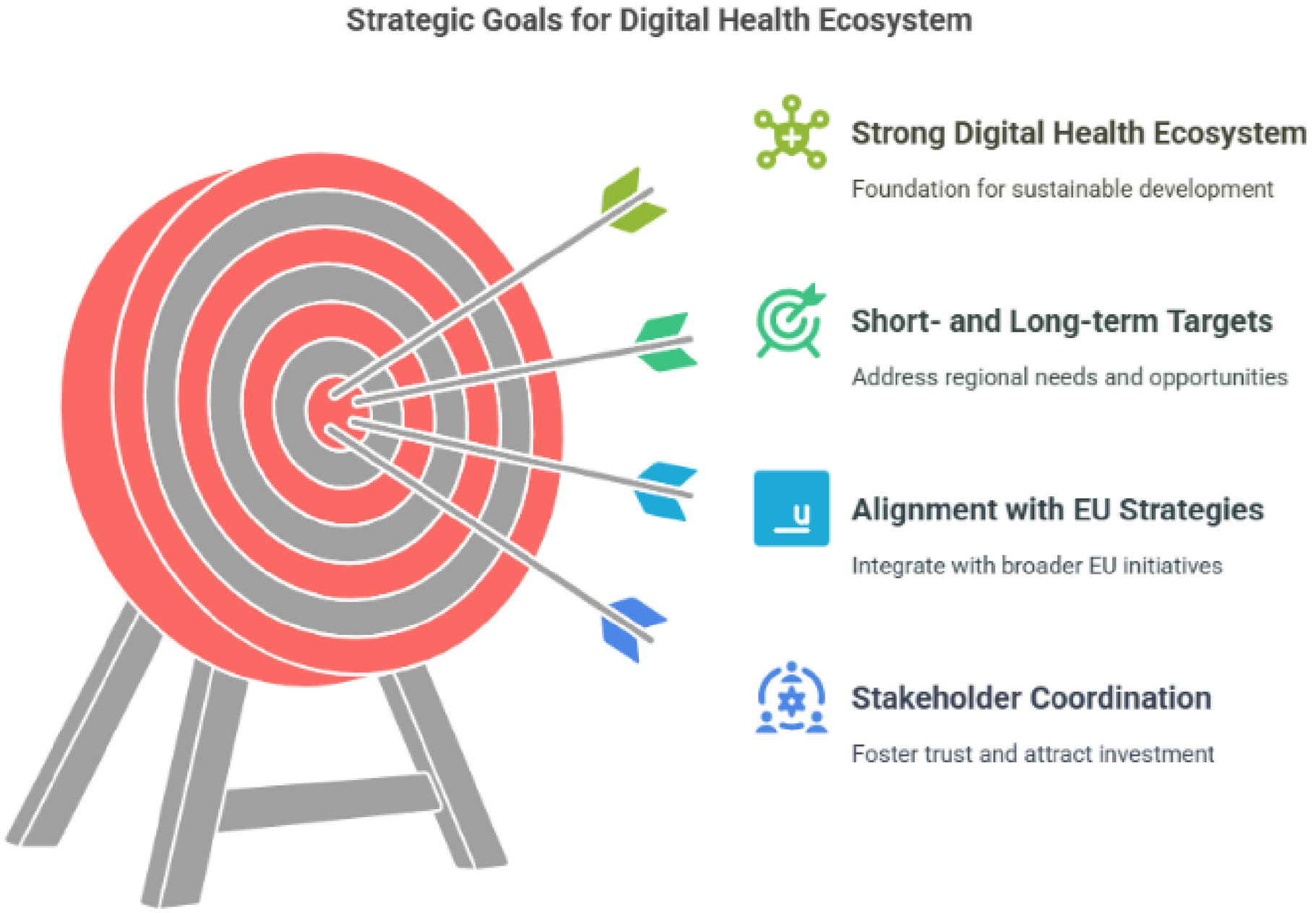
Initiatives such as the EIT Health Innovators Community provide an excellent starting point, offering a platform where startups, hospitals, MedTech companies, and innovation hubs can connect, share experiences, and co-create solutions tailored to the realities of CEE health systems.

By engaging in such communities, stakeholders gain access to mentorship, funding pathways, and international best practices — turning local obstacles into collective opportunities for growth.

Check it out

CHAPTER III
Strategic goals of the ecosystem

Transforming healthcare in Central and Eastern Europe (CEE) is not only about introducing new digital tools but also about ensuring that these innovations serve the long-term goals of the health system. Hospitals and policymakers are increasingly focused on reforms that improve outcomes, control costs, and make healthcare more sustainable. For innovators, this means success is measured not just by launching a pilot but by demonstrating how solutions align with system transformation, sustainability principles, and value-based healthcare models. This chapter provides a roadmap for understanding how digital health fits into broader strategies at both EU and national levels, and how stakeholders can design their efforts with the future in mind.

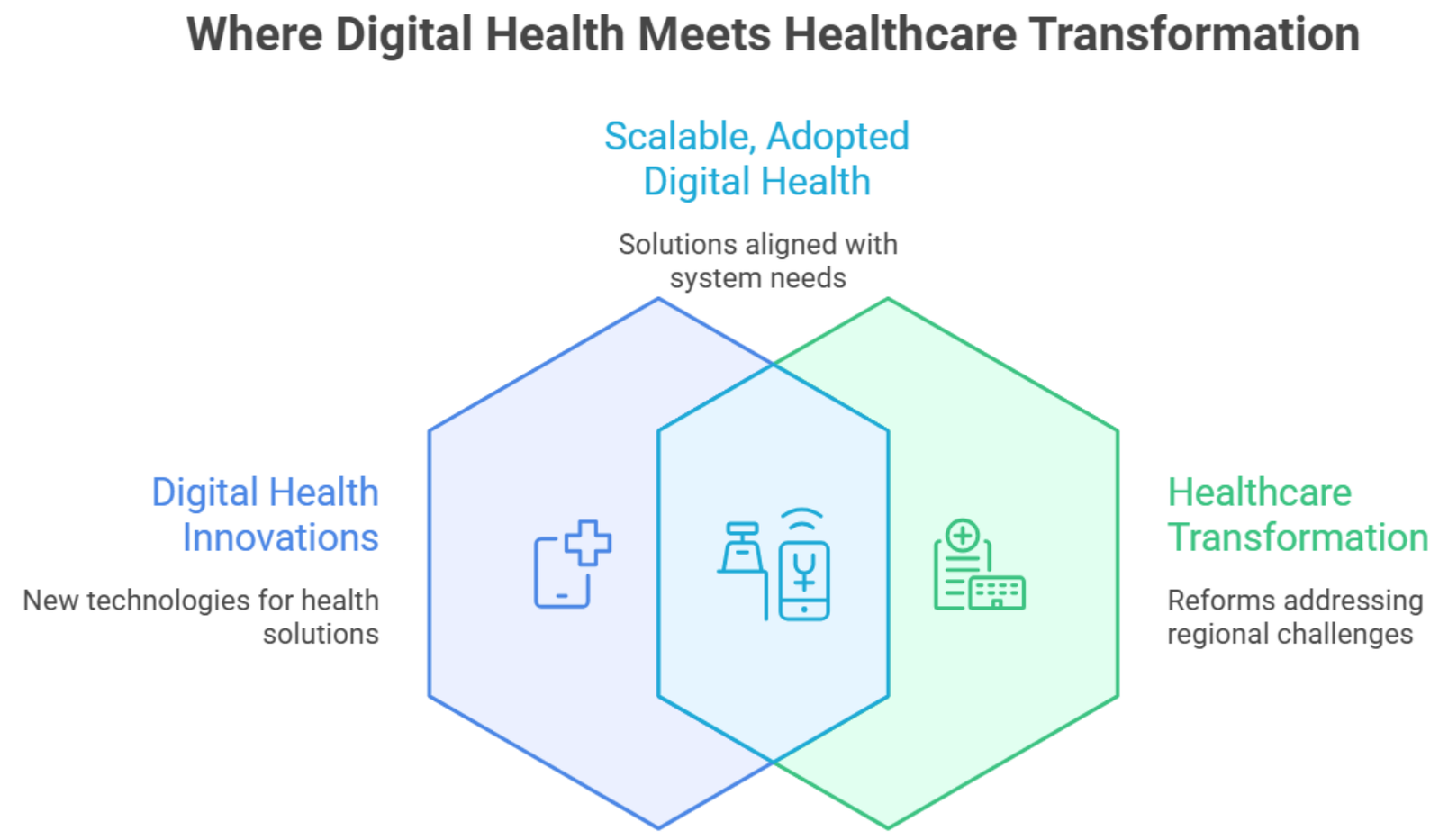


Why This Chapter Matters

The strategic goals of the ecosystem help stakeholders see the bigger picture.
By aligning with health system transformation, sustainability, value-based healthcare, and EU/national strategies, hospitals, MedTech companies, and innovation hubs can ensure that pilots do not remain isolated experiments but grow into lasting change. For stakeholders at more advanced levels (B and C), this chapter offers the orientation needed to connect innovation with long-term priorities, measure impact, and secure policy and funding support for scaling across CEE.

3.1 Aligning Innovation with Health System Transformation

Digital health innovations only succeed when they are connected to the bigger picture of healthcare transformation. In CEE, health systems are under pressure from aging populations, chronic disease burdens, and resource shortages. Policymakers are pushing for integrated care models, digitalization strategies, and prevention-focused health services. Innovations that directly support these reforms — for example, tools that reduce hospital overcrowding or enable chronic disease management at home — stand a better chance of being adopted and scaled.



Hospitals

Identify how potential pilots can align with ongoing reforms in your national health system.

- [ ] Does this pilot directly support a current national reform priority (e.g., digitalization, chronic disease management, cancer strategy)?
- [ ] Will it integrate with existing national infrastructure (e.g., e-prescription, national EHR, EHDS)?
- [ ] Could the results of this pilot be scaled to other hospitals in the region/country?
- [ ] Have we involved policymakers or payers early to ensure alignment?
- [ ] Do we have a plan to share outcomes with health authorities to influence policy?

MedTechs

Frame solutions in terms of system-level benefits (e.g., reducing hospitalizations, supporting prevention).

- [ ] Can we clearly state how our solution will reduce hospitalizations, complications, or costs?
- [ ] Do we have data (or a plan to collect it) showing clinical effectiveness and cost-effectiveness?
- [ ] Can we frame our product in terms of prevention or long-term system savings?
- [ ] Does our solution support value-based healthcare models (measured by patient outcomes)?
- [ ] Have we translated product features into policy-relevant language (e.g., fewer readmissions, improved continuity of care)?

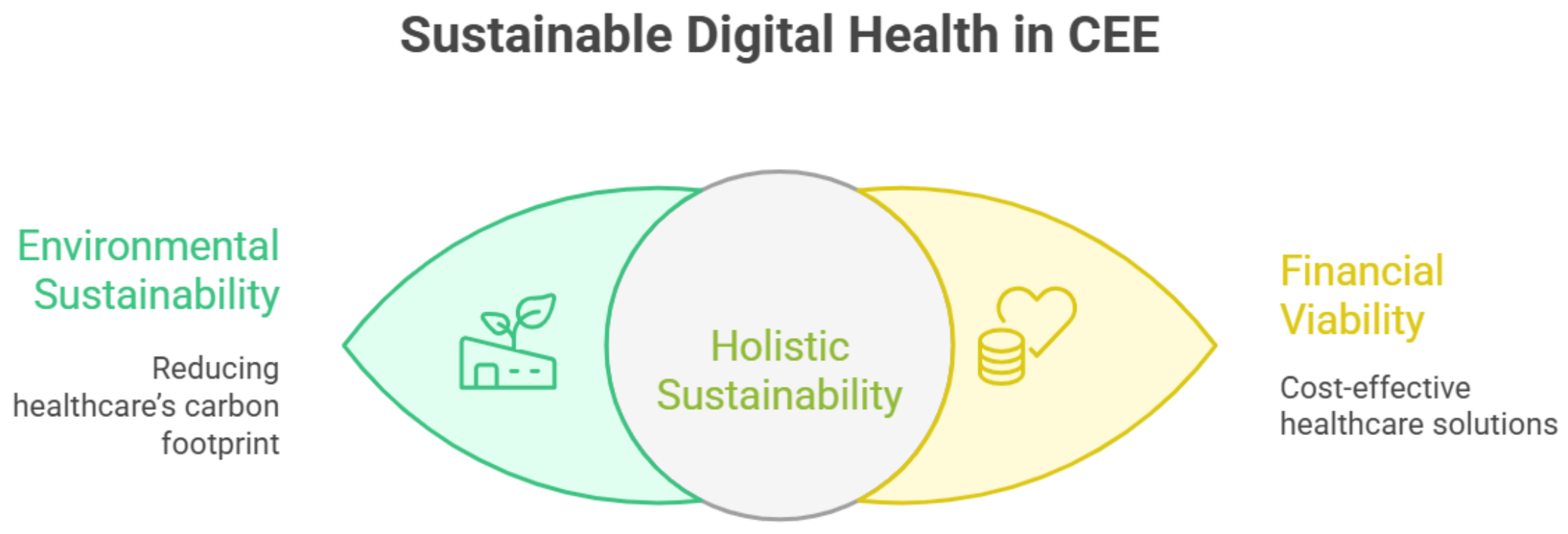
Innovation hubs

Encourage innovators to design with systemic challenges in mind, not just isolated problems.

- [ ] Are startups designing solutions that tackle specific problems while remaining aligned with broader systemic challenges?
- [ ] Have we provided training on national health system priorities and financing flows?
- [ ] Do our calls for innovation reflect pressing reform needs (e.g., reducing waiting times, improving chronic care)?
- [ ] Are pilots designed with multi-stakeholder input (patients, clinicians, payers, policymakers)?
- [ ] Do we help innovators map their solution onto a system-level pathway (clinical, financial, regulatory)?

3.2 Sustainability & Green Health Principles

Healthcare systems in CEE must deal not only with rising costs but also with increasing pressure to reduce their environmental footprint. Digital health can directly support both goals. For example, telemedicine reduces the need for patients to travel to hospitals, cutting transport emissions and easing the strain on outpatient departments. Remote monitoring tools allow earlier detection of complications, preventing costly hospitalizations. Digital workflows (e.g., electronic prescriptions, digital referrals, automated patient flow systems) can reduce paper use, optimize staff time, and make resource allocation more efficient.



But sustainability is not only ecological. It is also about financial viability.
A solution is not sustainable if it adds costs without bringing measurable savings or efficiency gains. Hospitals and payers increasingly expect digital innovations to prove long-term cost-effectiveness, whether through fewer admissions, shorter hospital stays, or better management of chronic diseases. At the EU level, "Green Health" principles are becoming part of funding and policy frameworks — tying innovation to climate neutrality and efficiency goals.

Hospitals

When considering a pilot, check not only clinical outcomes but also whether it reduces waste, energy use, or costs. For example, does a telehealth system cut the number of unnecessary patient trips, or does a digital scheduling tool reduce missed appointments?

MedTechs

Design products that are energy-efficient, use recyclable materials, or optimize clinical workflows. For example, a connected medical device could be built with low-power chips and packaging that reduces plastic waste. At the same time, highlight how the product reduces healthcare spending over the long term.

Innovation hubs

Add sustainability criteria into startup selection and mentoring. This could mean asking: Does the solution save resources? Does it lower emissions? Does it reduce costs? Startups that can answer "yes" to all three questions will be stronger candidates for EU support and international scaling.

For MedTech C (high experience)

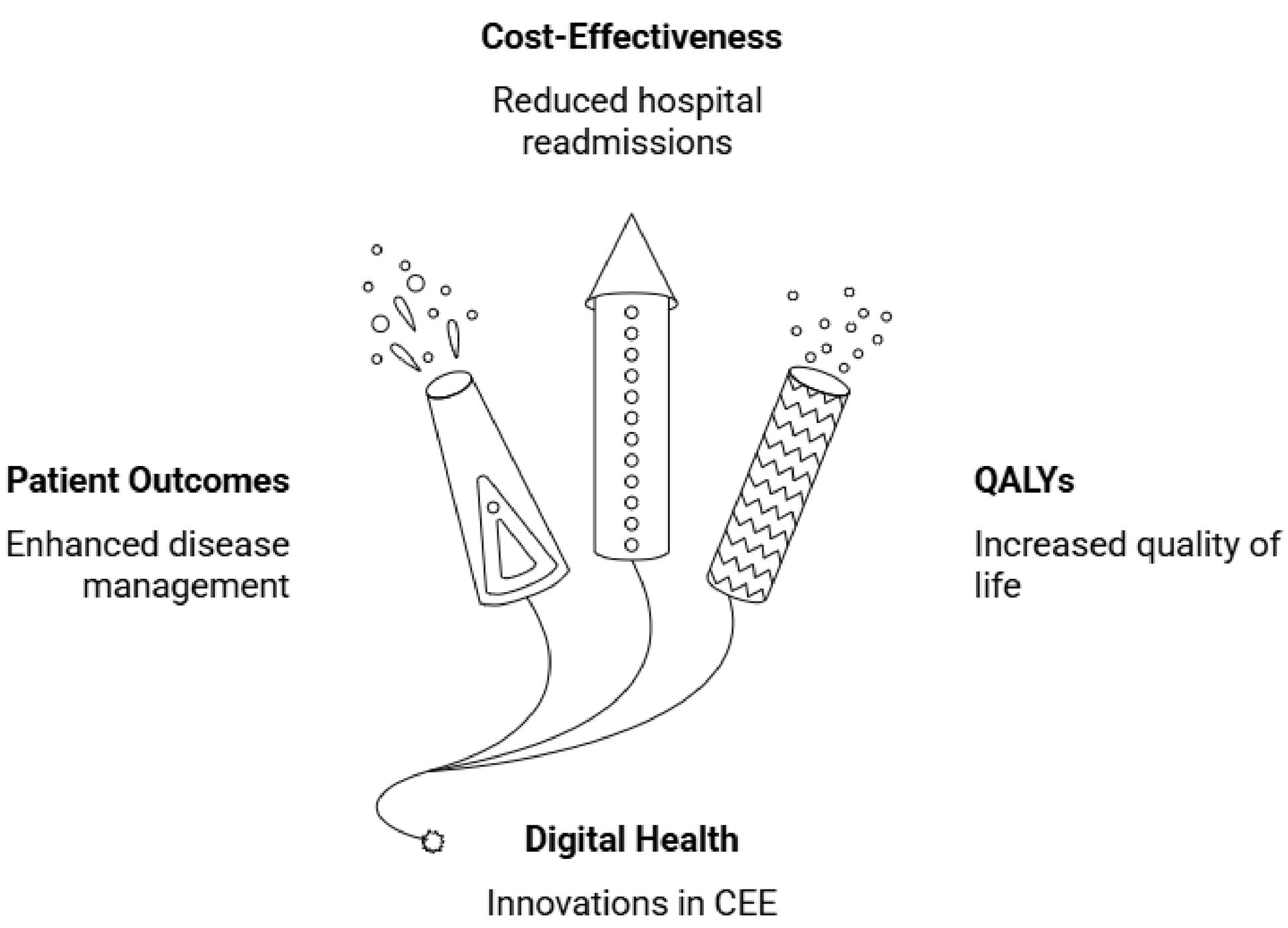
Build value dossiers that go beyond regulatory compliance, including robust health economics models, cost–benefit analyses, and system-level impact projections.

Partner with hospitals to co-design outcome-based contracts (e.g., risk-sharing models where payment is tied to avoided complications or reduced admissions).

Position products in line with EU-wide VBHC initiatives (such as EHDS, Europe's Beating Cancer Plan) to access reimbursement and scaling opportunities.

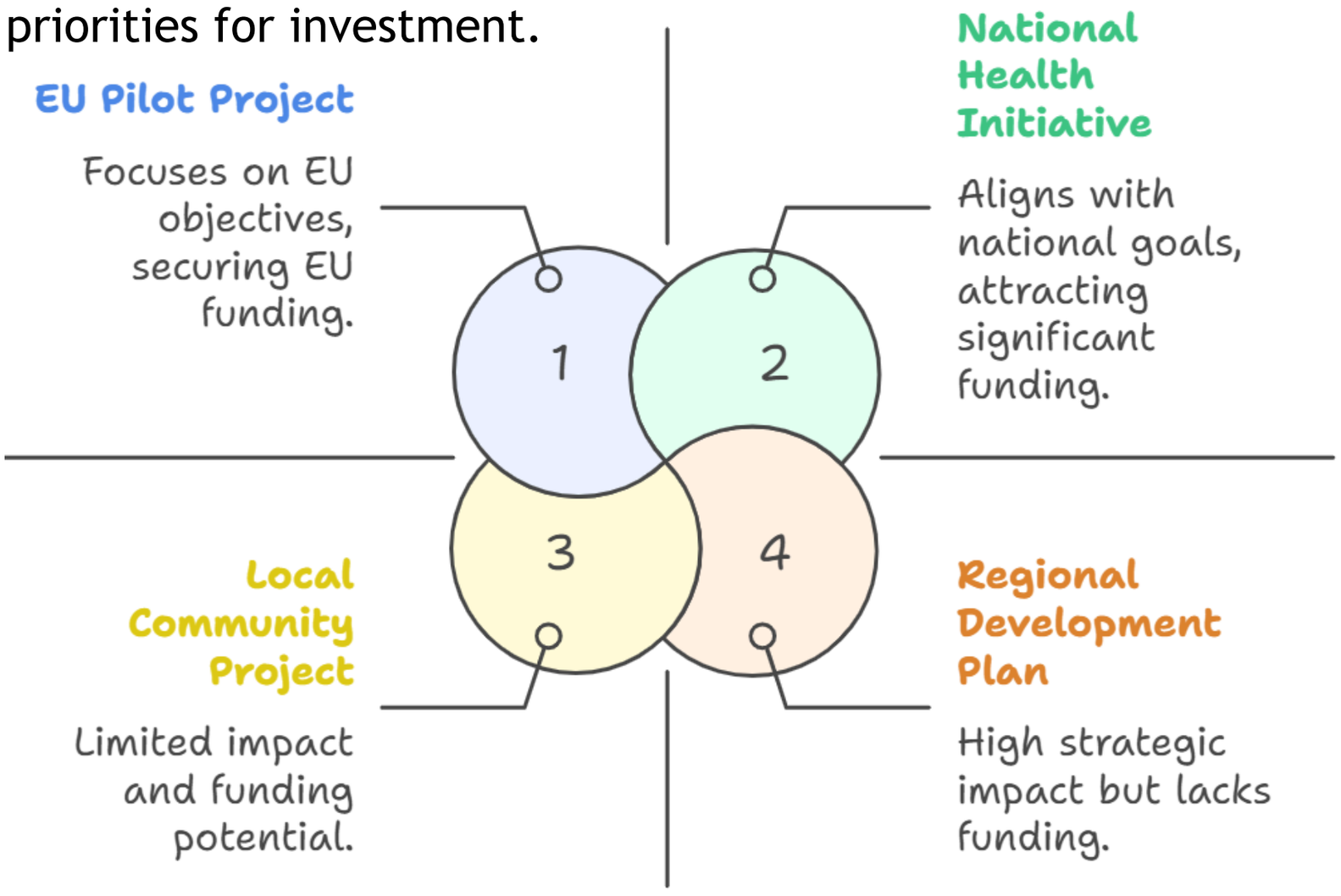
Example: A MedTech company offers a pay-for-performance model for its AI diagnostic tool: insurers pay only when the tool demonstrably reduces unnecessary imaging.

At this stage of maturity, stakeholders are no longer limited to running pilots — they are shaping the future of healthcare. By embedding VBHC into everyday practice, they unlock real improvements for patients, prove the value of innovation to payers, and set new standards for efficiency. Their influence goes beyond hospital walls, driving new reimbursement models and informing national and EU policy. This is where digital health becomes more than experimentation — it becomes lasting transformation with measurable impact.



3.4 EU & National Strategic Alignment

For digital health projects to succeed, they must connect to the broader reform agendas that guide healthcare in Europe and in each CEE country. At the EU level, this means contributing to flagship initiatives such as Europe's Beating Cancer Plan or Horizon Europe health missions, which focus on prevention, early detection, and system resilience. At the national level, most CEE countries have digital health roadmaps, oncology strategies, and chronic disease programs that set clear priorities for investment.



Projects framed as advancing these agendas are not just seen as isolated pilots, but as strategic tools for achieving national and EU goals. This framing makes them more likely to secure funding, attract decision-maker support, and remain relevant beyond the pilot stage.

While alignment with EU and national strategies is essential for sustainability and funding, local community projects also offer unique advantages. Their proximity to patients and healthcare providers allows faster implementation, better access, and stronger user engagement, making them valuable testing grounds for scalable digital health innovations.

For Hospital B (mid experience)

Start systematically linking pilots to national reform strategies. Use a simple framework that shows which initiative (oncology, chronic disease, prevention) each pilot contributes to.

Share this mapping internally to guide which projects should move from pilot to full adoption.

Example: A hospital's tele-diabetes project is positioned as supporting the national diabetes program, helping justify expansion funding.

For Hospital C (high experience):

Institutionalize policy alignment by integrating it into procurement and investment reviews — every innovation should be assessed on how it contributes to long-term strategies.

Build or join multi-hospital alliances that apply jointly for EU or national funding tied to cancer, chronic care, or sustainability programs.

Take an agenda-setting role by presenting outcome data to ministries and EU committees, shaping how new funding calls and reforms are designed.

Example: A hospital consortium publishes outcome data from digital oncology pilots, using it to influence the direction of the national cancer plan.

For MedTech C (high experience)

Explicitly align market-entry strategies with policy frameworks such as Europe's Beating Cancer Plan, sustainability targets, or national digitalization agendas

Build policy-ready dossiers that go beyond clinical performance, highlighting contributions to cost reduction, prevention, or strategic health goals.

Collaborate with leading hospitals on pilots that generate evidence tailored for policymakers and payers, making adoption easier.

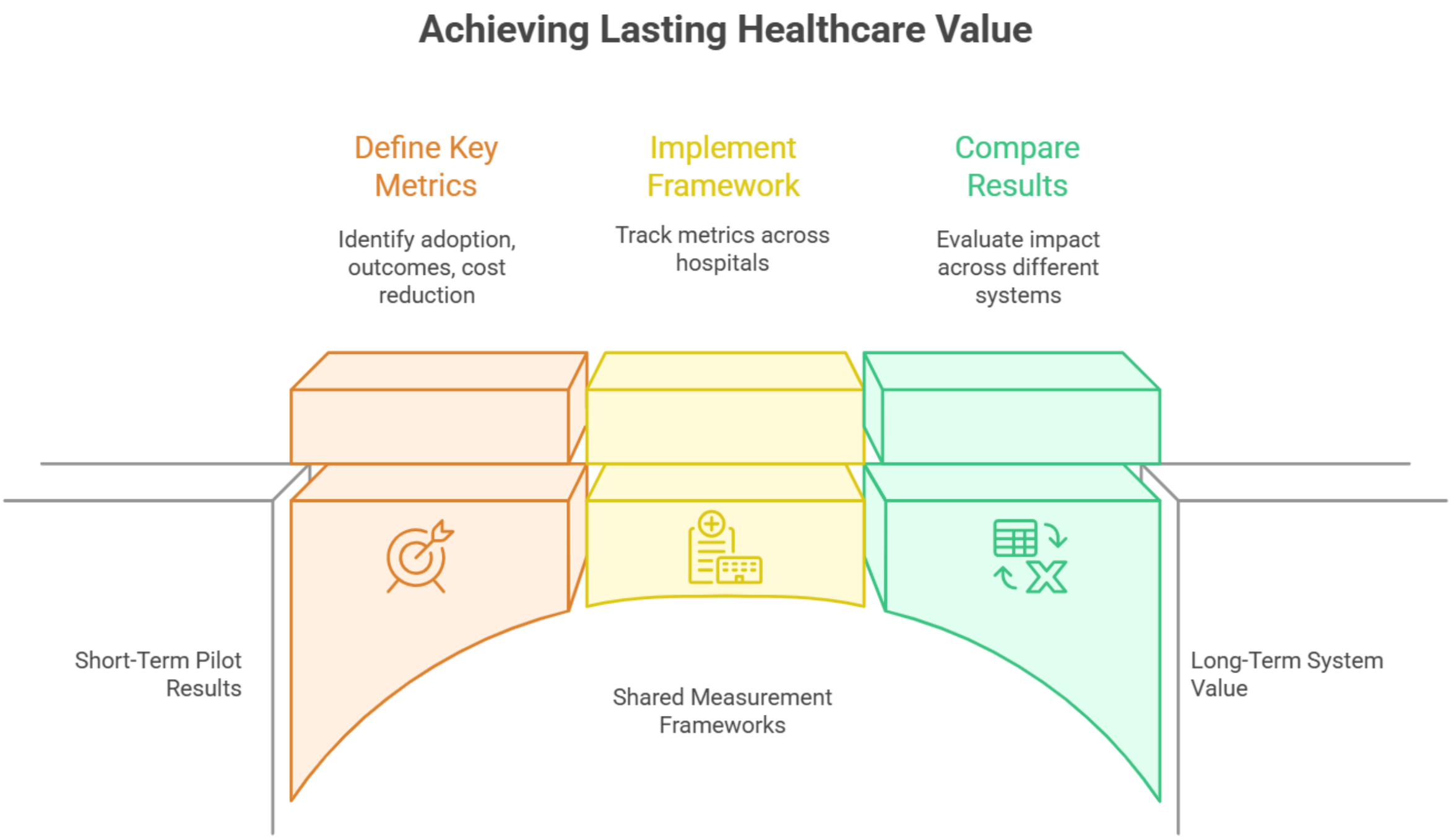
Example: A MedTech company launches a digital pathology platform framed as reducing diagnostic delays, directly supporting the objectives of Europe's Beating Cancer Plan.

For advanced hospitals and MedTechs, success depends not only on clinical outcomes but on the ability to demonstrate how innovations advance strategic health priorities. At this level, projects stop being pilots and become recognized as building blocks of system transformation.

3.5 Long-Term Metrics for Success

Short-term pilot results — like smoother workflows or satisfied clinicians — are important, but they don't prove whether a solution will last, scale, and deliver value to the health system. What really matters are long-term metrics: how widely a solution is adopted, whether patient outcomes improve, if it reduces costs over time, and whether it becomes part of standard care pathways. Increasingly, decision-makers expect evidence of impact that can be compared across hospitals and even across countries.

By building and using shared frameworks for measuring success, hospitals and MedTechs can show not just that their solution works locally, but that it is relevant for the entire health system.



For Hospital B (mid experience)

Go beyond reporting pilot outputs and start tracking longitudinal data, such as 12-month readmission rates, patient adherence, or follow-up visits.

Introduce patient-reported outcome measures (PROMs) to capture how patients experience improvements in quality of life.

Compare current results with baseline data from before the pilot to show real-world impact over time.

Example: A hospital tests a tele-cardiology program and tracks 12-month readmissions, showing a 15% reduction compared to pre-pilot levels.

For Hospital C (high experience)

Standardize measurement across departments and affiliated hospitals, creating a VBHC-aligned dashboard that tracks costs, outcomes, and adoption rates.

Incorporate national and EU-level metrics (e.g., cancer survival rates, chronic disease management indicators) to align with policymakers' expectations.

Use aggregated evidence to influence reimbursement negotiations and support scaling into national care pathways.

Example: A leading oncology hospital integrates digital pathology into its standard workflow, monitors 5-year survival and cost per patient, and uses the results to shape the national oncology reimbursement scheme.

Indicator Category	Example Metrics	Why It Matters	Stakeholders Most Concerned	Standardization Approach
Patient Outcomes	5-year survival rate, hospital readmission rate, patient-reported outcomes (PROMs), medication adherence	Measures clinical effectiveness and quality of care	Hospitals, policymakers, payers	Use EU-wide standards (e.g., OECD Health Statistics, ECHI, EHDS datasets)
Cost Savings	Cost per patient, reduced emergency visits, fewer hospitalizations, optimized staff time	Demonstrates financial efficiency and supports reimbursement negotiations	Payers, ministries of health, hospital CFOs	Apply Value-Based Healthcare (VBHC) cost–outcome frameworks
Sustainability Contributions	Reduced travel emissions (via telemedicine), lower energy use in facilities, digital workflow efficiency	Links digital innovation to environmental and resource sustainability goals	EU policymakers, ESG-focused investors	Align with EU Green Deal and ESG reporting metrics
System Integration	EHR interoperability rate, data-sharing across facilities, number of connected systems	Shows scalability and alignment with national and EU digital health strategies	National authorities, innovation hubs	Use EHDS interoperability standards and IHE frameworks
Adoption & Engagement	Active user rates, clinician adoption, patient satisfaction	Reflects usability	Hospitals, MedTech firms, patient groups	Standardize reporting through digital maturity models (e.g., HIMSS EMRAM)

For MedTech C (high experience)

Build robust data collection systems into the product design, ensuring hospitals can easily track long-term usage and outcomes.

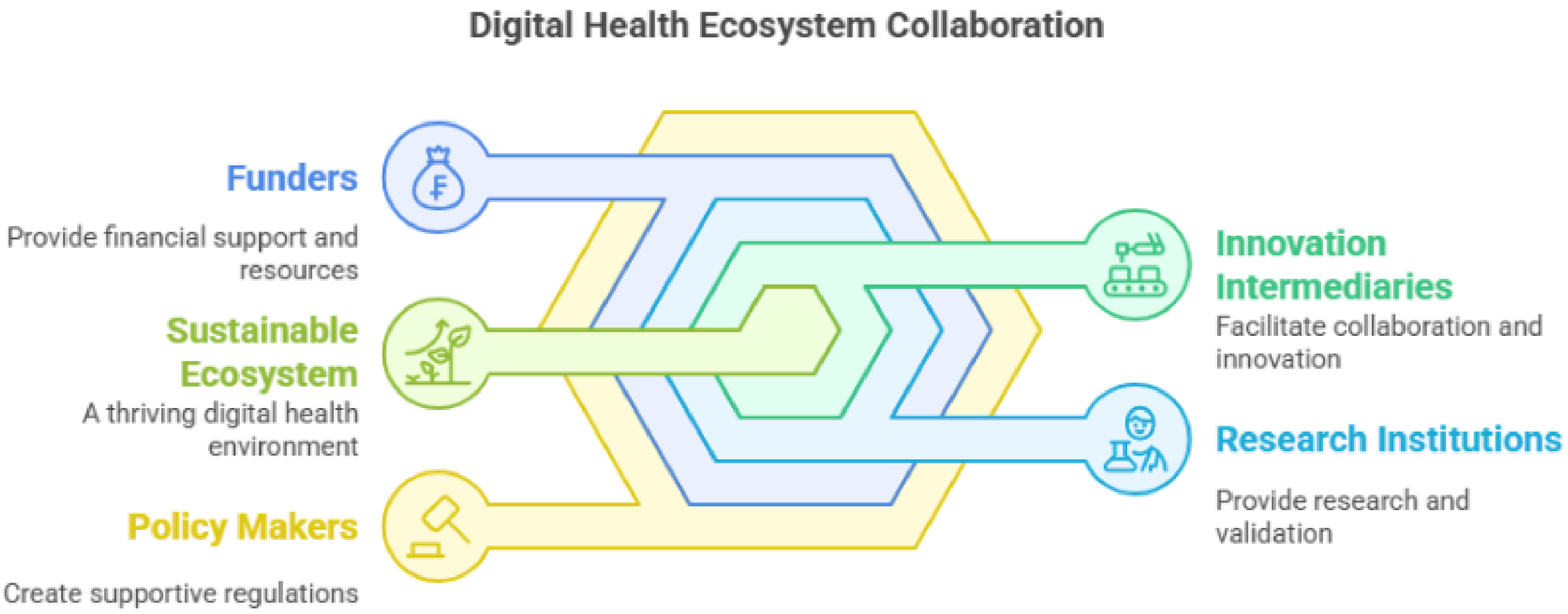
Prepare health economics models that demonstrate cost savings and efficiency gains over years, not just during pilots.

Offer outcome-based contracts (e.g., pay-per-patient-improved) to align directly with hospitals' and payers' expectations.

Example: A MedTech company providing a remote monitoring platform collects multi-year data on reduced emergency admissions and presents a cost–benefit analysis to insurers, supporting broad reimbursement.

CHAPTER IV
Mapping and engaging stakeholders

A successful digital health ecosystem relies on strong, coordinated collaboration between a diverse range of stakeholders—healthcare providers, startups, policymakers, funders, research institutions, and innovation intermediaries. Each plays a unique role in enabling the development, validation, and adoption of digital health solutions. However, in many regions across Central and Eastern Europe, these actors remain siloed or disconnected, limiting the speed and scale of innovation. Moreover, each stakeholder group often pursues distinct interests and goals regarding digital innovation, which makes it challenging to establish a shared vision and coordinated approach.



Why This Chapter Matters

The strategic goals of the ecosystem help stakeholders see the bigger picture. By aligning with health system transformation, sustainability, value-based healthcare, and EU/national strategies, hospitals, companies, and innovation hubs can ensure that pilots do not remain isolated experiments but grow into lasting change.

4.1 Identifying Stakeholder Groups

Every project should begin by answering the question: Who matters most to the success of this innovation? Typical groups include healthcare professionals (doctors, nurses, therapists), patients, hospital managers, payers and insurers, regulators, and innovation enablers like hubs or universities. For networks setting out on the creation of a new ecosystem, the goal is not to map everyone, but to identify the five or six groups that can directly influence adoption.

Healthcare Professionals - doctors, nurses, and therapists who actually use the solution.

Their goals include:

- Better patient outcomes and safety: fewer complications, errors, and rehospitalizations; earlier detection of deterioration.
- Smoother work with less administration: shorter documentation, fewer clicks, no duplicate data entry.
- Meaningful data in real time: quick access to information, clear clinical priorities, and support for high-quality care.
- Compliance with standards: proper documentation, full audit trail, and data protection.
- Sustainable workload: prevention of burnout, fair task distribution, and efficient resource use.
- Professional growth: access to modern tools, training, and evidence-based practice.

They expect from digital solutions:

- Time-saving interfaces (≤3 clicks to main action, auto-fill from existing data).
- Interoperability (integration with LIS (Laboratory Information System), PACS (Picture Archiving and Communication System), and EHR (Electronic Health Record) systems; no double entry).
- Reliability and availability (minimal downtime, relevant alerts only).
- Clear accountability (defined roles and validation steps).
- Training and support (quick onboarding, clinical champions for peer learning).
- Proof of value (clinical and economic benefits with early, visible results).

Patients - whose trust and willingness to use digital tools determine real adoption.

They seek:

- Safe, reliable, and user-friendly solutions that are easy to understand and integrate into daily life.
- Clear benefits such as better communication with doctors, quicker responses, and empowerment in managing their own health.
- Transparency on data use and strong privacy protection.

Hospital Managers – who control budgets, IT resources, and decision-making.

They aim for:

- Operational efficiency and improved outcomes at sustainable costs.
- Digital tools that integrate smoothly into workflows and existing IT systems.
- Clear evidence of ROI (Return of investment), regulatory compliance, and staff acceptance.

Payers and Insurers – who decide whether solutions will be reimbursed.

They expect:

- Demonstrated cost savings and better health outcomes.
- Scalable solutions with proven long-term effectiveness.
- Reliable, standardized data for performance-based reimbursement models.

Regulators – who ensure that solutions meet safety and legal standards.

They require:

- Full compliance with medical device regulations, patient safety standards, and data protection laws (e.g., EU MDR, GDPR).
- Transparent evidence generation and auditability of processes.

Innovation Enablers – hubs, accelerators, and universities that connect the ecosystem.

They look for:

- High-quality collaborations between startups, clinicians, and research institutions.
- Projects with clear innovation potential, scalability, and social impact.
- Opportunities for validation, testing, and dissemination of successful models.

Every project should begin by answering the question:
Who matters most to the success of this innovation?

Startup A (no experience)
Before engaging users or hospitals, verify whether your product already has CE marking (Conformité Européenne). If not, any testing in a clinical setting can only be conducted within a clinical investigation framework, following the Medical Device Regulation (MDR) requirements — including a clinical trial plan and ethics approval.

Once regulatory readiness is clear, write a simple list with at least one person from each stakeholder group: a patient with the condition you aim to address, a clinician in that specialty, a hospital manager who could host a pilot, and one payer contact (e.g., someone from a local insurer).

Hospital A (no experience)

Set up a small “innovation group” of three members: one clinician, one IT staff member, and one administrator/finance person. Assign a clear mandate: the group recommends Go/No-Go for new digital health solutions and documents all outputs in a shared folder or register.

Tangible Outputs: intake form, screening scorecard, Definition of Ready checklist, two-page leadership brief, pilot pack (onboarding, support, metrics), one-page Pilot Close-Out.

Example: When testing a telehealth platform, the clinician verifies clinical relevance, the IT member checks system integration, and the administrator evaluates resource needs and costs.

Hospital B (some experience)

Expand the innovation group by including a patient representative or payer in pilot committees to increase credibility beyond the hospital.

Example: In an oncology decision-support tool pilot, invite a cancer patient association leader for feedback and a payer representative to observe outcome data. Use the same 8-step process and outputs to maintain structure and documentation.

Startup A (no experience)

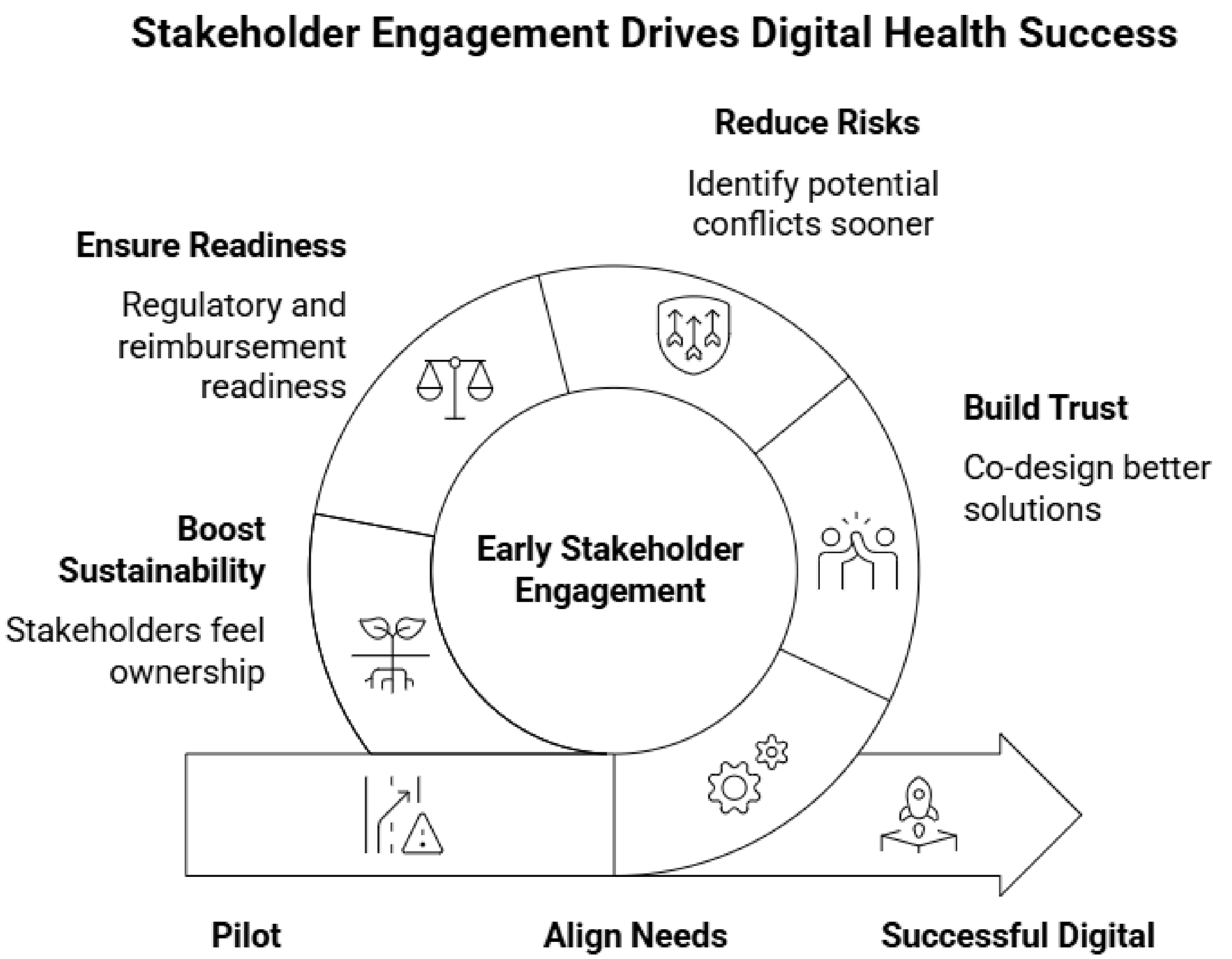
Identify everyday users such as nurses or clinicians as early design partners. Shadow them during their daily work to understand real workflows.

Example: If you're developing a digital wound-care system, spend time with a nurse during dressing changes to see how your tool could fit naturally into their routine.

Innovation Hub A (no experience)

Start a simple database of local stakeholders. For each entry, note the name, role (clinician, patient, payer, etc.), and interest in digital health.

Example: Your list might include the head of cardiology at a regional hospital, a diabetes patient group, a local insurer, and a startup developing AI diagnostics.



4.2 Tools for Stakeholder Mappin

Mapping stakeholders doesn't require expensive software. A piece of paper, a whiteboard, or even a spreadsheet can be enough to make the invisible visible. The simplest tool is an interest vs. influence grid:

- On the vertical axis, mark influence (low to high).
- On the horizontal axis, mark interest (low to high).
- Place each stakeholder in the grid.

Use a stakeholder grid to segment participants into four quadrants based on power (influence) and interest:

- High power / high interest: Engage closely — these stakeholders are critical for decision-making and adoption.
- High power / low interest: Keep satisfied — they have influence but may not be motivated; targeted updates or briefings help maintain support.
- Low power / high interest: Keep informed — they may not influence decisions directly, but their feedback can shape implementation and build grassroots support.
- Low power / low interest: Monitor — they require minimal attention but should be notified of progress occasionally.

EXAMPLE

For example: a chief hospital manager might initially fall into high power / low interest and need tailored communication to boost engagement; a nurse who uses the system daily is low power / high interest and can become a strong advocate if their input is heard; a payer or insurer is typically high power / medium interest, so involving them strategically early on can determine reimbursement outcomes.

This approach helps prioritize engagement efforts and tailor communication strategies for project success, while still allowing stakeholders to "move" between quadrants as their interest or influence changes over time.

Startup A (no experience)
Draw a 2×2 grid on paper. Write down the names of 5 people you know (e.g., a doctor, nurse, patient, manager, insurer) and place them on the grid. Circle the top two you need to talk to first.

Hospital A (no experience)
Make a list of all external partners currently involved in your hospital (e.g., IT vendors, startups, pharma companies). Rank them by how important they are for your current projects — "critical, useful, or optional."

Hospital B (some experience)
Use a flowchart tool (or even presentation slides) to map how your clinicians, managers, and external payers connect in a pilot. For example: "cardiology department → hospital board → regional insurer."

Mapping stakeholder connections helps clarify decision-making and communication channels, ensuring that pilots align with reimbursement pathways, demonstrate measurable quality improvements, and make the hospital's value visible to both payers and patients. This structured overview supports smoother approval, better resource allocation, and stronger justification for scaling successful interventions.

Startup A (no experience)
What to do:
Write one-page "user sheets" for the two people who will interact most with your product. Include their daily routine, main challenges, and what would make their work easier.

Understanding end-users at this level helps MedTech companies design solutions that truly address workflow pain points, improve adoption, and demonstrate clear value to hospitals and clinicians.

Better product-market fit, stronger user engagement, and evidence to support clinical and economic value propositions.

Innovation Hub A (no experience)
Create a simple Excel sheet with columns: Name, Role, Organization, Interest in Digital Health, Contact Info. Share it with startups and hospitals so everyone uses the same basic stakeholder map.

Mapping stakeholders at the ecosystem level ensures clarity on who is involved, their interests, and how they can contribute. This prevents duplicated efforts and fosters coordinated collaboration.

Efficient ecosystem management, clearer engagement strategies, and stronger connections between startups, hospitals, and other stakeholders.

4.3 Methods for Engagement

Engagement means building relationships step by step, not just handing over contracts. In CEE, many projects fail because innovators don't involve the right people early enough or only share results at the end. For those setting out on relation-building for the first time small, practical actions — such as asking for feedback, inviting people to a short workshop, or showing a simple prototype — can create momentum and trust.

Useful methods include:

- Co-creation workshops: clinicians, patients, and IT staff brainstorm together to design solutions.
- Advisory groups: small groups of key stakeholders meet regularly to give input.
- Living labs: safe spaces where new digital tools are tested in real hospital settings.
- Demo sessions: innovators present a prototype and gather immediate reactions.

EXAMPLE

A startup with a digital rehab app organizes a one-hour co-creation workshop with physiotherapists and patients. The result? They discover patients need bigger font sizes in the app, and therapists want automatic exercise reminders — simple adjustments that increase adoption later.

Startup A (no experience)
Before finalizing your product, meet with one clinician and one patient group. Show them your prototype (even on paper) and ask: "What's missing for you?"

Additional steps:

- Present your solution at conferences or workshops to gather broader feedback and increase visibility.
- Collaborate with universities through joint development projects. This allows the startup to co-develop the solution with academic expertise, secure partial development funding from grants (e.g., in the Czech Republic via the Ministry of Industry and Trade), and increase credibility through validated outcomes.
- Involve healthcare professionals throughout these projects, linking all three institutions—startup, university, and hospital—to ensure practical relevance and foster adoption from the outset.

Hospital A (no experience)
Organize a quarterly "innovation meeting" where nurses, doctors, and IT staff can try out new digital tools for 15 minutes and share opinions. Keep notes on what works and what doesn't.

Hospital B (some experience)
When running a pilot, invite a payer or insurer to join your steering committee. Even if they do not attend each session, engaging them in the committee builds trust and demonstrates transparency early in the process.

MedTech A (no experience)

Host demo days in hospitals. Bring your device, let clinicians test it for 30 minutes, and record their feedback. Example: a nurse testing a wound-care device points out that gloves make the touchscreen hard to use — you fix it before scaling.

Innovation Hub A (no experience)

Run short networking events (60–90 minutes) where 3 startups pitch to hospital managers and clinicians, followed by Q&A. Organize it as a round table where all interested parties are present. Keep it informal, focus on learning, and ensure everyone leaves with at least one new contact.

4.4 Building Trust and Alignment

In CEE, many pilots fail not because of specific technical shortcomings in the innovation, but because trust is missing. Clinicians often worry about extra workload, patients fear losing control over their data, and managers focus on costs. Trust isn't built with glossy presentations or big promises — it's built with small, visible wins and clear communication.

Trust also grows when stakeholders feel included. Showing transparency, sharing results (even modest ones), and speaking in a language everyone understands — health benefits for patients, time saved for clinicians, efficiency for managers — helps align diverse perspectives.

Startup A (no experience)

Share even small data points with stakeholders to build trust. Example: "In our pilot with 10 patients, 7 reported increased adherence to treatment." Be transparent about limitations and the level of documentation — honesty and robust processes help overcome distrust among hospitals and patients.

Hospital A (no experience)

Start with low-risk, easy-to-measure pilots. Example: test an e-prescription system in one department for 4 weeks and show how it reduces paperwork. Many hospitals are uncertain about what to request and what the law requires in this area, which can make them reluctant to engage in pilots. Time pressure on healthcare professionals is another barrier. Participation can be encouraged through financial compensation or by offering a stake in scientific outputs derived from pilot data, as demonstrated in the DIGIVITALITY project.

Hospital B (some experience)

Collect small success stories and share them inside the hospital.

Example: "Our cardiology ward saved 30 staff hours last month thanks to the new scheduling app." Post it on the intranet or present at staff meetings.

Startup **A (no experience)**

When engaging with early-stage companies that might purchase your product or services, focus on practical benefits that are immediately relevant to them. Instead of saying "our platform uses AI," highlight tangible outcomes: for example, "our tool reduces time spent on manual data entry by 20 minutes per patient." Emphasize how working with your startup can be low-risk and mutually beneficial, providing efficiency gains or early access to innovative solutions without requiring large upfront investments.

Innovation Hub A (no experience)

Gather short case studies from local pilots (2–3 paragraphs each).

Example: "Clinic X tested a telehealth app for 2 months, reduced travel for rural patients by 25%, and clinicians rated usability 4.2/5." Share them with your network to spread trust in innovation.

4.5 Avoiding Fragmentation

One of the biggest challenges in CEE is fragmentation: pilots often run in silos, with little coordination across hospitals or health systems. A startup might test its tool in one ward without involving management or payers. Hospitals sometimes keep pilots confined to a single department, and MedTechs push solutions without adapting them to local workflows. These isolated efforts rarely scale, because no one outside the pilot team understands or trusts the results.

Avoiding fragmentation means thinking system-wide from the start. In practice, this requires involving payers and regulators early, sharing results across departments, and designing solutions that fit into real hospital workflows. Innovation hubs can play a critical role by acting as neutral conveners, ensuring that pilots don't serve just one group but are seen as valuable across the ecosystem.

Startup A (no experience)

When preparing a pilot, focus on designing your solution for interoperability with hospital systems. Ensure the product aligns with standards such as HL7 FHIR (Fast Healthcare Interoperability Resources) and consider partnering with companies that specialize in integration platforms to connect your solution seamlessly. Example: if testing a telemonitoring app, make sure it can exchange data with the hospital's electronic health record or laboratory system. Early attention to interoperability not only supports smooth pilot implementation but also enables replication across other departments or hospitals, building credibility with payers, regulators, and hospital stakeholders.

Hospital A (no experience)

Don't keep pilots locked in one unit. After testing in cardiology, present results in internal hospital meetings or newsletters so other departments can see potential benefits.

Example: "The cardiology pilot reduced follow-up visits by 15% — could this work in pulmonology?"

Hospital B (some experience)

Document pilot results in a structured format that highlights outcomes, cost implications, and patient feedback, while also specifying system requirements and vendor responsibilities to ensure interoperability. Share these summaries with relevant authorities (e.g., Ministry of Health or regional bodies) to build credibility and support scaling.

Example: "In 6 months, our digital wound-care tool saved 200 clinic visits and €25,000. The system requirements and vendor responsibilities were clearly documented to enable expansion to other departments in compliance with data-sharing regulations."

MedTech A (no experience)

Instead of asking hospitals to change workflows for your tool, adapt your solution to existing processes.

Example: if nurses already use paper charts, design your app to mirror that workflow digitally rather than forcing them to learn a completely new system.

Innovation Hub A (no experience)

Host multi-stakeholder roundtables where startups, hospitals, payers, and regulators all discuss pilot results.

Example: organize a half-day session after a telehealth pilot where each actor shares their perspective — clinician workload, patient satisfaction, cost impact, and regulatory fit.

Practical checklist for Digital Health Pilots

Step 1: Identify Stakeholders
- List all relevant groups: clinicians, patients, hospital managers, payers, regulators, startups, innovation hubs.
- Assign a contact person for each group.

Step 2: Define Objectives and Roles
- Clarify the purpose of engagement (feedback, validation, policy alignment, scaling).
- Assign roles for facilitation, note-taking, and follow-up.

Step 3: Schedule Structured Sessions
- Organize workshops, roundtables, or advisory meetings (e.g., half-day sessions).
- Ensure all stakeholders can share perspectives on workflow, patient outcomes, costs, and regulatory compliance.

Step 4: Use Standardized Templates
- Capture discussions using consistent templates:
  - Pilot metrics and KPIs
  - Cost and resource implications
  - Patient and clinician feedback
  - Interoperability and regulatory notes

Step 5: Encourage Iterative Feedback
- Review outputs after each session and update the pilot design accordingly.
- Track improvements and lessons learned in a shared repository.

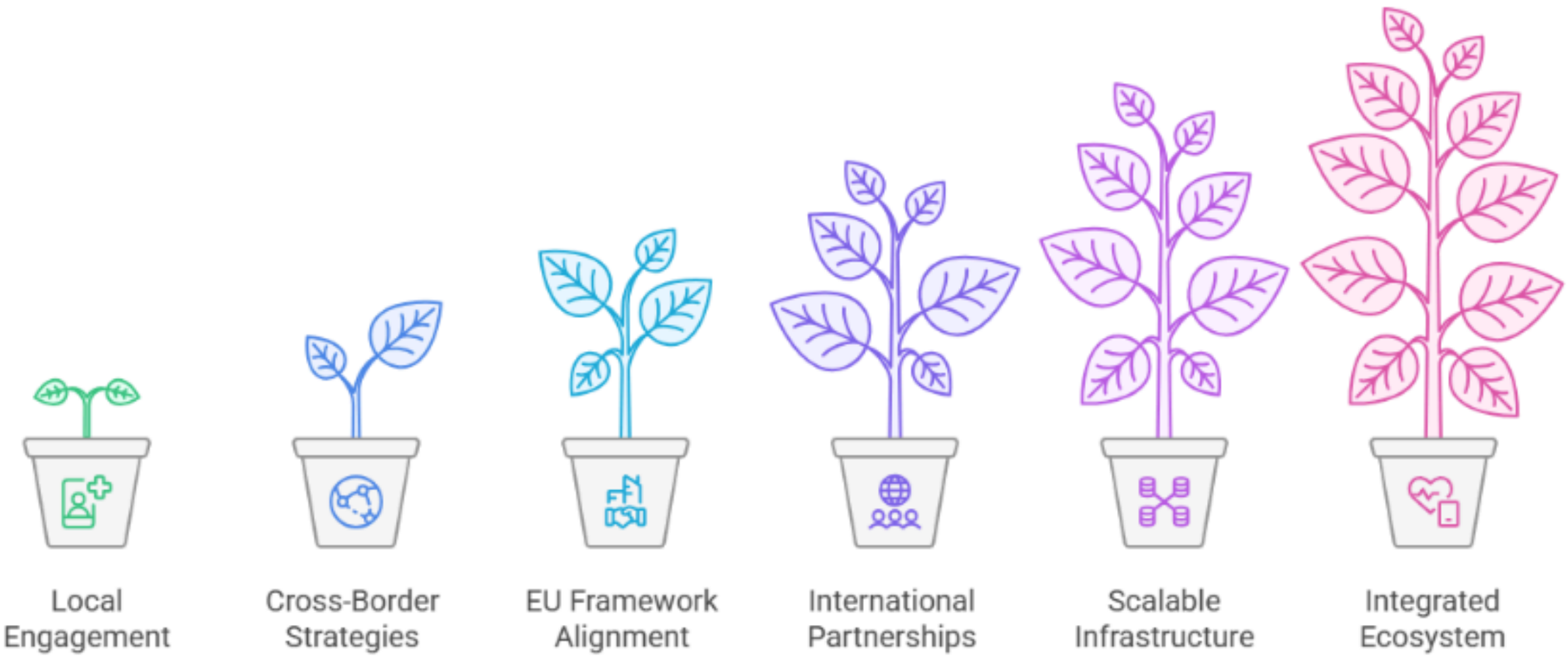
Step 6: Summarize Results
- Produce concise one-page summaries or dashboards for leadership, funders, and regulators.
- Include key outcomes, risks, and recommendations for scaling.

Step 7: Build Trust and Transparency
- Share all outputs with participants.
- Ensure accountability and clear communication about decisions and next steps.

Step 8: Plan for Scaling
- Identify which interventions are ready for broader deployment.
- Use evidence and stakeholder buy-in to replicate the solution across departments or hospitals.

CHAPTER V
From Local to International

Scaling from a successful local pilot to international adoption is one of the biggest challenges for digital health in CEE. Local validation is only the beginning: innovators must adapt to new regulations, understand market dynamics in other countries, and build cross-border partnerships. For many, the transition fails because they treat scaling as a copy-paste exercise instead of a structured process. This chapter provides tools and methods to expand strategically from local to international markets, increasing the chance of sustainable growth.



Why This Chapter Matters

Many digital health solutions in CEE prove themselves in local pilots but never move beyond their first hospital or region. The challenge is not only technical — it's about navigating different regulations, adapting to local needs (including local reimbursement & HTA routes and data), and building trust with international partners. Without a clear pathway, even strong innovations risk becoming "local champions" that never scale.

This chapter shows startups and MedTechs how to turn local success into international growth. It highlights the practical steps — from preparing for expansion and understanding foreign regulations, to adapting solutions for new markets and building cross-border partnerships. By focusing on scaling evidence and credibility, it helps innovators avoid common pitfalls and position their solutions for adoption across Europe and beyond.

For CEE stakeholders, this is especially important: scaling internationally not only grows individual companies but also strengthens the region's role as a contributor to Europe's health innovation ecosystem.

5.1 Preparing for International Expansion

Strong clinical results at home are a great start, but they don't guarantee success abroad. To grow internationally, companies must show that their product is scalable (can handle more users and larger systems), adaptable (fits local workflows including local patient pathways and languages), and credible (complies with legal, cultural, and clinical standards in new markets).

Preparation involves three key steps:

1. Protect your innovation – secure intellectual property (IP) rights so others can't copy your idea abroad.
2. Check compliance – verify that your certifications (like CE marking) are valid in the markets you want to enter.
3. Understand local context – know how healthcare is delivered, what patients expect, and how clinicians work in each target country.

EXAMPLE

A startup in Poland with a diabetes app cannot just "copy-paste" into Germany.
It needs CE marking, German-language documentation, servers that meet German data standards, and adaptations for how German insurers reimburse diabetes care.

Startup B (mid experience):

Run a stress test on your product. Can your system handle 10× the users you currently serve? Translate all key materials (user manuals, websites, training videos) into English.

Startup C (high experience)

Secure IP rights across the EU (via EUIPO) and confirm your CE mark covers all product versions. Prepare a "compliance folder" with all documentation ready for regulators abroad.

MedTech B (mid experience)

Select 2–3 target countries. For each, research: their top health priorities, reimbursement system, and key national programs (e.g., oncology in Czechia, digital chronic care in Finland).

MedTech C (high experience)

Build a cross-border expansion plan. Partner with one hospital or distributor in each target country and assign a local lead who understands the health system.

Example: sign a memorandum of understanding (MoU) with a university hospital in Italy to co-run your first pilot.

How do intellectual property protection, regulatory readiness, and cultural adaptation influence the success of digital health companies from CEE entering foreign markets?

The success of digital health companies, particularly those from Central and Eastern Europe (CEE) entering foreign markets, is influenced by three critical factors: intellectual property (IP) protection, regulatory readiness, and cultural adaptation. Each of these elements plays a significant role in how these companies navigate the complexities of internationalization, addressing both opportunities and barriers in new healthcare environments.

Intellectual Property Protection

Intellectual property protection is pivotal for digital health companies aiming to thrive in international markets. Strong IP rights can stimulate innovation by ensuring that companies can secure their proprietary technologies and reduce the risk of infringement, which is particularly pressing in the digital economy (Li, 2024). Research indicates that effective IP protection encourages business innovation, thereby supporting the creative growth essential for companies transitioning to foreign markets (Qi & Zhang, 2023). In the context of digital health, where technological advancements are rapid and intellectual capital is critical, a well-defined IP strategy can differentiate successful companies from their competitors.

Furthermore, companies facing barriers in IP can encounter significant challenges in market entry and expansion. Insufficient IP frameworks can deter foreign investment and partnerships, which are crucial for scaling operations and adapting products to meet local needs. Therefore, a robust understanding of both local and international IP laws is necessary for CEE companies seeking to protect their innovations and establish a competitive edge overseas.

Regulatory Readiness

Regulatory readiness encompasses the preparedness of digital health companies to comply with varying health regulations across jurisdictions. Different countries have unique regulatory landscapes that influence how quickly and effectively digital health technologies can be integrated into healthcare systems (Hughes et al., 2021; Lennon et al., 2017). CEE companies must navigate these often complex frameworks to ensure product compliance, which involves understanding safety, efficacy, and data protection requirements tailored to specific markets. Studies have shown that a lack of readiness can significantly hinder the adoption and scaling of digital health innovations, as demonstrated by challenges faced in bringing successful pilot projects into widespread use (Kelley et al., 2020).

Moreover, regulatory frameworks that incentivize interoperability and clinical endorsement can enhance the integration of digital health solutions into established healthcare practices. Companies aspiring to succeed internationally must not only be proactive in meeting regulatory demands but also engage with stakeholders in the healthcare system to facilitate smoother transitions into new markets (Lyles et al., 2021).

5.2 Navigating Regulations Abroad

Even within the EU, each country interprets and applies the same regulations in different ways. This can create surprises for newcomers. For example, Germany's DiGA fast-track allows certified digital therapeutics to be reimbursed nationally within 12 months of approval. In contrast, in many CEE countries, approval is slower and often tied to results from local pilots before reimbursement is considered.

EXAMPLE

Not knowing these differences can delay market entry by months or even years. Companies that succeed abroad are the ones that study the regulatory environment early, adapt their strategy to each country, and work with local experts who know how to navigate approvals.

A Polish startup with a telemonitoring app enters France without realizing that French law requires hosting all patient data on certified local servers. Without adapting, their pilot is delayed by six months.

- **Startup B (mid experience)**

Choose one target country and identify its most relevant regulatory pathway.

Example: In Germany, study the DiGA fast-track rules for digital health apps; in France, look into Haute Autorité de Santé (HAS) requirements for digital solutions.

Startup C (high experience)

Build a regulatory timeline for the countries you want to enter. Include milestones like "submit dossier Q3," "pilot required Q4," "expected approval Q2 next year." Keep it updated to anticipate delays.

MedTech C (high experience)

Create a dedicated compliance team (internal or external) that monitors regulatory updates in multiple countries. Their role: track changes, update your documentation, and ensure all markets stay aligned with local requirements.

Example: One member follows France and Belgium, another Germany and Austria.

5.3 Adapting to Market Needs

A solution that succeeds at home can stumble abroad if it isn't adapted to local realities. Healthcare systems differ in language, data standards, clinical practices and related costs, reimbursement, and even patient expectations. What works in Poland might not fit smoothly in Spain or Italy unless adjustments are made.

EXAMPLE

A diabetes monitoring tool validated in Poland might need:

- Translation into Hungarian with simpler interfaces for older patients.
- Integration with Hungarian regional electronic health record (EHR) systems.
- Adjustments for GDPR interpretations on data-sharing rules.
- Proof of compatibility with Hungarian national diabetes registry before adoption.

Adapting to market needs means listening carefully to local stakeholders, testing early, and tailoring the product to match the workflows and expectations of each country.

Startup B (mid experience)
Conduct 5–10 structured interviews with clinicians in your target country. Ask specific questions: "What slows you down in diabetes care?" "How do you record patient data?" Summarize insights and compare them with your current solution.

Startup C (high experience)
Before launching abroad, run a small pilot in one hospital.

Example: Partner with a Hungarian hospital for a 3-month pilot of your app with 30 patients. Collect real-world feedback and refine features before committing to a full rollout.

MedTech B (mid experience)
Adapt your solution to local IT systems and reimbursement pathways.

Example: In Germany, make sure your platform integrates with SAP-based hospital IT; in France, prepare reimbursement documentation aligned with HAS (Haute Autorité de Santé).

MedTech C (high experience)
Build partnerships with national medical societies (e.g., cardiology, oncology). Work with them to adapt your training materials and educational content.

Example: Co-publish a best practice guide in collaboration with the Italian Society of Cardiology to support adoption of your device.

5.4 Building Cross-Border Partnerships

Scaling abroad is rarely possible alone. Success in international markets depends on strong local partners who understand the system, have access to local costs, can provide credibility, and can open doors. Hospitals can provide pilots and clinical evidence, distributors know how to navigate the local procurement process, payers determine reimbursement potential, and research centers bring academic credibility. Without such partners, many companies fail to gain traction.

A Czech startup with a telemonitoring tool wanted to enter France. Instead of pitching directly to insurers, it partnered with a French university hospital, ran a joint clinical study, and co-published results. The hospital's endorsement gave credibility, and the insurer agreed to cover the tool after seeing the French data.

Startup B (mid experience)
Apply to international accelerators or programs like EIT Health Bridgehead or Startup Europe. These provide introductions to hospitals, insurers, and investors abroad.

Example: Through EIT Health, a Polish startup connects with a Dutch hospital and runs its first cross-border pilot.

Startup C (high experience)
Sign a formal partnership agreement with a foreign hospital to co-develop clinical evidence.

Example: Partner with a German hospital to collect local patient data, ensuring your product fits DiGA reimbursement requirements.

MedTech B (mid experience)
Secure distribution agreements with local companies that know procurement rules and hospital networks.

Example: A Hungarian MedTech firm entering Italy partners with an Italian distributor who already supplies 30 hospitals.

MedTech C (high experience)
Build long-term alliances with payers and policy influencers to support reimbursement.

Example: In Spain, collaborate with a regional health authority and a payer to design a reimbursement model for your AI diagnostic tool, positioning it as part of the chronic disease management program.

5.5 Scaling Evidence for International Markets

Local pilot data is important, but it often isn't enough to convince regulators, insurers, or hospitals abroad. Foreign stakeholders want standardized, internationally credible evidence that proves a solution works beyond one country. This means publishing in peer-reviewed journals, aligning data with recognized frameworks (like CONSORT or ISO standards), and building multi-country evidence packages that demonstrate consistent outcomes.

A tele-cardiology tool tested in Poland showed reduced readmissions, but French insurers only accepted it once results were published in European Heart Journal and validated in a French pilot. Evidence must travel across borders — and so must credibility.

Startup B (mid experience)
Create a 2–3 page clinical evidence summary in English. Include study design, number of patients, key outcomes, and cost savings.

Example: "In a 3-month pilot with 50 patients, our diabetes app reduced HbA1c levels by 0.6 points and cut emergency visits by 12%."

Startup C (high experience)
Strengthen credibility by publishing pilot results in peer-reviewed journals. Even small studies in recognized journals (e.g., JMIR mHealth or Frontiers in Digital Health) boost international trust.

MedTech B (mid experience)
Build a multi-country evidence package. Combine results from pilots in 2–3 countries into one document that compares outcomes.

Example: "In Poland, Italy, and Hungary, our wound-healing device reduced recovery time by an average of 18%."

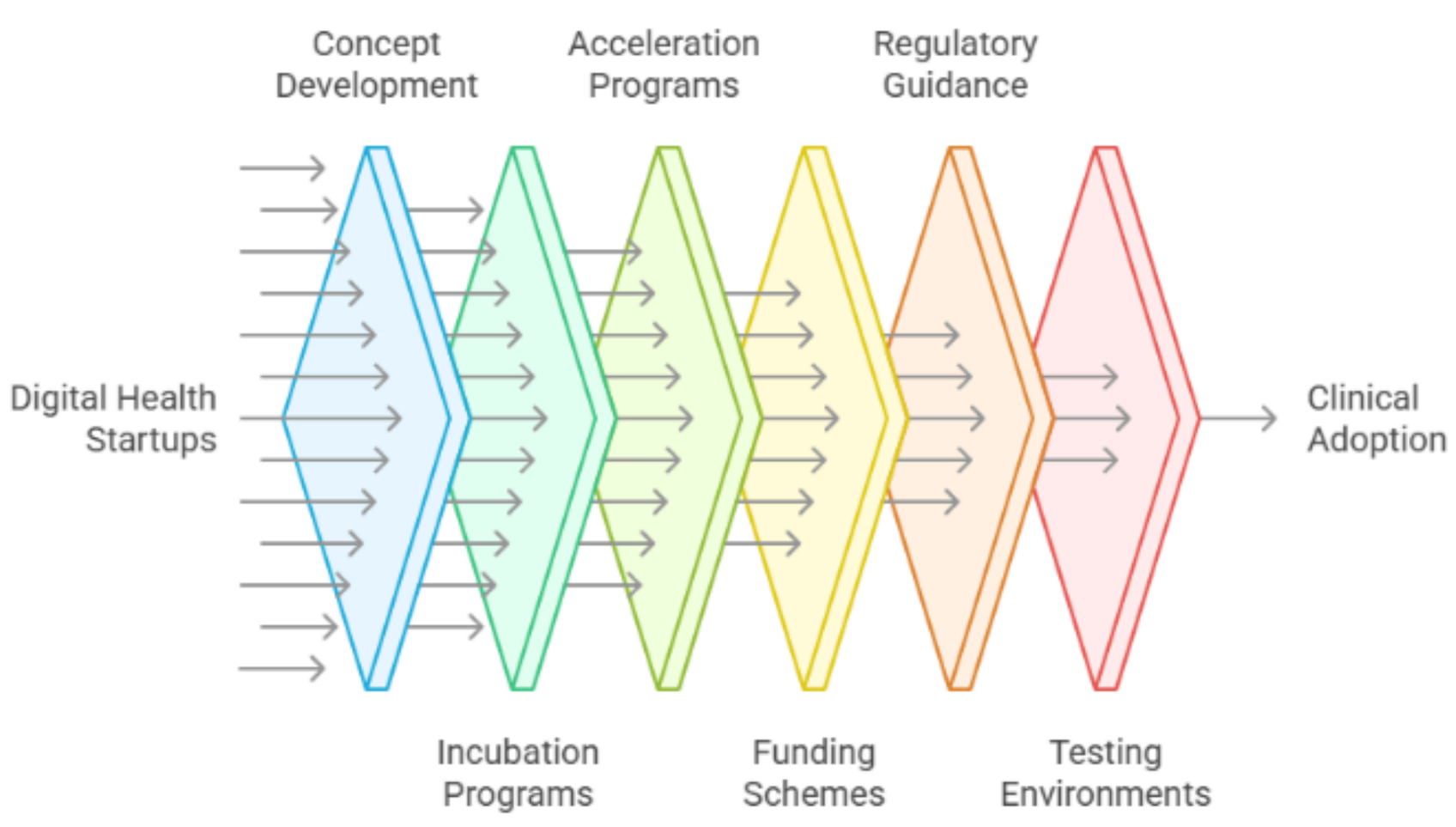
MedTech C (high experience)
Set up real-world evidence (RWE) studies across 2–3 countries. Collaborate with hospitals to collect data in routine care settings, not just controlled pilots.

Example: Launch a registry with hospitals in Germany, Spain, and Czechia tracking long-term patient outcomes for your device.

CHAPTER VI
Designing the supporting framework

Digital health doesn’t grow in a vacuum. Even the strongest idea can fail if the ecosystem around it doesn’t provide funding pathways, regulatory guidance, mentorship, and validation opportunities. In CEE, many innovators face this challenge: they may have talent and prototypes, but lack structured support to turn ideas into scalable, reimbursable solutions.

This chapter explores how accelerators, incubators, and innovation hubs can design frameworks that connect innovators with the right resources at the right time. By building structured support systems, CEE can close the gap with Western Europe and provide startups and hospitals with environments that make scaling possible.



Why This Matters

Without strong support structures, digital health solutions remain scattered pilots. A well-designed framework connects innovators with funding, regulatory expertise, mentors, and validation opportunities. For CEE, this is crucial to catch up with Western Europe and ensure that startups and hospitals can compete internationally. By investing in accelerators, incubators, and hub networks, the region can transform fragmented initiatives into a sustainable pipeline of scalable digital health innovations.

6.1 Creating Funding Pipelines

For many innovators in CEE, the biggest challenge is not building a prototype, but finding money at the right stages. Startups often get a small seed grant or accelerator prize but then hit the "valley of death" — the gap between early funding and serious investment. Without structured support, promising solutions die before reaching hospitals or payers.

A strong funding pipeline connects public grants, private investors, and hospital budgets into a sequence that innovators can follow. Accelerators and hubs play a key role in showing startups how to move from one stage to the next.

EXAMPLE

An accelerator in Hungary pairs EU grants (like Horizon Europe or EU4Health) with local venture capital. Startups that complete the program can apply for EU funding while being introduced to VCs willing to co-finance pilots. One diabetes monitoring startup received €50,000 in EU seed funding, then secured a €500,000 co-investment from a local VC to run pilots in three hospitals.

National and European Funding Opportunities (Czech Republic):

- OP TAK (Ministry of Industry and Trade) – Supports innovation, digitalization, marketing, and expert services for startups. Best used for funding digitalization modules, buying external services, or supporting go-to-market activities.
- Technology Agency of the Czech Republic (TA CR) – SIGMA programme – Focuses on applied research and commercialization, including business–university collaborations. Suitable for bringing R&D outputs to market or clinical validation.
- CzechInvest – Technology Incubation (HealthTech focus) – Provides incubation support, mentoring, small grants, and validation of product–market fit for early-stage startups.
- Ministry of Industry and Trade – DeepTech Fund – Public fund planning up to CZK 1 billion for early deep-tech companies; ideal for early-stage equity financing alongside grants.
- Ministry of Health / AZV (Czech Health Research Council) – Offers health research grants, including funding for patient organizations. Appropriate for clinical or translational research and patient-reported outcomes.
- National Recovery Plan (NPO) – Supports eHealth, interoperability, and digitalization in hospitals. Best suited for hospital-led or consortium-led digital projects.
- European Programmes (Horizon Europe – Cluster 1: Health) – Open to Czech entities; funds research and innovation in digital health, AI, and data-driven solutions. Calls are managed by HaDEA.

By mapping available funding sources to the stage of the startup or project, innovators can plan a sequential funding path: early-stage support (incubators, small grants), R&D and clinical validation (TA CR, AZV), pilot funding (hospital budgets, NPO), and scaling or commercialization (VC co-investment, DeepTech Fund, HE).

Hospital B (some experience)

Create a list of active funding schemes (EU calls, national grants, regional programs) relevant to digital health pilots. Share this list with startups during meetings or publish it on your hospital website.

Example: A hospital innovation office highlights that telemedicine pilots can be co-financed by an EU4Health grant combined with regional government subsidies.

Case Study – OP TAK Knowledge Transfer Partnership:

The 1st Faculty of Medicine, Charles University in Prague, is partnering with a startup to develop a diabetes monitoring app under the OP TAK Knowledge Transfer Partnership. Through this collaboration, the startup gains access to university know-how while expert work is funded by the project (time-bound, with clear objectives). The startup is connected to a hospital for clinical validation with doctors, who benefit both financially and scientifically while helping co-design the tool. This arrangement builds real clinical buy-in, and the startup can receive up to CZK 12 million for product development.

Startup Benefits:

- Faster, credible validation in a real clinical setting, generating evidence needed for regulatory approval (MDR) and future reimbursement.
- Co-design with end users, ensuring better usability and adoption of the solution.
- Interoperability guidance (EHR/LIS/PACS, HL7 FHIR) for smoother integration and scaling across departments or hospitals.
- Stronger go-to-market strategy supported by university and hospital backing, with lower costs and reduced risk due to funded expert time.

Innovation Hub B-C (more experience)

Build connections with 3–4 local investors or corporate funds and use them to design funding roadmaps for startups.

These roadmaps should clearly outline:

a. Early-stage options (accelerator grants, national innovation funds).
b. Mid-stage options (EU Horizon grants, corporate co-investment).
c. Growth-stage options (VC or private equity for international scaling).

Example: A Lithuanian hub provides each startup with a one-page “funding roadmap,” showing them how to go from a €25,000 seed grant → €200,000 EU co-financing → €2M VC round.

6.2 Providing Regulatory & Reimbursement Support

One of the main reasons startups fail in digital health is underestimating regulation and reimbursement. Many think that having a working prototype is enough — but without MDR certification or a reimbursement pathway, hospitals cannot legally adopt their solution and payers won't cover it.
Support frameworks must therefore include regulatory experts (MDR, GDPR, data security), reimbursement specialists (HTA, payer requirements), and direct access to payers or insurers. Getting this guidance early prevents startups from wasting years on solutions that cannot be commercialized.

EXAMPLE

A Czech accelerator runs weekly "regulation clinics" where startups can book 1-hour sessions with legal and reimbursement experts. One startup working on an AI radiology tool discovered they needed additional clinical evidence for CE marking. By adjusting their study design early, they avoided a 12-month delay.

Hospital B (some experience)
Share your procurement and compliance checklist with startups before pilots.

Example: A hospital tells startups upfront that any solution must meet ISO 27001 data security standards and MDR classification before it can be tested. This saves time and avoids failed pilots.

Innovation Hub B-C (more experience)
Set up a "regulatory desk" with a small pool of on-demand experts. These could include a regulatory consultant, a reimbursement advisor, and a payer representative.

Example: A Polish hub offers startups access to a part-time MDR consultant who reviews technical documentation and an HTA specialist who helps them prepare cost-effectiveness dossiers.

Making support tangible means giving innovators a place to ask tough regulatory questions early — and ensuring hospitals and hubs don't waste resources on solutions that will never pass compliance or get reimbursed.

6.3 Mentorship & Knowledge Transfer

In Western Europe and the U.S., many innovation hubs benefit from serial entrepreneurs — people who have built and scaled multiple companies. In CEE, this experience is limited, which leaves startups without role models who know how to navigate fundraising, reimbursement, or international expansion. To close this gap, support frameworks must connect startups and hospitals with mentors who have already scaled products in pharma, MedTech, or health IT.

Mentorship isn't about giving general advice — it works best when structured and targeted, pairing innovators with mentors who can answer specific questions: How do I negotiate with a payer? How do I design a clinical study that will satisfy HTA requirements? How do I pitch investors in Western markets?

EXAMPLE

An Estonian hub builds a network of alumni founders who mentor younger startups. Each startup is matched with one mentor for business strategy (fundraising, scaling, negotiation) and one mentor for clinical context (integration into workflows, procurement processes). As a result, startups not only refine their pitches but also learn how their product fits into everyday hospital practice.

Hospital B (some experience)

Nominate 1–2 "digital champions" — a motivated clinician and/or manager — to mentor startups on hospital realities.

Example: A head nurse explains how patient data is entered daily, helping a startup redesign their app so it actually fits into the workflow. Universities often have their own innovation centers, and partnering with them can provide additional support, expertise, and resources, creating a bridge between academic knowledge, hospital operations, and startup innovation.

Innovation Hub B-C (more experience)

Build a structured mentorship program. Pair each startup with:

a. A business mentor (an entrepreneur, investor, or MedTech executive with scaling experience).
b. A clinical mentor (a doctor or nurse familiar with digital health integration).
c. Require mentors to meet startups at least once a month, and track progress with short reports.

Example: A Polish hub matches a cardiology AI startup with a former pharma executive (business mentor) and a practicing cardiologist (clinical mentor). Within six months, the startup secures its first €500,000 seed round.

Tangible mentorship in CEE means going beyond informal coffee chats. It's about structured programs with clear mentor roles, regular meetings, and measurable outcomes, ensuring knowledge is passed from experienced actors to the next generation of innovators.

6.4 Designing Validation Pathways

Validation is often the breaking point for digital health projects. Many pilots fail not because the technology is bad, but because data collection is inconsistent, KPIs are unclear, or results aren't credible to payers and regulators. Without strong validation, even a promising solution cannot move into reimbursement or scale internationally.

A good validation framework gives startups and hospitals ready-made tools: templates for pilot design, checklists for data collection, and shared KPI sets. This makes pilots more efficient, reduces wasted resources, and ensures the evidence collected is actually useful for reimbursement and scaling.

EXAMPLE

A Polish hub developed a "validation playbook" with standard templates. Startups use it to design pilots that track KPIs like readmission rates, staff workload, and cost per patient. Hospitals collect data in the same format, and results can be compared across projects. One wound-care startup used this playbook to demonstrate a 20% reduction in healing time, convincing an insurer to fund a larger rollout.

Hospital B (some experience)
Provide startups with standardized data-collection protocols before starting a pilot.

Example: Require every pilot to track at least three core indicators: (1) length of hospital stay, (2) readmission rate within 30 days, (3) staff time saved. This ensures results can be compared across pilots. Additionally, consider establishing sandbox environments in collaboration with hospitals and payers, allowing startups to test their solutions safely and under controlled conditions before full deployment.

Innovation Hub B-C (more experience)
Create a shared KPI repository that all startups and hospitals can use.

Example: A Czech hub builds an online dashboard with 10–15 standard indicators (clinical, economic, patient-reported). Every pilot uploads its results into the system, making it easy to benchmark across projects and countries.

Designing validation pathways is about removing guesswork. By standardizing how pilots are planned and how evidence is collected, CEE innovators can move faster from small pilots to large-scale reimbursement and adoption.

6.5 Building Collaborative Hub Networks

No single innovation hub can provide everything a startup needs — regulatory expertise, reimbursement & HTA expertise, investor access, hospital test sites, and payer connections. To truly accelerate digital health in CEE, hubs must collaborate across borders, pooling expertise and giving startups access to multiple countries through a single program. This prevents duplication, increases credibility, and makes scaling faster.

EXAMPLE

Innovation hubs in Poland, Lithuania, and Slovenia form a joint network. Startups admitted to one hub automatically gain access to test sites in all three countries. A cardiology AI startup from Poland first validates in a Lithuanian hospital, then collects payer feedback in Slovenia — all coordinated under one program. This cross-border setup makes the solution more attractive to investors and EU funders.

Hospital B (some experience)
Join at least one regional hub network to host international pilots.

Example: A Czech hospital partners with a Baltic hub, allowing Estonian startups to run small-scale pilots locally. In return, Czech startups get access to test sites in Estonia.

Innovation Hub B–C (more experience)
Formalize partnerships with 2–3 hubs in different countries. Sign MoUs to share access to hospitals, mentors, and regulatory experts.

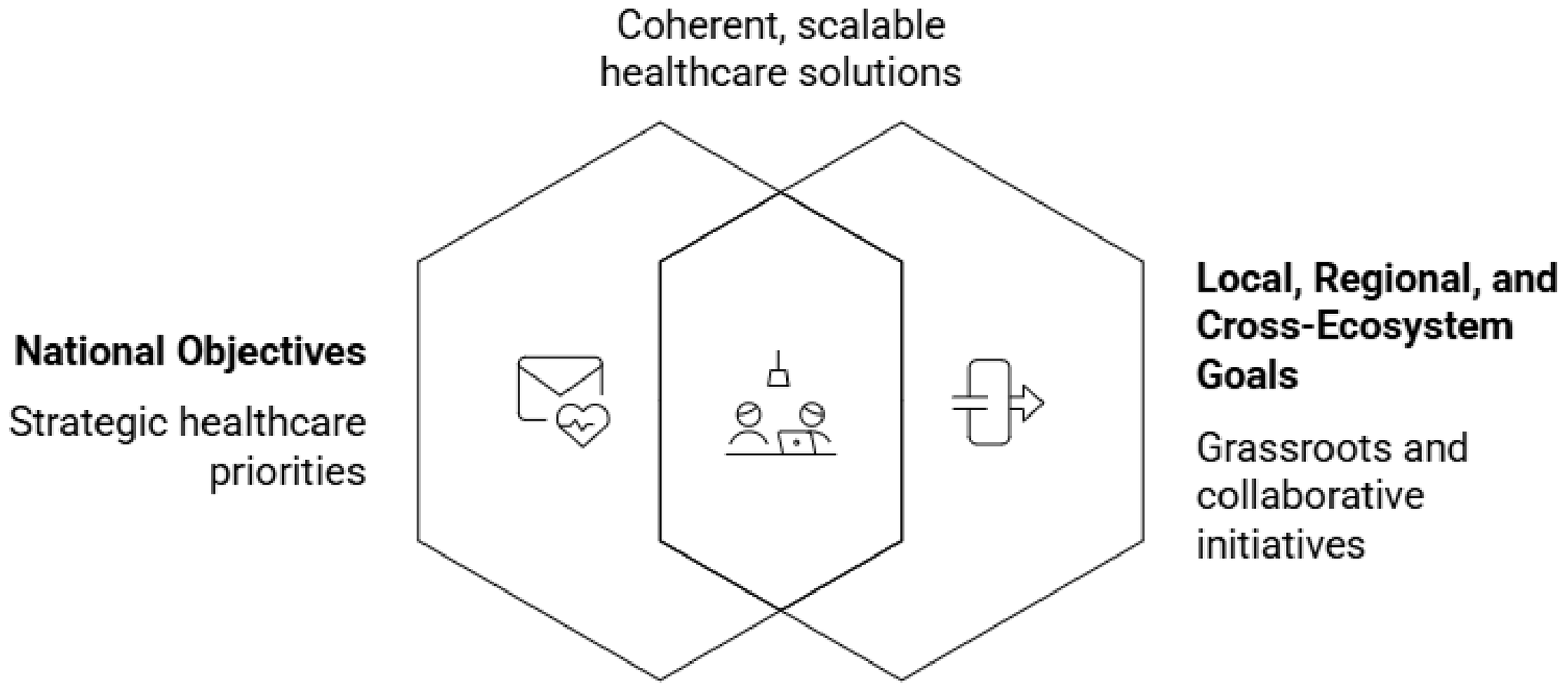
Example: A hub in Hungary partners with hubs in Austria and Romania, giving startups automatic entry to three ecosystems and fast-tracked pilot opportunities abroad.

Collaborative hub networks turn fragmented ecosystems into cross-border launchpads. For startups, this means quicker access to multiple markets; for hospitals, it means exposure to international innovation; and for the region, it means greater visibility and bargaining power in the European health landscape.

CHAPTER VII
Setting up an Ecosystem

Creating a digital health ecosystem means moving from individual pilots and ad-hoc projects to a structured environment where startups, hospitals, MedTechs, payers, and regulators collaborate continuously. In CEE, this is especially challenging: health systems are often fragmented, funding is scarce, and collaboration approaches are still under continued development and evolution. But building ecosystems is possible — and necessary — if innovations are to survive and scale.

This chapter provides guidance for hospitals and hubs that want to set up their own innovation ecosystems, covering governance, collaboration models, maturity stages, and sustainability.



Why This Matters

Without ecosystems, innovation remains fragmented. By setting up governance structures, collaboration models, and sustainable funding, hospitals and hubs in CEE regions can move from scattered pilots to structured, long-term innovation environments. This not only accelerates adoption but also positions CEE as a credible partner in European and global digital health networks.

7.1 Governance: Who Leads the Ecosystem?

An ecosystem without leadership quickly becomes a set of disconnected pilots. Governance means deciding who coordinates activities, who sets priorities, and how decisions are made. This role can be played by a hospital, an innovation hub, or a coalition of regional actors — but what matters is that responsibility is clear.

EXAMPLE

At the 1st Faculty of Medicine of Charles University and University Hospital Martin, dedicated innovation offices coordinate collaboration between startups, researchers, and healthcare payers. These offices ensure that every pilot aligns with the hospital's long-term digital and clinical strategy. By centralizing governance, they prevent duplication — for example, avoiding situations where two startups test similar telemedicine tools in different departments without coordination — and create a clear entry point for innovators seeking clinical validation.

Hospital A (no experience)
Appoint one innovation lead — a doctor, manager, or IT specialist — whose official role is to coordinate all digital health projects.

Example: A cardiologist is named "innovation lead" and becomes the point of contact for all startups approaching the hospital.

Innovation Hub A-B (early to mid experience)
Create a steering group with 5–7 representatives — one from a hospital, one from a payer, one from a startup, one from academia, and one patient advocate. Meet quarterly to review pilot proposals and decide which to prioritize.

Example: A Czech hub convenes a steering group that decides only pilots aligned with national chronic disease priorities will move forward.

Tangible governance means an appropriate group has the mandate to filter innovation proposals based on clear filtering criteria and assessment rubrics. This avoids wasted resources, prevents duplication, and ensures all projects push in the same direction.

7.2 Collaboration Models

An ecosystem grows stronger when partners understand how to work together in structured ways. Without collaboration models, hospitals, startups, and payers often run parallel pilots that duplicate efforts and waste resources.

Different models offer different levels of intensity and structure:

- Living labs: Controlled environments (e.g., one hospital department) where startups test solutions with clinicians and patients under supervision.
- Consortia: Formal partnerships between hospitals, universities, startups, and payers, often tied to EU-funded projects.
- Public–Private Partnerships (PPPs): Long-term agreements where hospitals, governments, and companies share risks and benefits of implementing innovation.
- Open innovation platforms: Digital or physical spaces where startups, researchers, and hospitals exchange ideas and match solutions to problems.

EXAMPLE

In Hungary, hospital partners with an accelerator and a local insurer to co-design pilots in telemedicine. Instead of each actor testing different solutions separately, they jointly select startups, run pilots, and pool the results — cutting duplication and speeding up adoption.

Hospital A (no experience)
Launch a small living lab in one department (e.g., cardiology or oncology) where startups can test solutions with staff and patients. Define simple rules: pilots run for 3–6 months, clinicians give structured feedback, and results are shared with hospital management.

Innovation Hub A–B (early to mid experience)
Organize multi-stakeholder roundtables every 6 months. Invite hospitals, startups, payers, and patient groups to discuss ongoing pilots and align priorities.

Example: A Czech hub holds a roundtable on oncology, bringing together 2 hospitals, 3 startups, and a payer to coordinate next year’s pilot activities.

What impact do different collaboration models (living labs, consortia, PPPs, open innovation platforms) have on the scalability and adoption of digital health solutions in CEE?

The scalability and adoption of digital health solutions in CEE are significantly influenced by various collaboration models, including living labs, consortia, public-private partnerships (PPPs), and open innovation platforms. Each of these models contributes uniquely to the ecosystem by facilitating innovation, fostering partnerships, and enhancing user engagement, which are critical for the effective implementation of digital health interventions.

Venture capital activity in the region is slowly growing, but usually concentrated in major hubs like Warsaw, Prague, or Budapest. Public–private partnerships and corporate innovation arms (for example, large pharmaceutical or MedTech companies) are becoming more active and may co-finance pilots.

Startups

Apply for small grants or join accelerator programs to build your first proof of concept.

Hospitals

Explore whether EU or national schemes can help co-finance pilot projects with innovators.

Large MedTech Companies

Partner with startups to co-develop and test solutions using external funding. This refers specifically to established MedTech corporations, as early-stage startups operating in the medtech space are considered separately in this document.

Innovation hubs

Act as connectors, guiding applicants toward funding opportunities and helping build consortia for EU proposals.

Living labs, as a collaborative model, serve as dynamic environments where stakeholders, including healthcare providers, technology developers, and end-users, converge to co-create digital health solutions. This direct engagement fosters a practical understanding of user needs and preferences, boosting acceptance and adherence to new technologies. Carrilho et al. assert that living labs enhance awareness among citizens about health issues and available digital solutions, thereby accelerating the development of validated solutions through co-creation (Carrilho et al., 2023). Such participatory approaches not only lead to more relevant digital interventions but also enable a quicker response to local health challenges, which is essential for scalability in diverse CEE contexts.

Consortia and PPPs further amplify the impact of digital health solutions by leveraging diverse expertise and resources. These collaborations often involve public health institutions, private sector innovators, and academic entities, creating a multidisciplinary approach that enriches the development and implementation phases of digital health technologies. Gray et al. highlight that collaborative care models, often stemming from such partnerships, improve system efficiencies and expand the reach of digital health tools, ultimately enhancing their adoption rates (Gray et al., 2022). Furthermore, Karamagi et al. emphasize the necessity of coordinated efforts in scaling up digital health interventions, which can better address health system challenges when multiple parties work together (Karamagi et al., 2022).

7.3 Maturity Stages of Ecosystems

Ecosystems don't appear fully formed — they grow step by step. Recognizing your stage helps you plan the next move instead of jumping too far ahead.

Nascent
Innovation happens in silos — one-off pilots, no coordination, no long-term strategy.

Developing
Pilots are coordinated, governance is emerging (e.g., innovation offices, steering groups), but funding is still project-based.

Mature
Structured programs exist, KPIs are tracked, funding is sustainable (hospital budgets, memberships, or PPPs), and the ecosystem connects internationally.

EXAMPLE

Estonia's e-health journey began with scattered, hospital-level digital projects in the early 2000s, largely funded through EU Structural Funds and small national modernization grants. By 2008, Estonia introduced a national e-prescription system, marking a significant milestone in its transition from fragmented initiatives to coordinated national infrastructure. However, at that stage, funding was still predominantly project-based, with most digital health activities implemented under temporary EU-funded programs or specific Ministry of Social Affairs initiatives rather than through permanent national budgets.

Over the following decade, Estonia consolidated its governance model and moved toward a more institutionalized structure. The establishment of the Health and Welfare Information Systems Centre (TEHIK) in 2017 provided stable operational funding, centralized oversight, and long-term strategy implementation.

Today, Estonia represents a mature digital health ecosystem, characterized by nationwide interoperability via the X-Road platform, electronic health records (EHRs) accessible to both patients and professionals, robust data exchange frameworks, and a clear legal foundation under the Health Information System Act. The system connects hospitals, primary care providers, pharmacies, insurers, and regulators in real time and is recognized internationally as one of the most advanced examples of digital health integration in Europe.

Estonia's trajectory reflects the evolution from project-based development (developing stage) to institutionalized, data-driven governance (mature stage)—a model demonstrating how consistent policy support and sustainable funding can transform digital health ecosystems from fragmented initiatives into cohesive, scalable systems.

Hospital A (no experience)
Assess your maturity. If you only run one-off pilots, you're at the nascent stage. Start by documenting all ongoing innovation projects and identifying overlaps.

7.4 Ensuring Sustainability

Many ecosystems in CEE start strong with EU grants or enthusiastic leaders, but collapse once the money runs out or champions leave. Real sustainability means making innovation part of the system itself — written into budgets, job descriptions, and long-term partnerships, not dependent on one project or person.

EXAMPLE

A Polish hub, "MediHUB" of the Medical University of Łódź, operates through a university-owned company that invests in startups by purchasing shares or initial prototype batches for use in university hospitals. This approach ensures that pilots, training, and evidence collection continue even after EU funding ends, as costs are covered locally and roles are embedded within the university's innovation structures.

Hospital A (no experience)

Set aside a small but dedicated annual budget for pilots. This shows staff and startups that innovation is not a "one-off project" but a permanent hospital activity.

Example: A cardiology ward gets €7,000 yearly to test small-scale digital tools like telemonitoring apps.

Innovation Hub A-B (early to mid experience)

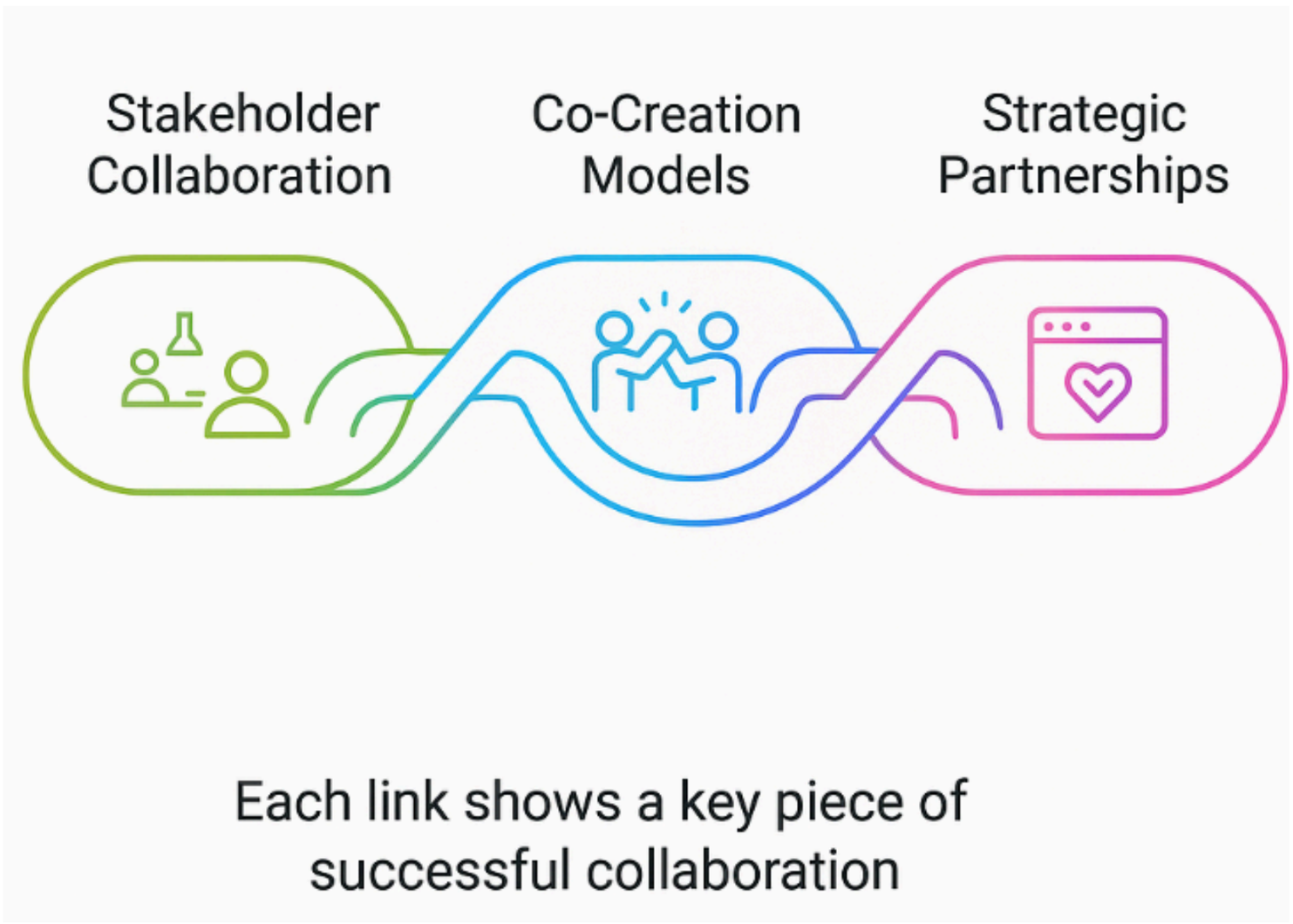
Instead of a simple membership model, the hub can participate directly in projects, gain national recognition to access public funding, or implement a success-fee model where fees are tied to the outcomes or adoption of supported digital health solutions.

Example: Each hospital pays €2,000 per year, startups €500, and payers €5,000. In return, members get access to pilot opportunities, events, and regulatory support. This spreads financial responsibility and makes the hub more sustainable.

Ensuring sustainability means treating innovation like core hospital work, not a side project. Even small budgets, formal roles, and shared membership fees can keep ecosystems alive long after initial funding ends.

CHAPTER VIII
Bringing stakeholders together

This chapter explores models and tools that make collaboration work in practice. It highlights living labs, pilot steering committees, public–private partnerships (PPPs), and matchmaking platforms that bring startups, hospitals, MedTechs, payers, patients, and innovation hubs into the same process. Each model is explained with examples from CEE and DIGIVITALITY, showing how collaboration moves from informal networking to structured partnerships.



Why This Matters

In CEE, digital health ecosystems face a recurring problem: fragmentation. Startups often approach hospitals without understanding clinical workflows. Hospitals test tools in silos, without involving payers or regulators. MedTechs may launch products without patient input, leading to poor adoption. Regulators and policymakers are typically brought in late, when redesign is costly.

The result? Promising pilots fail to scale. Trust breaks down, duplication wastes resources, and innovations remain stuck as “local experiments.”
Bringing stakeholders together is not only about communication, it is about shared ownership. When clinicians, managers, patients, payers, and innovators co-design pilots, everyone has a stake in the outcome. Hospitals get tools that fit their needs, startups gain credibility, payers see validated cost savings, and patients feel their voice matters.

This chapter provides practical methods to overcome fragmentation. It shows how CEE stakeholders can move from isolated projects to trusted partnerships, where every pilot builds credibility for long-term adoption.

8.1 Living Labs: Safe Spaces for Co-Creation

A living lab is a real clinical setting — one hospital ward, outpatient clinic, or community unit — where new digital health tools are tested under supervision and iteratively improved. Living labs use structured processes: defined timelines, clear feedback loops, and transparent data collection.

Living labs work because they:

- Reduce risk – clinicians and patients test solutions in a controlled way, limiting disruption.
- Build trust – staff and patients feel their voices matter in shaping the tool.
- Accelerate adoption – small adjustments during the pilot make solutions easier to scale later.

EXAMPLE

In Poland, a hospital transformed its cardiology ward into a living lab for telehealth tools. Nurses recorded usability issues daily, patients gave feedback on comfort and privacy, and IT staff checked system integration with existing EHR. Within 6 months, resistance to telemonitoring dropped significantly because staff felt co-ownership of the process.

Hospital B (some experience)

1. Pick one department (e.g., cardiology, oncology).
2. Define a pilot window of 3–6 months.
3. Set up a feedback routine: nurses fill a short checklist after use, patients complete a weekly survey, IT logs integration issues.
4. Share results monthly with hospital management.

Startup B (mid-experience)

1. Enter the living lab with a minimal viable product (MVP), not a finished tool.
2. Observe how clinicians and patients use it in practice.
3. Adjust features quickly (e.g., simplify interface, add local language).
4. Document changes and lessons learned for future reimbursement dossiers.

Innovation Hub B (intermediary-experience)

Draft living lab rules in cooperation with hospital: pilot duration, patient consent, data-sharing agreements, evaluation templates.
Set clear objectives and expectations with startup before it enter the living lab
Provide a shared KPI sheet (e.g., patient satisfaction, clinician time saved, error reduction).
Facilitate regular review sessions between startups and hospital staff.

A living lab is not just a “test site.” It’s a structured co-creation process where each pilot produces usable evidence, stronger trust, and solutions better adapted to real healthcare needs.

8.2 Pilot Steering Committees

Many digital health pilots fail because they are “owned” by a single group — usually one enthusiastic doctor or one startup team — while others are left out. This creates blind spots: clinicians worry about workload, managers worry about costs, patients are unsure about usability, and payers don’t see value.

A pilot steering committee solves this by bringing all critical voices together from the start: clinicians, hospital managers, IT staff, patients, and payers. When everyone helps define goals and evaluation metrics, results become credible for decision-makers inside and outside the hospital.

Hospital B (some experience)

1. Make it a rule that every pilot has a steering committee.
2. Minimum members: one clinician, one finance/management representative, one IT expert, and one patient representative.
3. Meet at kick-off, mid-point, and end of pilot to review progress.

Startup B (mid-experience)

1. Prepare monthly updates for the committee.
2. Share problems as well as wins (e.g., “integration took longer than expected, but usability feedback is positive”).
3. Ask the committee to validate your KPIs — don’t invent them alone.

MedTech B (mid-experience):

1. Use the committee to ensure your validation metrics match payer and hospital needs.

Example: Instead of only measuring “technical accuracy,” add metrics like “reduced readmissions” (payer interest) or “time saved per nurse” (hospital interest).

A steering committee makes a pilot multi-owned instead of single-owned. This not only increases credibility but also creates champions across the system who are more likely to support scaling.

8.3 Consortia & PPPs for Scaling

Some healthcare challenges — like cancer care, chronic disease management, or building national registries — are simply too complex and resource-intensive for a single startup or hospital. To tackle these, actors need to form consortia (formal alliances of hospitals, universities, startups, and payers) or public–private partnerships (PPPs), where hospitals, government bodies, and companies share both the risks and benefits.

Consortia and public–private partnerships (PPPs) enhance credibility: when insurers, hospitals, and companies jointly back a pilot, they can generate stronger and more comprehensive evidence to inform decision-making by policymakers and payers. These collaborations also reduce financial pressure on individual partners by sharing costs, expertise, and responsibilities.

EXAMPLE

In Hungary, a PPP joined a hospital, a national insurer, and a MedTech company to co-fund a telemedicine pilot for chronic patients. The hospital provided clinical expertise, the insurer covered part of the costs, and the MedTech delivered the platform. Because the results were jointly owned, the insurer trusted the data and moved forward with reimbursement discussions.

Hospital B (some experience)

a. Identify one strategic priority (e.g., oncology diagnostics, diabetes monitoring).
b. Invite at least one startup, one payer/insurer, and one MedTech partner to form a PPP.
c. Draft appropriate documentation (e.g., a Memorandum of Understanding) defining funding responsibilities and how results will be shared.

MedTech B (mid-experience)

a. Move beyond “selling devices” — offer co-investment in pilots.
b. Example: Provide your device at reduced cost for 6 months in exchange for being listed as a partner in a reimbursement dossier.

Innovation Hub B (mid-experience)

Act as the neutral convener. Organize workshops where hospitals present needs and startups/MedTechs pitch solutions.

Facilitate joint EU proposals (Horizon Europe, EU4Health). These require he participation of at least two countries and multi-stakeholder consortia — a natural way to formalize collaboration

Tangible consortia and PPPs mean moving from “one hospital, one pilot” to multi-actor projects with shared funding, shared ownership, and stronger credibility.

8.4 Matchmaking Platforms & Events

DIGIVITALITY

Most collaborations in CEE still start with cold emails or adh-hoc networking, which often misses the real needs of hospitals. Matchmaking platforms and events solve this by creating a structured process: hospitals present their actual challenges, and startups pitch solutions designed for those needs.This flips the dynamic: hospitals pull solutions to their most pressing problems.

EXAMPLE

During DIGIVITALITY, the consortrium organized a Demo Day where startups pitched their solutions in front of hospital representatives, MedTech companies, and investors. Hospitals could immediately signal interest in pilots, MedTechs explored partnership opportunities, and investors assessed scalability. Several pilots and collaborations were initiated directly after the event.

Hospital B (some experience)

Before an event, prepare 2–3 concrete problems (e.g., “high readmission rates in COPD,” “manual patient scheduling overload”).
Present these as short challenges, not long presentations.
Be open to unexpected solutions — even from outside your specialty.

Startup B (mid-experience)

Tailor your pitch to a specific challenge. Show not just features, but impact (e.g., “Our scheduling tool cut waiting times by 20% in another hospital”).
Bring a demo or case study so stakeholders can see how it works.
Avoid generic “sales pitches” — connect directly to the hospital’s pain points.

Innovation Hub B (mid-experience)

Ensure balance: at least as many hospitals presenting needs as startups pitching solutions.
Provide a template for hospitals to describe challenges and for startups to structure pitches.
Collect results — track how many pilots emerge from each event.

8.5 Building Trust and Commit

Collaboration in digital health doesn't fail merely due to technical shortcomings — it often falters because of a lack of product-market fit, insufficient validation evidence, or other critical factors for success. Clinicians may worry about increased workload, managers about costs, payers about unproven value, and patients about safety or privacy. Trust is earned through transparency, honesty, and small, demonstrable wins that build confidence over time.

Short-term, measurable improvements keep stakeholders engaged. Over time, co-ownership of results (where hospitals, startups, MedTechs, and hubs all share the data and the story) builds the credibility needed for reimbursement and scaling.

Hospitals

- Level A (no experience): Share a simple 1-page pilot summary with staff after each project. Include one success and one challenge.
- Level B (some experience): Standardize reporting across departments — publish quarterly pilot updates internally.
- Level C (advanced): Create an innovation dashboard showing results (cost, outcomes, adoption rates) accessible to all hospital leaders.

Startups

- Level A: Write a short usability + patient feedback note (2–3 key points) after each pilot.
- Level B: Produce 2–3 page structured reports with KPIs (outcomes, time saved, costs avoided).
- Level C: Publish pilot data in peer-reviewed journals or white papers to strengthen credibility with payers.

MedTechs

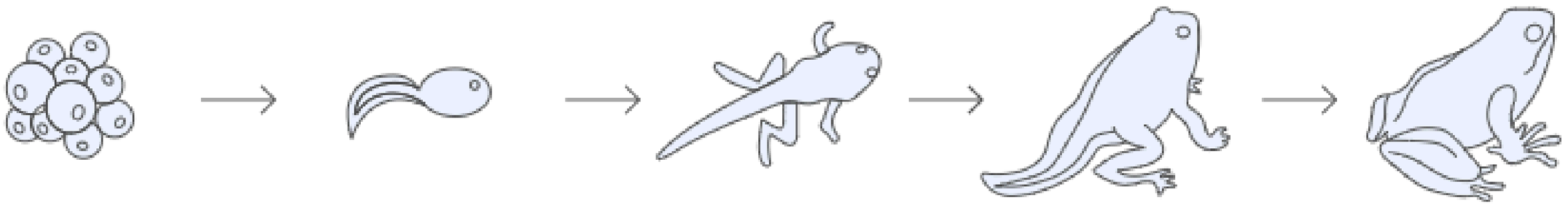
- Level A: Convert technical benefits into practical hospital terms (e.g., "saves 15 min per nurse per shift").
- Level B: Build cost–benefit scenarios based on hospital accounting data (e.g., "reduced bed days by 12%, saving €25,000 annually").
- Level C: Present multi-site or multi-country impact data directly linked to reimbursement criteria.

Innovation Hubs

- Level A: Collect short case studies (1 page) from pilots and share them with local partners.
- Level B: Create a regional case study repository (shared online, searchable).
- Level C: Facilitate cross-country evidence sharing (CEE-wide benchmarking reports, KPI repositories).

CHAPTER IX
Guidance for Supporting Startups

This chapter outlines a practical, stage-by-stage roadmap for moving digital health solutions from initial scouting to long-term adoption and scale-up. It builds on the DIGIVITALITY experience, where startups, hospitals, innovation hubs, and MedTech partners collaborated to design, test, and validate pilots in real healthcare settings.



Initial Phase
Scouting and recruitment of startups

Hospital Preparation
Data governance, ethics, staff engagement

Matchmaking
Aligning startup capabilities with hospital needs

Validation
Testing solutions in clinical environments

Solution Uptake
Showcasing validated solutions to stakeholders

While the DIGIVITALITY framework includes a five-dimension validation process (covering clinical, technical, user, organizational, and economic aspects), this chapter focuses instead on the implementation pathway — the sequence of actions and decisions that enable a pilot to evolve into a sustainable, adopted solution. The five dimensions of validation complement this roadmap by defining how each stage is assessed for quality and impact.

Why This Matters

Many digital health projects in CEE stop at small-scale pilots. Without a clear roadmap, results stay fragmented, and solutions never reach payers or international markets. The DIGIVITALITY approach proved that with a structured process — from scouting to Demo Day — pilots can generate credible evidence, attract payers, and build trust across stakeholders.

9.1 Scouting & Recruitment of Startups

The first step in the roadmap is scouting — actively identifying startups and digital health solutions that address pressing challenges within healthcare organizations. Priority areas can be defined based on regional or institutional needs, such as oncology, chronic disease management, remote care, or data integration. Open calls or targeted outreach can then be used to attract startups whose offerings align with these priorities, ensuring that the selection process is transparent and structured.

Scouting is not simply about identifying any startup; it focuses on matching supply with demand. Conceptually, this involves creating a marketplace of healthcare needs and innovative ideas, where hospitals articulate their priority challenges and potential solutions can be assessed for feasibility.

Feasibility considerations include technical capabilities of the startup, expected measurable outcomes in a pilot, and the alignment with regulatory and organizational constraints. In practice, innovation hubs or intermediaries can support this matching process by evaluating which startups are realistically able to deliver results, helping hospitals prioritize solutions that are both impactful and implementable. Where real-life examples exist, such as pilots coordinated by hospital innovation offices, they illustrate how structured scouting can efficiently align stakeholder needs with startup capabilities; where examples are hypothetical, the focus is on conceptual feasibility and lessons learned from similar implementations elsewhere.

EXAMPLE

A wound-care startup with an ultrasound insole for diabetic foot ulcers was initially selected because it matched a clear hospital demand (better wound healing), offered a tangible metric (healing time reduction), and had potential to scale beyond a single site. However, during the project it became clear that the startup was very early-stage and not fully prepared to collaborate with a hospital. The team was overwhelmed by participation in other programs and lacked sufficient staff to run the pilot effectively. This experience highlighted the need for a more thorough early-stage assessment and filtering of startups, ensuring they have the capacity, focus, and resources to engage meaningfully in clinical pilots.

Startup B/C (mid to advanced experience)

- Apply to programs where challenges are clearly defined upfront.
- Highlight in your application how your solution directly addresses a hospital need (e.g., “reduces readmissions for COPD by 15%”).
- Prepare basic validation evidence (even small case studies) to stand out.

Hospital B (some experience):

- Identify and prioritize 2–3 problem areas
- Share these problems with hubs so scouting efforts attract relevant startups.
- Involve clinical leads early to ensure problems are real and not just administrative.
- Consider using hackathons as an initial approach to surface innovative
- solutions and engage multidisciplinary teams in tackling
- healthcare challenges.

Innovation Hub B-C (mid to advanced experience):

- Design a structured scouting process: open call + targeted outreach.
- Use diverse channels (accelerators, EU networks, startup databases) to reach beyond local players.
- Apply selection criteria (problem fit, pilot feasibility, evidence potential, scaling readiness).
- Ensure diversity: not just digital apps, but also MedTech devices, AI, and hybrid models.

How does problem-driven scouting and recruitment of startups, aligned with hospital-defined needs, influence the quality and outcomes of digital health pilots in CEE?

The influence of problem-driven scouting and recruitment of startups aligned with hospital-defined needs is critical in enhancing the quality and outcomes of digital health pilots in Central and Eastern Europe (CEE).

Targeted scouting and recruitment of startups

A structured, need-driven recruitment process helps hospitals identify startups whose solutions align with specific operational challenges and clinical workflows. In CEE hospitals, this means focusing on interventions that are feasible to implement, measurable in impact, and capable of integrating with existing systems. While tailored digital health solutions have been shown to improve outcomes and adoption (Palacholla et al., 2019; Petrov et al., 2023), the practical focus in a roadmap should be on how to find, filter, and select suitable startups efficiently.

Practical considerations for scouting and recruitment:

- Define priority problem areas clearly with input from clinical leads to ensure relevance.
- Screen startups for readiness to engage in pilots, including staffing capacity, prior pilot experience, and alignment with hospital workflows.
- Use structured channels for sourcing candidates, such as open calls, innovation hubs, or hackathons.
- Assess the technical and operational feasibility of solutions early, including interoperability with hospital IT systems (EHR/LIS/PACS) and alignment with data standards like HL7 FHIR.
- Consider startup support needs, such as mentoring or co-development guidance, to prevent early-stage companies from being overwhelmed.
- Document the expected metrics and outcomes for pilots upfront, including patient impact, staff efficiency, and potential scalability.

By following these practical steps, hospitals can maximize the likelihood that recruited startups will deliver usable, scalable, and measurable digital health solutions while reducing the risk of misaligned or unsuccessful pilots.

9.2 Preparing Hospitals through Workshops

Many hospitals in CEE have little experience running structured pilots with startups. Clinicians may not know what data to collect, IT staff may be unprepared for integration, and managers may not understand the validation process. This often leads to delays or poor-quality evidence (EC).

To avoid these issues, DIGIVITALITY introduced pre-pilot workshops. The objective of the pre-pilot workshop is to prepare hospital staff for an upcoming pilot by clarifying the workflow, stakeholder roles, and the type of evidence required for validation. These workshops can involve the startup, particularly to explain the solution, answer technical questions, and align expectations, but the primary focus is on ensuring that hospital teams understand how the pilot will run and what is needed from them. By preparing hospitals early, pilots became smoother, faster, and generated more credible and actionable evidence.

Hospital B (some experience)

- Select a small team (1–2 clinicians, 1 IT staff member, 1 manager) to attend a pre-pilot workshop, ideally organized in cooperation with an innovation hub to ensure proper guidance on pilot readiness, workflows, and evidence requirements.
- Define clear roles and responsibilities (e.g., clinicians record outcomes, IT ensures system fit, managers monitor cost impact).
- Bring one concrete health-related challenge that the startup will address (e.g., “high readmissions in COPD patients”) so that preparation — including workflow mapping, data collection, and roles — is directly relevant to the real-world problem.

Innovation Hub B (mid-experience)

- Organize pilot-readiness workshops 1–2 months before pilots start, after pre-pilot workshops. These sessions focus on confirming hospital readiness, finalizing workflows, ensuring IT integration, and reviewing data-collection protocols with the startup.
- Cover basics: pilot timeline, KPI collection, validation dimensions (medical, business, technical, eHTA, market).
- Provide hospitals with templates for data collection and reporting.

Facilitate discussion between hospital staff and startups so expectations are aligned.

Preparing hospitals through workshops is about making them active partners, not passive test sites. When hospitals know the process, pilots run smoother, generate better data, and are more likely to convince payers and policymakers.

To make hospital–startup collaboration operationally feasible, pre-pilot and pilot-readiness workshops should move beyond theory and focus on how to implement cooperation in practice. The following guidelines provide a structured yet flexible framework for organizers and participants.

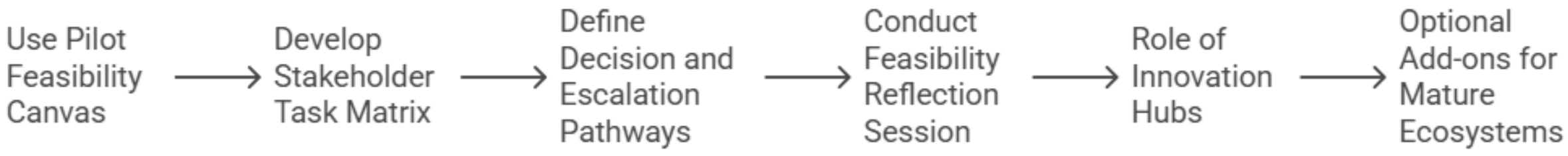
Practical guidelines for Pilot-Readiness Workshops

Each workshop should include a short, structured exercise where the hospital and startup jointly complete a Pilot Feasibility Canvas. This one-page template helps both sides clarify what will actually be required for the pilot to start and succeed.

It typically includes:

- Stakeholder roles: who does what (e.g., clinical lead, IT officer, innovation hub mentor, startup contact).
- Resources and constraints: staff time, devices, data access, ethical approvals, or integration dependencies.
- Key performance indicators (KPIs): agreed, measurable, and feasible outcomes (e.g., number of patients enrolled, reduction in readmissions, improved workflow time).
- Risk–mitigation mapping: identification of potential barriers (data protection, staff availability, IT delays) and mitigation actions.
- Readiness status: a “traffic-light” scale (green = ready, yellow = partial, red = pending) for immediate visualization of pilot maturity.

This tool ensures that each pilot starts with a realistic and shared understanding of operational feasibility.



Once readiness factors are mapped, the Stakeholder Task Matrix breaks the pilot down into concrete actions on a weekly timeline.

It includes:

- Workstream separation: clinical, technical, managerial, and evaluative tasks separated by color or symbol.
- Dependencies and milestones: e.g., “IT integration must be tested before clinical enrollment,” “first interim data report due in week 6.”
- Accountability: a named responsible person for each task (not just departments).
- Check-in rhythm: short biweekly updates between the startup, innovation hub, and hospital coordinator.

This makes project management transparent and allows the innovation hub to step in early if bottlenecks appear.

Many pilots fail due to unclear communication channels. Each workshop should establish a decision and escalation pathway, showing how operational or strategic issues move through the system.

For example:

- Operational level: Clinician ↔ Startup project manager
- Tactical level: Hospital coordinator ↔ Innovation hub liaison
- Strategic level: Hospital management ↔ Project steering committee

This simple structure prevents paralysis in decision-making, which is especially common when pilots involve external actors and sensitive clinical settings.

Every workshop should conclude with a 30–45-minute reflection block focused on identifying potential bottlenecks and defining immediate next steps.

Participants discuss:

- What might delay or derail the pilot in their environment?
- Which barriers can be resolved internally, and which require external support (hub, regulator, or funder)?
- What quick wins could demonstrate early progress?

Documenting this session creates accountability and learning material for future pilots, turning workshops into iterative learning platforms rather than one-off events.

Innovation hubs act as neutral facilitators and implementation coaches.

Their role includes:

- Preparing and moderating both the Pilot Feasibility Canvas and Task Matrix sessions.
- Ensuring hospitals and startups speak a “shared language” — clarifying technical, regulatory, and business aspects.
- Providing templates, data-collection forms, and examples of successful pilots from other sites.
- Supporting evidence documentation, so hospitals can use pilot results for internal decision-making or funding applications.

By ensuring that every actor knows what to do, when, and with what support, innovation hubs bridge the gap between conceptual readiness and practical execution.

In more experienced settings, additional layers of feasibility testing can be included:

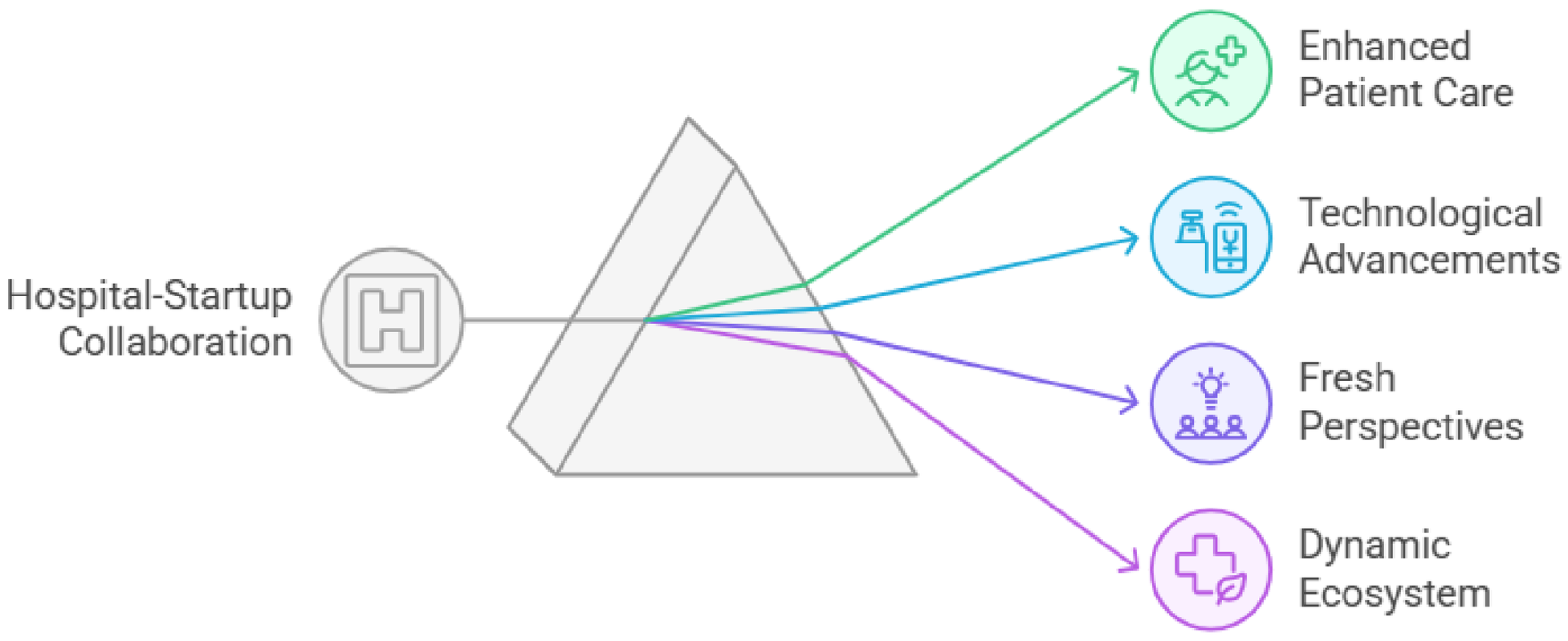
- Mini-hackathons or design sprints before workshops to jointly redefine hospital challenges and shortlist relevant startups.
- Digital twin simulations of workflow or IT integration to test feasibility before real deployment.
- Peer-learning sessions where hospitals share lessons learned from prior pilots, helping others avoid common pitfalls.

9.3 Matchmaking Hospitals & Startups

After scouting and recruiting a diverse pool of startups — and training hospitals on how to effectively collaborate with them — the next step is to matchmake startups with hospitals. This stage serves as a readiness checkpoint for both sides, ensuring that hospitals are operationally prepared and that startups have the capacity, maturity, and resources to engage in a structured pilot. The matchmaking process verifies alignment in goals, technical feasibility, and evidence expectations before formal pilot setup begins.

Hospitals (some experience)

- Define clear priorities: Identify 2–3 concrete clinical or operational challenges (e.g., “reduce COPD readmissions,” “improve oncology data integration,” or “optimize remote patient monitoring”).
- Prepare a challenge brief: Summarize each challenge in one page, including background, current workflow, barriers, desired outcomes, and key performance indicators. This document helps startups understand your real needs.
- Engage proactively: Present your challenges during the matchmaking session rather than waiting for unsolicited offers. This ensures that the dialogue is driven by genuine clinical demand and results in higher-quality matches.
- Involve the right team: Bring at least one clinician, one IT specialist, and one project coordinator to the session to provide diverse perspectives during discussions.



Startups (mid-experience)

- Study hospital briefs before the session to assess whether your solution aligns with the described needs and to identify potential integration challenges.
- Tailor your presentation: Prepare a short pitch or demo that directly addresses the identified problems — highlighting use cases, evidence from prior pilots, and measurable benefits.
- Be transparent: Clearly communicate your solution’s current readiness level (TRL), what support you need from the hospital, and the expected outcomes of collaboration.
- Show usability: Whenever possible, demonstrate a prototype, mock-up, or demo environment — hospitals value practical evidence more than technical descriptions.

Establishing meaningful collaboration between hospitals and startups without the involvement of an innovation hub would be extremely difficult — and in many cases, nearly impossible. Hospitals often lack the dedicated personnel, experience, and frameworks needed to evaluate the readiness of startups, manage innovation processes, or ensure compliance with data protection and procurement regulations. Startups, on the other hand, may struggle to navigate the complex structures of healthcare institutions, communicate effectively with clinical stakeholders, or understand the evidence requirements necessary for validation. Innovation hubs bridge this gap by acting as trusted intermediaries — they translate clinical needs into innovation opportunities, help startups adapt their technologies to hospital environments, and provide neutral coordination to align timelines, expectations, and deliverables.

Innovation Hubs (mid to advanced experience)

- Coordinate the matchmaking process by collecting hospital challenge briefs, verifying their clarity, and sharing them with startups in advance.
- Provide structured templates: Offer both hospitals and startups clear formats for challenge descriptions and solution pitches to ensure comparability and consistency.
- Facilitate structured sessions: Organize the event in three parts: (1) hospitals present challenges, (2) startups pitch tailored solutions, and (3) moderated discussion for Q&A and feedback.
- Ensure fairness and quality: Use a transparent scoring system to assess fit, feasibility, scalability, and validation potential. Share results with participants to guide next steps.
- Support follow-up: After matchmaking, facilitate bilateral meetings and help formalize cooperation through Memoranda of Understanding or pilot agreements, ensuring that discussions translate into concrete pilot projects.

Hubs are motivated to engage in this process because it aligns directly with their mission to accelerate innovation, strengthen regional ecosystems, and attract external funding opportunities such as Horizon Europe or EIT Health. Their involvement ensures that partnerships are not only initiated but also managed efficiently, producing credible results that can later be scaled or implemented sustainably. Without hubs, the matchmaking process would likely remain fragmented, informal, and dependent on personal networks rather than a systematic and transparent collaboration framework.

Key takeaway

Successful matchmaking requires preparation, transparency, and clear roles.
Hospitals must articulate real problems, startups must present realistic and evidence-backed solutions, and innovation hubs must serve as neutral facilitators ensuring that collaborations are feasible, structured, and lead to measurable pilot outcomes.

9.4 Validation in Five Dimensions

In digital health, successful validation is not only about proving that a technology "works" — it's about demonstrating that it brings measurable value to patients, clinicians, and payers. In the DIGIVITALITY approach, pilots were validated across five complementary dimensions, creating a comprehensive evidence base that supports scaling, reimbursement, and long-term adoption. Each dimension requires active participation from different stakeholders — startups, hospitals, innovation hubs, and evaluators — whose collaboration determines the overall quality and credibility of results.

Medical Validation

Who leads: Hospitals (clinical teams)
Who supports: Startups, innovation hubs

Hospitals are primarily responsible for verifying the clinical safety, usability, and effectiveness of digital solutions. Clinicians collect data on patient outcomes (e.g., healing times, adherence, recovery rates) and assess how the technology integrates into daily workflows.

- Early-stage startups often require more guidance from clinicians to adjust their solution for real-world hospital use and to define relevant outcome measures.
- Experienced startups can co-design clinical protocols and proactively propose KPIs.
- Innovation hubs coordinate communication and help structure data collection templates to ensure consistency across sites.

Business Validation

Who leads: Innovation hubs
Who supports: Startups, Med-Techs

Innovation hubs play a central role in helping startups understand the business context of healthcare. They guide startups in refining value propositions, pricing models, and sustainability plans, while Med-Techs managers provide data on operational costs and savings potential.

- Early startups need structured support to translate technical value into economic terms.
- More mature startups can simulate different reimbursement or partnership scenarios.
- The goal is to produce a clear business case demonstrating cost-effectiveness and resource optimization.

Technical Integration

Who leads: Startups
Who supports: Innovation hubs (as facilitators) and hospital IT teams

This dimension ensures the solution works seamlessly with hospital infrastructure — especially Electronic Health Records (EHRs), Laboratory Information Systems (LIS), or Picture Archiving and Communication Systems (PACS).

- Early-stage startups often need to adapt their software to interoperability standards (e.g., HL7 FHIR).
- Hospitals provide technical requirements, data security standards, and integration testing environments.
- Innovation hubs mediate between both sides, managing technical documentation, sandbox environments, and data governance compliance.

eHTA (Early Health Technology Assessment)

Who leads: Independent evaluators or research institutes
Who supports: Startups, hospitals, and Innovation hubs

An early health technology assessment analyzes the potential cost-effectiveness, safety, and patient outcomes to support future reimbursement discussions.

- Startups provide clinical and usage data.
- Hospitals validate assumptions with real-world evidence.
- Innovation hubs ensure data quality and liaise with external evaluators (such as Syreon Institute).
- This step generates standardized evidence aligned with frameworks such as the European Taskforce for Harmonised Evaluation of DMDs and the EDiHTA project.

Market potential

Who leads: Innovation hubs
Who supports: Payers, policy advisors, and hospital management, Med-Techs

The final dimension frames results in the language of payers and policymakers. Evidence from pilots is translated into metrics such as cost savings, workflow efficiency, and population health impact.

- Hospitals highlight operational benefits and improved patient satisfaction.
- Startups prepare investment and reimbursement arguments.
- Innovation hubs synthesize outcomes into policy briefs or scale-up proposals, aligning them with national or regional health priorities.

Each stakeholder has a distinct and essential role in the validation process. Hospitals provide clinical and operational insight; startups deliver technological solutions and data; innovation hubs ensure structure, documentation, and coordination; independent evaluators bring credibility.
For early-stage startups, the focus should be on learning hospital processes, adapting technology, and generating preliminary clinical data.
For more experienced startups, emphasis shifts to scalability, regulatory compliance, and economic evidence.
Likewise, less experienced hospitals benefit from hands-on mentorship and innovation hub support in defining KPIs and managing pilots, while advanced hospitals can lead multi-site validations and mentor others in the ecosystem.
By engaging all stakeholders systematically across these five dimensions, validation becomes not only a technical exercise but a strategic pathway to sustainable adoption and payer recognition.

9.5 Showcasing validation results: From Pilot to Market Entry

The ultimate impact of a pilot is realized only when validated results reach the right decision-makers. In DIGIVITALITY, this process was formalized through Demo Days and Pitching Events, structured to bridge the gap between pilot validation and real-world implementation. These events go beyond typical startup showcases by focusing on evidence, feedback, and actionable next steps, rather than storytelling alone.

Demo Days

Aim: Present pilot results, including clinical evidence, patient outcomes, and cost implications, to hospitals, payers, investors, MedTech companies, and policymakers.

Format: Startups demonstrate validated solutions, highlighting measurable benefits, while hospitals and pilot sites provide feedback and endorsements.

Value for startups: Enables creation of a reimbursement- and market-ready pitch, demonstrating not only efficacy but also financial and operational impact.

Value for hospitals: Offers insights into innovations that could improve workflow, reduce readmissions, enhance patient satisfaction, and informs potential collaborations.

Value for investors/payers: Evidence-driven presentations reduce uncertainty, showing which solutions have real-world impact and scalability potential.

Pitching Events

Aim: Shorter, targeted sessions focused on securing investment or partnership commitments.

Format: Typically more formal, timed pitches followed by Q&A with investors, innovation hubs, or corporate partners.

Pitching events are primarily fundraising-oriented, while Demo Days emphasize validation feedback and stakeholder engagement. Both formats are complementary components of a matchmaking ecosystem.

A structured roadmap is essential for startups to translate pilot validation into successful market entry. This roadmap should guide progression from the pilot stage, where the focus is on validating clinical efficacy, patient outcomes, workflow integration, and cost implications, to regional or national adoption, demonstrating reproducibility of results across multiple sites and generating broader clinical and operational evidence. The final goal is market entry with reimbursement readiness, where startups are prepared to engage payers, hospitals, and regulatory authorities by clearly demonstrating both health benefits and financial value.

A key component of this roadmap is the preparation of evidence briefs. Startups should produce concise, digestible documents of 2–3 pages tailored to each stakeholder group, including investors, payers, and hospitals. These briefs should summarize clinical outcomes (e.g., improved recovery rates, reduced readmissions), cost savings (per patient, per ward, or per procedure), and patient-reported outcomes (satisfaction, adherence, quality of life). Evidence should be presented in a way that addresses the specific needs and decision criteria of each audience, strengthening the case for adoption and investment.

Startups also need to clearly define their scaling requirements, including regulatory approvals for national or international deployment, operational integration (training, IT systems compatibility, workflow adaptation, and change management), and strategic partnerships with hospitals, insurers, MedTech companies, or technology vendors. A detailed timeline and milestone plan should outline the steps from pilot completion to market entry, ensuring all necessary preparations are in place.

Innovation hubs and coordinators play a crucial role in this process by organizing and hosting Demo Days and Pitching Events at the end of each validation cycle. These hubs facilitate matchmaking by connecting startups with investors, hospital decision-makers, and other key stakeholders, providing curated introductions and pre-event briefings. Post-event follow-up is critical: hubs share recordings and materials, maintain structured contact lists, track engagement progress, and support follow-up meetings or negotiations to increase the likelihood of funding or partnerships. They also help startups prepare tailored pitches, evidence briefs, and reimbursement-ready documentation to maximize impact during these events.

Evidence from DIGIVITALITY and similar initiatives indicates that structured showcasing and pitching events significantly enhance the visibility of validated startups, accelerate access to funding and partnerships, and provide actionable feedback from hospitals and payers that strengthens product integration into care pathways. These events build credibility and trust, with public endorsements from hospitals, payers, and policymakers increasing confidence among future stakeholders. For hospitals, participation ensures early exposure to innovations, the ability to influence development to meet clinical needs, and access to collaborations that can improve patient care and operational efficiency. For startups, the roadmap and structured events provide a clear path from validated proof-of-concept to scalable, reimbursed, and commercially viable products, effectively closing the gap between pilot success and market entry.

CHAPTER X
Conclusion & Recommendations

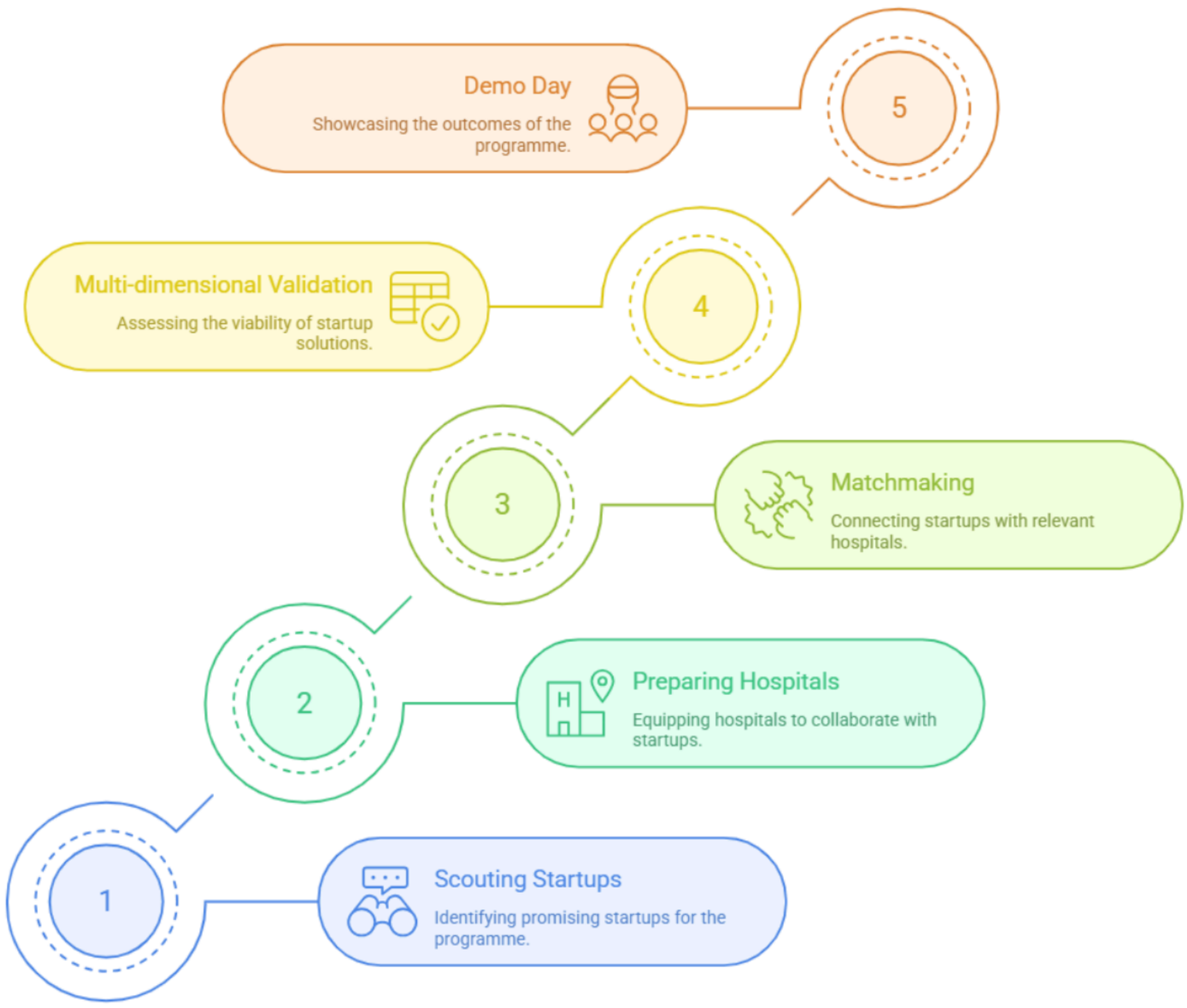
This final chapter distills the key lessons, tools, and recommendations from DIGIVITALITY. It highlights what worked best in assessing startup maturity, how the validation framework was implemented, and what improvements are needed for replication and scaling across Europe. The focus is on actionable insights for hospitals, startups, MedTech companies, innovation hubs, and policymakers.

Why This Matters

Without structured reflection, innovation programmes risk being one-off experiments. DIGIVITALITY created a model that combined lightweight tools, coaching, multi-dimensional validation, and transparent collaboration. These elements gave startups, hospitals, and hubs a clearer pathway from early-stage ideas to mature solutions. By capturing lessons and recommendations here, the Playbook ensures that future programmes can avoid pitfalls, replicate what worked, and move faster toward scaling healthtech innovation in CEE and beyond.

10.1 What We Learned from DIGIVITALITY

DIGIVITALITY demonstrated that healthtech validation in CEE is possible and impactful when done through a structured, transparent process.



The programme followed a clear journey — from scouting startups → preparing hospitals → matchmaking → multi-dimensional validation → Demo Day — and several lessons stood out:

- Startup maturity assessment is essential.

Many startups claimed to be “market-ready,” but the Initial Assessment (a structured Google Form completed with hub coaches) revealed gaps in areas such as go-to-market strategy, financial runway, or regulatory awareness. This reality check across four dimensions — market, investment, product/clinical, regulatory — allowed support to be tailored instead of generic.

A startup rated itself at TRL 8, but during the assessment it became clear that regulatory approval was missing. The correction helped redirect resources toward certification.

- Validation must be multi-dimensional.

Focusing only on clinical results is not enough. DIGIVITALITY's five-dimension framework ensured startups generated evidence that hospitals, investors, and payers could all use:

a. Medical (safety, usability, outcomes)
b. Business (model, pricing, scalability)
c. Technical (interoperability with hospital IT)
d. eHTA (cost-effectiveness, value for money)
e. Market (payer language, policy alignment, product-market fit, market readiness, go-to-market)

A rehab app validated patient adherence (medical), prepared a reimbursement case (business + eHTA), and demonstrated integration potential with EHRs (technical) identifying the journey to paying customers.

Lightweight tools are more effective than complex platforms. Instead of building a heavy digital system, DIGIVITALITY relied on simple, shared tools: the Initial Assessment form and the Business Feasibility Validation and Development Plan (BFVDP) in spreadsheet file. These tools enabled all hubs to onboard startups consistently and track progress without high overhead. However, lessons learned showed that the BFVDP still required further simplification to be fully effective.

Startups updated their BFVDPs quarterly with progress on market traction, regulatory steps, and fundraising. This gave coaches a quick, comparable snapshot of maturity.

- Trust is built when processes are clear.

Matchmaking sessions, mentoring, and the final Demo Day worked because roles and expectations were explicit. Hospitals knew what data to collect, startups understood how to present evidence, and mentors had defined goals. Transparency created accountability and credibility across the ecosystem.

At Demo Day, a hospital publicly endorsed a startup's solution after being involved from the first workshop to the last validation step — a level of trust that would not have been possible without this structure.

DIGIVITALITY showed that with structured maturity assessments, multi-dimensional validation, lightweight tools, and transparent collaboration, even fragmented CEE ecosystems can produce credible evidence and foster trust between startups, hospitals, payers, and investors.

10.2 Defining Startup Maturity in Healthtech

DIGIVITALITY

DIGIVITALITY confirmed that startup maturity in healthtech is multi-dimensional and cannot be captured by TRL (Technology Readiness Level) alone. TRL gives a technical snapshot but misses critical aspects such as market fit, investment readiness, or regulatory progress.

To address this, the programme developed a framework where maturity = progress + readiness across five interconnected dimensions, aligned with the validation framework used throughout the programme:

1. Medical / clinical validation – demonstrating safety, efficacy, and improved patient outcomes.
2. Business viability – ensuring financial sustainability, reimbursement readiness, and operational feasibility.
3. Market potential – assessing target population, adoption barriers, competitive landscape, and real-world applicability.
4. Regulatory – defining regulatory pathways and milestones for CE/MDR or FDA approval.
5. Technical / operational readiness – product development status, integration into clinical workflows, scalability, and infrastructure readiness.

This model was operationalised through the Initial, Midterm, and Final Assessments. Each assessment combined structured metrics (quantitative data such as users, revenue, or runway) with reflective questions (qualitative insights such as pivots or strategic priorities). This approach offered a balanced reality check, correcting exaggerated self-assessments and highlighting gaps that might otherwise remain hidden.

The process delivered three key benefits:

- Accuracy – by combining hard data with guided discussions, the assessments produced a more realistic maturity picture than self-reported TRL levels.
- Actionability – results fed directly into the Business Feasibility Validation and Development Plan (BFVDP), ensuring that support was tailored to actual needs.
- Progress tracking – repeating the assessments allowed hubs and startups to monitor growth over time and adjust development plans dynamically.

Tips for future programmes:

- Always assess startups across all four dimensions; do not rely on TRL alone.
- Use structured, coach-led assessments instead of self-reporting, to surface blind spots and reduce bias.
- Keep tools lightweight and easy to update, so they can be applied consistently across hubs without technical barriers.
- Connect the assessment directly to support plans (like BFVDP) and update them regularly, so the results remain a living reference rather than a one-off exercise.
- Align the framework with international standards (e.g., KTH IRL, TRL, Healthcare Innovation Cycle framework including Innovation Maturity Levels (IMLs) to enable comparability across regions and cohorts.
- Segment activities by maturity stage: validation for early-stage (TRL 4–6), market entry for mid-stage (TRL 7–8), and scaling for late-stage (TRL 9).

10.3 Lessons on the Validation Framework

DIGIVITALITY's validation framework showed that business validation can be structured without becoming heavy or bureaucratic. The combination of assessments, planning tools, expert input, and public milestones gave startups both discipline and visibility.

The core value of the framework was its ability to turn assumptions into evidence: teams moved from saying "we believe customers need this" to showing "we have proof through pilots, interviews, or contracts." This shift created credibility for both investors and hospitals.

Key lessons that emerged:

- Lightweight structure works – tools like the Initial Assessment and BFVDP kept all actors aligned without requiring complex platforms.
- Learning with application: webinars and workshops were useful not only for content, but also as entry points to mentoring and opportunities for pilot testing. Demo Day acted as a closing milestone where startups shared their achievements with stakeholders
- Visibility motivates – Demo Day gave startups a tangible deadline to prepare validated business plans, helping focus their efforts.

Challenges also surfaced:

- Over-complexity of planning tools – the BFVDP tried to capture too much detail, which reduced its use as a living document.
- Uneven mentoring – despite access to expert pools, some startups barely used mentoring hours, while others lacked enough.
- Maturity mismatches – startups at TRL 4 and TRL 9 were in the same track, leading to frustration for both sides since their requirements for business and clinical validation were not aligned.

Tips for future frameworks:

- Keep tools simple: focus on 3–4 core goals per startup, updated regularly, rather than detailed activity breakdowns.
- Introduce basic tracking for mentoring (hours used, key outcomes) and adjust allocations based on startup maturity and complexity.
- Segment participants by stage: provide validation modules for early-stage teams and scaling modules for late-stage teams.
- Embed assessments into international standards (e.g., KTH IRL, TRL, Healthcare Innovation Cycle IML) so maturity levels are comparable across countries and programmes.
- Ensure each cohort has a clear progression pathway from entry to Demo Day, with milestones that match their level of readiness.

10.4 How This Can Be Replicated or Scaled

DIGIVITALITY proved that its validation framework is lightweight enough to be portable yet structured enough to deliver credibility. Because it uses simple, standardised tools and a guided coaching approach, the model can be transferred to other EU regions, national programmes, or hospital innovation offices without the need for heavy infrastructure.

Why it works for replication:

The DIGIVITALITY framework works because it relies on standardised and low-barrier tools. Simple resources can be rolled out anywhere, which makes onboarding consistent across hubs and ensures that progress is tracked in a uniform way. This removes the need for heavy, expensive platforms and keeps the process accessible.

Another strength is its focus on evidence-based reality checks. Instead of relying on assumptions, startups are asked to demonstrate whether their claims are backed by data. This approach helps teams identify gaps early, pivot when necessary, and refine strategies before investing significant resources.

The framework also prioritises guided coaching instead of self-reporting. Startups often overestimate their readiness, but trained hub coaches can challenge these perceptions, highlight blind spots, and provide a more accurate maturity assessment. This makes the process far more reliable than questionnaires alone.

Support is delivered through a blended model that combines cohort-based learning with tailored mentoring. Workshops and webinars cover common gaps such as go-to-market strategies or product validation, while one-to-one expert sessions allow for deep dives into startup-specific challenges. This ensures both breadth and depth of support.

Finally, the framework creates accountability and visibility through public milestones. Demo Day serves as a clear endpoint for startups, pushing them to consolidate results into validated business plans. At the same time, it provides hospitals, investors, and payers with an opportunity to see which solutions have real potential, creating momentum for scaling beyond pilots.

The DIGIVITALITY framework can be scaled because it is simple, structured, and adaptable. By combining easy-to-use tools, guided coaching, and visible milestones, it can be applied by accelerators, hubs, and hospitals to create comparable, credible validation pathways across Europe.

Tips for scaling the framework:

- National accelerators: Embed the Initial Assessment and BFVDP as part of onboarding, so every startup begins with a reality-based maturity profile.
- European innovation hubs: Share a common assessment template to make results comparable across countries and cohorts.
- Hospital-led innovation offices: Adapt the five-dimension validation model (medical, business, technical, eHTA, market) to evaluate all in-house pilots consistently.
- Policy-level use: Link the framework to EU-wide standards like KTH IRL,TRL or Healthcare Innovation Cycle IMLs to allow benchmarking across different innovation programmes.
- Scalability measure: Use Demo Days not just locally but cross-border, pooling startups from several countries to create visibility at the European level.

9.5 Key Recommendations by Stakeholder

Hospitals should take a proactive role in innovation by integrating dedicated innovation offices with clear responsibilities for piloting and validation. To ensure consistency, they can adopt DIGIVITALITY's KPI templates—tracking outcomes such as length of stay, readmission rates, and staff time saved—across all pilot projects. Hospitals should also move beyond being passive test sites by jointly generating and leveraging evidence with startups and sharing results transparently with payers, helping to accelerate reimbursement discussions.

Startups Assessments and validation tools should not be seen as formalities but as opportunities for structured reflection. Used well, they create rare moments for teams to pause, check progress, and realign strategy. Future programmes should emphasise this benefit and link assessments directly to tailored support, so startups both capture honest insights and translate them into reimbursement-ready validation data (combining clinical, cost, and patient outcomes). Demo Day can then act as a platform not only for investors but also for hospitals and payers who are critical for scaling.

MedTech companies can increase their impact by partnering with startups early in the validation process, co-developing evidence packages that strengthen credibility for reimbursement. They should also provide support in areas such as eHTA preparation and technical integration, helping startups meet the expectations of hospitals and payers more quickly. Aligning pilots with global reimbursement dossiers ensures that local validation efforts also contribute to international market strategies.

Innovation hubs are the glue holding ecosystems together. They should adopt lightweight assessment and tracking tools, such as the Initial Assessment and a simplified BFVDP, to provide a consistent baseline across startups. Stronger mentor matching is needed, along with better monitoring of how mentoring is used, to ensure value is fully realised. Finally, hubs can strengthen their role by connecting validation results to international frameworks like KTH IRL, TRL or or Healthcare Innovation Cycle IMLs, making maturity assessments comparable across cohorts and geographies.

Final Reflection

DIGIVITALITY showed that CEE can lead in building structured validation models for healthtech, combining pragmatic tools, collaborative governance, and transparent evidence generation. If future programmes refine startup maturity assessments, simplify business validation tools, and connect more directly to policy frameworks, they will not only support startups but also accelerate systemic change in European healthcare.

Annexes, Tools, and References

1. Policy-Ready Startup Framework for Sustainable and Scalable Health Innovation
2. Stakeholder Mapping and Pilot Readiness for Digital Health Innovation
3. Technical Readiness, Pilot Formalization, and Demo Days as Scaling Instruments
4. Stakeholder-Specific Guidance and Value Propositions
5. References

Policy-Ready Startup Framework for Sustainable and Scalable Health Innovation

This appendix provides a practical framework to help startups align their solutions with the needs of policymakers, hospitals, and payers. While startups often focus on product features and technological novelty, health systems require evidence of system-level impact. The Policy-Ready Startup Framework supports innovators in translating innovation into outcomes that matter at national and European levels.

To be successful in real healthcare systems, startups must present their solutions not only as innovative products, but as answers to concrete system-level challenges. The Policy-Ready Startup Framework supports startups in structuring their value proposition in a way that is understandable and relevant for hospitals, policymakers, and payers.

Start with a clear definition of the system problem your solution addresses. This should go beyond a clinical or technical issue and describe the broader challenge for the healthcare system. Typical examples include hospital overcrowding, rising costs of chronic disease management, long waiting times for diagnosis and treatment, workforce shortages, or fragmented care pathways. A strong problem definition shows that the startup understands healthcare as a system and positions the solution within national and European priorities.

Next, describe your contribution to system-level improvement. Explain how your solution leads to measurable changes in the way healthcare is delivered. This can include shorter hospital stays, fewer avoidable admissions, improved continuity of care, or better use of limited resources. Wherever possible, express these effects in indicators that hospitals and payers can monitor and evaluate.

Then, provide a projection of long-term value. Show how your solution can generate sustainable benefits over time, such as reduced complication rates, lower overall healthcare expenditure, increased efficiency of medical staff, and better patient outcomes. Even simple models or scenario-based estimates help decision-makers understand the strategic impact of your innovation.

Ensure alignment with Value-Based Healthcare (VBHC) and Health Technology Assessment (HTA) requirements. Your evidence should demonstrate not only clinical effectiveness, but also economic value and organizational impact. This means linking your data to outcomes that matter for reimbursement decisions, such as cost-effectiveness, budget impact, and comparative performance against existing solutions.

Translate your technology into policy-relevant language. Avoid describing your solution only in technical terms. Instead, show what these technologies mean for the system. An “AI prediction model” should be presented as a tool for reducing complications and avoiding unnecessary admissions. “Remote monitoring” should be framed as a way to improve continuity of care and strengthen prevention. “Automation” should be linked to workforce efficiency and cost containment. This translation allows non-technical stakeholders to immediately understand the relevance of your innovation.

Startups that apply this framework move from product-centric communication to system-oriented impact communication. As a result, they gain faster acceptance from hospitals, stronger interest from investors, and higher credibility with policymakers. Most importantly, they significantly improve their chances of entering reimbursement pathways and achieving long-term market adoption.

Sustainability as a Measurable Innovation Parameter

Sustainability should be treated as a measurable system benefit rather than a marketing concept. Startups should assess whether their solution:

- Reduces unnecessary patient travel and hospital visits
- Lowers energy consumption or paper usage
- Decreases staff workload or overtime
- Minimizes waste (e.g., disposable sensors, printed documentation)
- Includes credible digital scheduling and resource optimization
- Demonstrates a long-term cost-saving model

This approach allows hospitals to justify innovation adoption in terms of:

- Environmental sustainability
- Operational efficiency
- Financial responsibility

Case Study 1: BioMedicalLab – Sustainable Digital Architecture

BioMedicalLab demonstrated how modular digital architectures can support both ecological and operational sustainability. Their solutions function either independently or integrated into existing hospital systems, which:

- Reduced IT burden for hospitals with limited digital maturity
- Enabled adoption without costly infrastructure upgrades
- Supported scalable and resource-efficient transformation
- This approach is particularly relevant for healthcare systems in Central and Eastern Europe.

- Higher credibility with health authorities
- Stronger positioning for international expansion

Case Study 2: UCare Medical – Quantifiable Financial Sustainability
UCare Medical's AI diagnostic tool achieved:

- A 20% reduction in average hospital stay duration
- Early prediction of acute kidney failure
- Cost savings exceeding €2,000 per patient
- This provides:
- Clear economic value for hospitals
- A strong reimbursement argument for payers
- Direct alignment with financial sustainability objectives

Case Study 3: VR Vitalis – Evidence for Digital Therapeutics
VR Vitalis illustrated how early clinical evidence and structured outcome measurement enable long-term adoption. During DIGIVITALITY:

- Clinicians tracked functional outcomes and patient experience
- Evidence supported value-based healthcare discussions
- Data created a foundation for future reimbursement
- This demonstrates how pilots can evolve into policy-relevant evidence.

Strengthening Market Access Through Long-Term Evidence Planning
Startups can significantly improve their market access strategy by planning outcome measurement early. Recommended actions include:

- Collecting baseline data before pilot implementation
- Designing evidence packages aimed at payers, not only clinicians
- Embedding outcome tracking into the product (e.g., automated dashboards)
- Demonstrating economic value through simple cost-effectiveness models
- Preparing policy-oriented evidence summaries for national and EU programs

Startups that generate longitudinal, policy-ready evidence gain:

- Competitive advantage in reimbursement negotiations
- Higher credibility with health authorities
- Stronger positioning for international expansion

Stakeholder Mapping and Pilot Readiness for Digital Health Innovation

Digital health pilots succeed when the right people are involved from the very beginning. Beyond clinical and managerial roles, hospitals should identify a small group of “hidden” but critical stakeholders who often determine whether a pilot can move forward. These include IT and cybersecurity leads, who define what is technically feasible and safe; the Data Protection Officer, who ensures compliance with GDPR, consent, and data-sharing rules; ethics committee representatives, especially when patient data or new workflows are involved; and nurse leaders or ward managers, who usually feel the operational impact most strongly. If these actors are not engaged early, pilots are likely to be delayed, blocked, or quietly abandoned. A simple rule applies: no pilot should start without at least one named contact person for IT, data protection, and clinical operations.

For startups with little or no hospital experience, preparation is the first step toward credibility. Before approaching a hospital, startups should be able to answer three questions clearly and in non-technical language. What exact problem does the solution solve for this specific hospital? What does the startup need from the hospital to run a pilot, such as data access, staff time, IT integration, or ethical approval? What concrete benefits will the hospital see in the first three to six months, not only in the long term? Startups that can communicate these points simply are far more likely to secure pilots and build trust.

Hospitals that are new to innovation pilots can reduce uncertainty by creating a basic “pilot starter pack.” This should include a short description of hospital priorities, such as chronic care, oncology, or workflow efficiency; a list of key contacts including a clinical lead, IT representative, and DPO; basic technical and security requirements; and a short template for pilot proposals describing the problem, expected outcomes, and required resources. This starter pack helps filter proposals, align expectations, and ensure pilots support strategic goals instead of becoming isolated experiments.

Stakeholder mapping should always be connected to regulatory readiness, infrastructure constraints, and strategic alignment. Early involvement of IT, data protection, clinicians, and where possible payers helps ensure that pilots comply with medical device regulations, integrate with existing hospital systems, and contribute to national or regional health priorities. In this way, stakeholder mapping becomes a practical bridge between early validation, strategic planning, and real-world implementation.

Startups should create a simple stakeholder engagement plan before starting a pilot. This plan should identify one or two contacts in each key group: clinician, nurse, IT, manager, DPO, and ideally a patient representative. For each group, startups should define what is needed, such as approval, feedback, data access, or visibility. Communication should be tailored: clinicians care about workflows and outcomes, IT teams about integration and security, and managers about costs and risks. Even a one-page plan shared with the hospital partner signals professionalism and reduces misunderstandings.

Engagement should follow a clear timeline rather than involving everyone at once. Before the pilot, hospitals should identify internal champions and clarify decision-making authority, while startups validate the problem with clinicians and patients and share a basic data and risk plan with IT and the DPO. During the pilot, teams should maintain short feedback loops with frontline staff and regularly share interim results with managers and, where possible, with payers. After the pilot, results should be presented to hospital leadership and ideally to regional authorities or insurers. Both sides should then decide whether to scale, redesign, or stop the project and document the reasons. This phased approach prevents “black box” pilots that lack visibility and institutional support.

For international expansion, startups should prepare a Minimum Viable International Evidence Package. This package should include a short summary of clinical evidence from at least one completed pilot, a simple economic model showing cost savings or efficiency gains, real-world user data on adoption and usability, a description of IT integration requirements and system architecture, and, where possible, feedback from clinicians in more than one country. This package shortens the path to trust, regulatory review, and reimbursement discussions abroad.

Blended financing models can accelerate pilot deployment. Some accelerators combine EU grants, such as Horizon Europe or EU4Health, with local venture capital. This allows startups to de-risk early pilots using public funding while attracting private co-investment for scaling. For example, a diabetes monitoring startup received €50,000 in EU seed funding and later secured €500,000 from a local VC to run pilots in three hospitals. Such models demonstrate how public and private funding can work together to speed up adoption.

Finally, every stakeholder meeting should be supported by a concrete demonstration. Startups should bring a working demo or a real case study that shows how the solution functions in practice. Instead of generic sales pitches, innovators should demonstrate how the interface, data fields, or workflows can be adapted to the hospital’s specific environment, such as matching terminology used in the EHR system. Showing real customization and direct relevance to hospital pain points builds credibility and accelerates decision-making.

Technical Readiness, Pilot Formalization, and Demo Days as Scaling Instruments

Rule 1: No pilot without technical readiness.

Clinical potential alone is not sufficient to start a pilot. Every solution must first be verified against the hospital's real IT environment. A common failure example was the AKI diagnostics startup that developed an AI tool for early prediction of acute kidney failure. The solution showed excellent clinical promise and strong alignment with hospital strategy, including the potential to reduce costly ICU stays. However, the pilot was cancelled because the startup required data input in a modern standard (HL7 FHIR), while the hospital's EHR system could only export data in an outdated proprietary format. Integration was technically impossible.

Interoperability and data standards must be verified before any pilot agreement is signed.

Before confirming a pilot, always run a Technical Readiness Check:

- What data formats does the startup require?
- What formats can the hospital export?
- Is middleware or conversion realistic within time and budget?
- Are cybersecurity and access rules compatible?
- Can integration be done without major infrastructure changes?

If any answer is unclear, the pilot is not ready to proceed.

Rule 2: Matchmaking must end with formal commitment.

Matchmaking events and meetings only create value if they result in concrete next steps. Innovation hubs should actively support follow-up by facilitating bilateral meetings and helping partners formalise cooperation through:

- Memoranda of Understanding (MoU), or
- Pilot agreements.

Before every hospital–startup meeting, require both sides to submit their Top 3 Critical

Questions or Concerns, for example:

- Data security and GDPR responsibility
- IT integration effort
- Staff training time
- Pilot budget ownership
- Regulatory classification

This forces transparency and ensures meetings focus on solving "Go / No-Go" issues, not repeating introductions.

Rule 3: Meetings must be decision-oriented, not exploratory.

Pilot preparation meetings should aim to confirm feasibility and commitment.
They should answer:

- Can we run this pilot?
- Under what conditions?
- Who is responsible?
- By when?

Structure meetings around:

1. Technical feasibility
2. Legal and data protection readiness
3. Operational capacity
4. Budget ownership
5. Timeline to pilot start

If one of these is blocked, the pilot should pause immediately.

Rule 4: Demo Days present evidence, not promises.

Aim:
Demo Days are designed to showcase validated pilots to:

- Hospitals
- Payers
- Investors
- MedTech companies
- Policymakers

Format:

- Startups present measurable results:
  - Clinical outcomes
  - Patient impact
  - Cost implications
  - Operational efficiency
- Hospitals provide feedback and endorsements
- Innovation hubs summarize lessons learned and scaling recommendations

This transforms pilots into policy- and reimbursement-ready assets.

Rule 5: Demo Days must create market readiness.

Demo Days are not startup pitch events in the traditional sense. They are evidence validation platforms where real-world results are translated into system-level value. Their purpose is not to showcase ideas, concepts, or promises, but to demonstrate what has been proven in practice. Demo Days mark the moment when a pilot moves from experimentation to credibility. They are the point at which innovation becomes understandable and actionable for payers, policymakers, hospital management, and industry partners.

Demo Days serve as the bridge between successful pilot execution and large-scale adoption. They transform local results into transferable evidence that can support reimbursement, procurement, and policy decisions. This is why every presentation must be structured around outcomes, not features.

Each startup presentation must answer four core questions in a clear and measurable way:
First, what changed in clinical practice?

This includes improvements such as earlier diagnosis, reduced complications, shorter length of stay, better patient monitoring, or more efficient workflows. The focus should be on how care delivery is different because the solution was implemented.

Second, what changed in costs or efficiency?
Startups should show whether the pilot reduced hospital costs, optimized staff time, decreased resource consumption, or improved patient throughput. Even simple estimates help decision-makers understand economic impact.

Third, what data supports these claims?
All statements must be backed by pilot data, such as outcome metrics, usage statistics, comparative baselines, or qualitative feedback from clinicians and patients. Evidence is the core currency of Demo Days.

Fourth, what would be needed to scale nationally or regionally?
This includes regulatory readiness, integration requirements, staffing needs, financing models, and reimbursement pathways. This step transforms pilot results into a realistic implementation roadmap.

Together, these four elements create a reimbursement-ready and procurement-ready narrative. They allow hospitals and payers to see not only that the solution works, but that it can be realistically adopted within healthcare systems.

Stakeholder-Specific Guidance and Value Propositions

This appendix translates eHTA scoping review outputs into practical, role-specific guidance that can be directly used by hospitals, startups, payers, innovation managers, and partners when designing and implementing hospital-startup collaboration and innovation pilots.

It is designed as a reusable template that can be filled for any future pilot or startup.

Stakeholder Group	Role in Pilot	Decision Power	Primary Interest
Hospital Management	Strategic sponsor	Budget approval, priority setting	Financial sustainability, reputation
Clinical Leaders	Clinical validation	Adoption in care pathway	Patient outcomes, workflow
IT Department	Technical enabler	System integration approval	Data security, interoperability
Finance Department	Economic validator	Procurement and payment model	Cost savings, ROI
Startup Team	Solution provider	Product design, delivery	Market access, evidence generation
Payers / Insurers	Long-term buyer	Reimbursement eligibility	Cost-effectiveness
Patients	End users	Acceptance and adherence	Safety, usability
Innovation Hubs / Accelerators	Process facilitators	Pilot quality control	Success rate, scalability

Each stakeholder section follows the same structure:

1. What this stakeholder cares about
2. What they need to see before approving a pilot
3. How the innovation should be framed to them
4. What documents or data are required
5. Typical risks & mitigation

Hospital Management / Board

They care about:

- Financial sustainability
- Strategic positioning
- Risk minimization
- Capacity utilization

They need to see:

- Clear financial logic
- Alignment with hospital strategy
- No reputational or regulatory risk

Hospital Management / Board

Key focus:
Hospital management evaluates innovation pilots primarily through the lens of financial sustainability, strategic alignment, and institutional risk.

Value proposition:
“The pilot demonstrates a clear and controlled financial logic, supports the hospital’s strategic objectives, and can be implemented without exposing the organization to legal, financial, or reputational risk.”

Required inputs:

- A concise one-page financial impact estimate outlining potential savings, cost avoidance, or revenue generation
- A clearly defined pilot budget and implementation timeline
- Formal legal approval, including GDPR compliance and data protection clearance

Risks to be actively managed:

- The pilot unintentionally reduces activity-based revenues or reimbursable procedures
- Hidden IT, infrastructure, or personnel costs emerge during implementation

Clinical Leaders / Medical Staff

Key focus:
Clinical stakeholders assess whether the innovation improves patient care, maintains safety standards, and integrates smoothly into everyday clinical practice.

Value proposition:
“The solution delivers measurable improvements in patient outcomes while fitting naturally into existing clinical workflows and responsibilities.”

Required inputs:

- A clearly defined comparator (current standard of care or alternative technology)
- Quantified expected clinical benefits (e.g. reduced healing time, improved diagnostic accuracy)
- A clinical workflow map showing how the solution is embedded into routine practice

Risks to be actively managed:

- Increased documentation or administrative burden for clinicians
- Unclear clinical responsibility or accountability for the use of the solution

IT Department

Key focus:
IT departments are responsible for ensuring system stability, cybersecurity, and compliance with data governance standards.

Value proposition:
“The pilot can be integrated safely into the hospital’s digital ecosystem without disrupting existing systems or compromising data security.”

Required inputs:

- Definition of interoperability standards (e.g. HL7, FHIR, APIs)
- Clear data flow diagrams describing how information is transferred and stored
- Hosting architecture and cybersecurity documentation

Risks to be actively managed:

- Incompatibility with legacy hospital systems
- Unclear ownership of integration, maintenance, and technical support

Finance Department

Key focus:
Finance teams evaluate whether the pilot is financially predictable, compliant with procurement rules, and economically justified.

Value proposition:
“The pilot operates within a defined financial envelope and either reduces operational costs or creates new revenue opportunities.”

Required inputs:

- Unit cost definitions (per patient, per bed, per month, or per procedure)
- Financial comparison with the current standard of care
- A clearly articulated payment model scenario

Risks to be actively managed:

- Open-ended or poorly controlled pilot costs
- Lack of a credible reimbursement or financing pathway

Startup Team

Key focus:
Startups use pilots to validate their product, generate real-world evidence, and test their business model.

Value proposition:
“The pilot provides structured real-world validation, high-quality evidence, and reference use cases that support market entry and scaling.”

Required inputs:

- Clearly defined success metrics and evaluation criteria
- Access to anonymized clinical and operational data
- Explicit ownership of pilot coordination and responsibilities

Risks to be actively managed:

- Undefined evaluation framework
- The pilot turning into unpaid service provision without strategic value

Payers / Insurers

Key focus:
Payers assess whether the innovation delivers measurable health benefits at an acceptable or improved cost.

Value proposition:
“The solution reduces long-term healthcare expenditure while improving patient outcomes and system efficiency.”

Required inputs:

- A structured economic model
- A clinically relevant comparator
- Cost-offset and budget-impact calculations

Patients

Key focus:
Patients care about safety, dignity, transparency, and ease of use.
Value proposition:
“The innovation improves quality of care without increasing physical, cognitive, or administrative burden for patients.”
Required inputs:

- Clear informed consent procedures
- Transparent privacy and data-use information
- Usability and acceptability testing

Innovation Hubs / Project Manage

Key focus:
Innovation intermediaries ensure that pilots are well designed, scalable, and transferable.
Value proposition:
“The pilot establishes a structured, replicable model that can be reused across hospitals and innovation programs.”
Required inputs:

- A formal pilot evaluation framework
- A lessons-learned and risk log
- A scalability and replication checklist

Stakeholder Readiness Checklist
Before launching any pilot, confirm that all critical dimensions are addressed:

Clinical
Is the comparator clearly defined?

Technical
Is system integration technically feasible?

Financial
Is the payment model fully described?

Legal
Is data protection and GDPR compliance approved?

Organizational
Are roles and responsibilities clearly assigned?

Strategic
Does the pilot align with hospital strategy?

Each stakeholder group evaluates the success of an innovation pilot through a different primary performance lens. Hospital management focuses on overall financial impact, typically measured by indicators such as the amount of money saved per patient. Clinicians assess value through clinical benefit, expressed for example as a percentage improvement in patient outcomes compared to standard care. IT departments concentrate on integration efficiency, where key indicators include deployment time and the ease of system implementation. Finance departments look at budget predictability, often using metrics such as cost per treated case to understand financial control and sustainability. Startups view success mainly in terms of market validation, with a critical KPI being the conversion rate from pilot projects into long-term commercial contracts.
Payers and insurers, in contrast, prioritize cost-effectiveness, most commonly assessed through metrics such as the cost per quality-adjusted life year (QALY) gained.

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DIGIVITALITY aims to enhance the digital transformation of healthcare systems in Central Europe by developing and implementing innovative digital solutions. The project focuses on fostering cooperation among hospitals, innovation hubs, startups, and large MedTech companies to improve patient care, efficiency, and accessibility of healthcare services. By creating practical guidelines, pilot actions, and knowledge exchange platforms, DIGIVITALITY supports the adoption of digital tools and encourages sustainable innovation in the region.

For detailed and current contact details of project partners, visit our knowledge portal: