Interreg North Sea

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DigiH4A

Digi H4A
Digital Health for All

Digital Health market access across the North Sea Region

WP 2.1: State of the art – Digital Health Market Access across Europe Report

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Authors: Biotech Santé Bretagne, Bax Innovation

Proofreaders: Bax Innovation, Eurasanté, National Teams, external reviewers

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Summary & Introduction

This report sits within the DigiH4A – Digital Health for All initiative of the Interreg North Sea programme, a three-and-a-half-year EU-funded collaboration launched in October 2024 to accelerate the region's adoption of digital health solutions. DigiH4A brings together health authorities, research institutions, and innovation actors to tackle two system-level bottlenecks that repeatedly stall scale: establishing workable reimbursement pathways and building trust among providers and patients with real-world evidence (RWE). By 2027, the consortium aims to deliver a strategic action plan that helps payers and decision-makers integrate digital solutions into routine care, while working hands-on with more than 200 SMEs to refine cost-benefit methods that prove value in real health-system conditions.

The stakes are high. Ageing populations, rising chronic disease, and constrained public budgets make the case for digital health not merely attractive but necessary; analyses cited by the project estimate that in Germany alone, well-implemented digital health could yield savings of up to €35 billion per year. Yet without clear routes to reimbursement and trust-building evidence, promising tools stall in pilots, never reaching patients at scale. DigiH4A is designed to close this gap by aligning technical innovation with credible economic evaluation and policy-ready implementation guidance across the North Sea region.

This state-of-the-art report on digital health market access across Belgium, Denmark, Germany, France, the Netherlands, and Sweden directly serves DigiH4A's mission. It complements the WP1.1 mapping of reimbursement by comparing the practical market-entry factors that shape whether SMEs can progress from pilot to paid deployment, for example by examining evidence expectations, procurement dynamics, data-protection and interoperability requirements, and the timing realities of budget cycles. The analysis blends desk research with interviews conducted by national teams, distilling frontline lessons that help SMEs plan credible studies, target early adopter regions, and frame value in country-specific terms—inputs that are essential to both reimbursement model design and the project's forthcoming strategic action plan.

In short, what follows is not only a comparative reference for companies expanding within the consortium's six markets; it is a building block for DigiH4A's broader objective of making digital health adoption faster, safer, and more cost-effective across the North Sea. By grounding policy ambitions in lived market experience, the report provides high level insights, actionable guidance to innovators and concrete signals to policymakers on how to streamline access without compromising efficiency, trust, security, or clinical value.

Please keep in mind that the insights and recommendations in this report are based on many sources including interviews with selected SMEs in the digital health market, two per country. While these provide valuable perspectives, they may not fully represent the entire landscape or apply universally to all digital health innovations.

Readers should view these insights as supplementary guidance rather than a definitive overview of market entry, regulatory processes, or commercialisation. For tailored advice, further research and consultation with local experts are strongly recommended.

Comparative cross-country analysis

This first section is dedicated to a comparative cross-country analysis between the six countries participating in the DigiH4A project, enriched by the insights of two major macro-level actors in the European health sector (COCIR and MedTech Europe).

Market overview and structural typologies

In this part, we observe the market typology and some overall comparative data about the six countries' health and digital health sectors.

Digital health reimbursement in the DigiH4A countries falls into three broad governance models: centralised national pathways (e.g., strong state-led listing and HTA), decentralised regional systems (where regions/municipalities procure and fund), and insurer-led contracting (where payers negotiate coverage and tariffs). This structural choice shapes how quickly innovations reach patients, who the key gatekeepers are, and whether scale comes via a single national route or through region-by-region agreements. Against this backdrop, the map of healthcare spending as a share of GDP helps contextualise each country's fiscal room and priorities, framing how these models are likely to operate in practice.

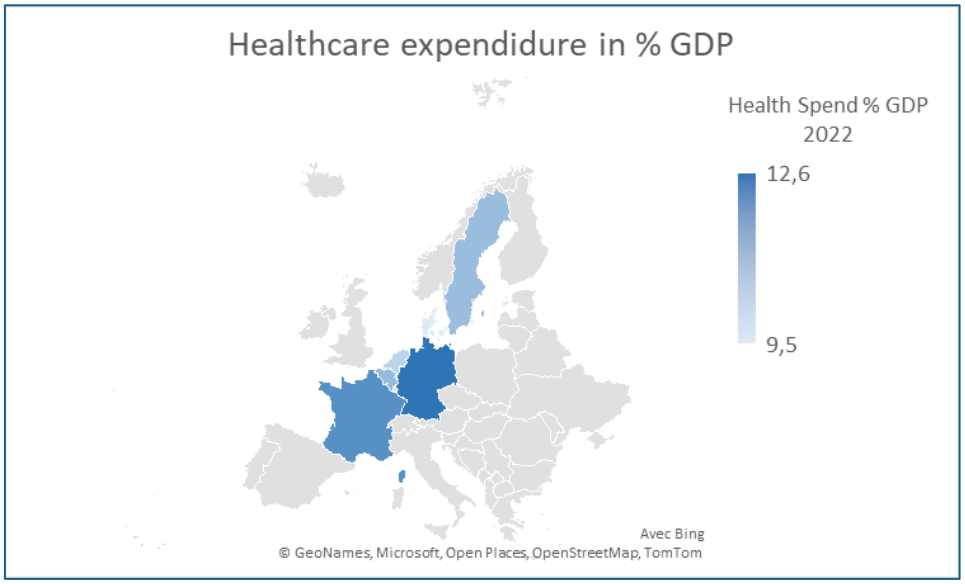

Figure 1: *Healthcare expenditure in % GDP (Average in the European Union: 10.4%)*

EU Average	10,4%
Denmark	9,5%
France	11,9%
Germany	12,6%
Netherlands	10,01%
Sweden	10,07%
Belgium	10,8%

Figure 2: *Eurostat (2023). Healthcare expenditure statistics - overview*

The digital health market access landscape

The digital transformation of healthcare represents a core ambition for the European Union, promising to enhance care for citizens and improve system efficiency. The DigiH4A project is designed to accelerate this transition, specifically by tackling the integration of innovative solutions into the reimbursement frameworks of North Sea region healthcare systems. To effectively address these local challenges, it is essential to first understand the broader European landscape. Therefore, to build the most complete picture, we supplemented project-level information with insights from digital health experts who provide a systemic EU-level perspective: MedTech Europe (the European trade association representing the medical technology industries) and COCIR (the European trade association representing the medical imaging, radiotherapy, health ICT, and electromedical industries). This chapter provides a high-level overview of the digital health market access environment, outlining the systemic barriers innovators face—primarily driven by market fragmentation—and underscoring the consensus on the urgent need for greater harmonisation.

There was agreement that market access is fundamentally defined by the fragmentation of EU markets. Both industry associations confirmed that the interpretation of national reimbursement systems' specificities remains the most significant barrier, forcing companies to adopt costly and resource-intensive market-by-market strategies. According to the COCIR interviewee, this challenge is amplified by a pervasive lack of predictability, which stems not only from the patchiness of national legislation but also from the limited availability of the expertise required by notified bodies to assess such new applications.

Another area of convergence was the urgent need for greater harmonisation of technical standards and clinical evidence requirements to lower these barriers. This is further highlighted by *`Future governance of medical technologies in Europe`*, a joint discussion paper released in March 2025 by key EU MedTech associations (MedTech Europe, AESGP, COCIR, FIDE, EUROM, EEAR). COCIR further emphasised that deep-seated cultural factors will always play a role in the pace of adoption, and that the burden of generating robust clinical and economic evidence remains a major hurdle for innovators.

In terms of SMEs, both interviewees noted that they occupy a particularly challenging position within this ecosystem compared with the larger digital health companies that are members of both organisations. In the MedTech and digital health sphere, their agility is often negated by structural barriers. Their smaller size makes it difficult to develop the expertise needed to navigate the complex regulatory landscape and, crucially, to build the trust with payers and providers that is required for widespread adoption.

In this context, both MedTech Europe and COCIR identified the countries in the North Sea region as early adopters of digital health technology, with some of the more advanced and structured reimbursement frameworks in the EU. The MedTech interviewee noted that they were part of a European taskforce working on the harmonisation of required evidence and assessment criteria for digital health and had selected these countries as case studies. Thus, they provide a clearer, but still challenging, pathway for digital health solutions.

Looking ahead, major legislative initiatives such as the European Health Data Space (EHDS) regulation and the AI Act will require significant investment in new infrastructure and processes from all Member States. It is therefore expected that, in the coming years, additional Member States will follow those in the North Sea region and develop the necessary infrastructure and processes, ensuring innovation is not stifled by unfunded mandates.

Digital health adoption and maturity landscape

As mentioned in the previous chapter, the six countries participating in the DigiH4A Interreg North Sea project all demonstrate a robust baseline in digital health, but with important variations in maturity and implementation. Across the region, there is a notable prevalence of digital health tool adoption: for example, the use of digital health applications is widespread in France, where 90% of patients utilise digital tools, and Belgium leads in online prescription rates at 91.8%. Similarly, in the Netherlands, more than 90% of general practitioners offer e-consultations, and Denmark stands out with over 70% of patients maintaining digital contact with their GPs. These high rates of adoption are underpinned by generally advanced Electronic Health Record (EHR) systems in France, Denmark, the Netherlands, and Belgium. E-prescription systems are also highly used in Denmark, the Netherlands, and Belgium. Conversely, while Germany is making noticeable progress in these areas, it continues to lag behind the frontrunners.

Patient acceptance is similarly positive throughout much of the region. In Denmark, Germany, Belgium, the Netherlands, and France, digital health solutions are met with high levels of confidence and user satisfaction, creating fertile ground for the expansion of these technologies. The commitment to digital health is further evidenced by ongoing investments in infrastructure and sustained efforts to promote digital literacy among both healthcare professionals and patients. Each of the six countries has signalled a strong intent to continue advancing their digital health capabilities.

However, when examining the landscape on a country-by-country basis, significant differences emerge, particularly in terms of digital maturity and governance structure. Denmark is widely recognised as having the most mature digital health ecosystem, with the Netherlands and Sweden not far behind in terms of digital health strategy and implementation. Belgium and France are making steady advancements but have yet to reach the digital sophistication of their northern and western neighbours. Germany continues to face barriers to integration, maintaining a developmental pace that leaves it trailing the regional leaders.

Differences also appear in governance. Germany and France use mixed systems that blend national strategy with regional or local adaptations. Belgium combines centrally guided strategy with implementation shared across federal and federated levels. The Netherlands, Denmark, and Sweden tend to provide stronger national direction with regional or local delivery. Infrastructure investment is comparatively advanced in the most mature systems and developing elsewhere, with national direction often complemented by regional implementation.

Each country also features signature national portals or app frameworks that support patient access, professional workflows, and data exchange; details of these tools are addressed in the country profiles. Telemedicine adoption further underscores country-level variations: Denmark and Sweden are consistent leaders with widely available services; the Netherlands remains on stable footing following post-pandemic adjustments; Belgium experienced rapid expansion and is adapting as reimbursement evolves; and Germany continues to grow but at a more cautious pace. France is consolidating digital health, and telemedicine is now mainstream, propelled by major platforms, with post-pandemic volumes stabilising under clearer reimbursement rules and care-pathway safeguards.

In summary, while all six DigiH4A countries invest in future digital growth, differences in maturity, policy structure, infrastructure, and implementation shape each country's market access landscape and the routes innovators must take to scale.

Table 1: Cross-country comparison – Digital Health themes

Aspect	Germany	France	Belgium	Netherlands	Denmark	Sweden
Digital Maturity Level	Lags behind	Moderate	Transition phase, progressing	Mature	Highly mature	Mature
Central vs. Regional Structure	National policy, regional	National policy, regional	Central governance with regional split	National policy, regional	National policy, regional	National policy, regional
Infrastructure Investment	Improving, fragmented	Strong ("Mon espace santé")	Strong, EU4Health, national eHealth systems	Already digitalised	Strong national/ regional	Integrated national-local
Unique Tools/Programs	ePA, E-Rezept, TI, DiGA, Health Data Use Act	"Mon espace santé"	myHealth portal, mHealthBelgium, BHIR	90% + GP portals	"Min Læge" app (50% pop)	1177.se, national and regional
Telemedicine Adoption	Growing, slow	75% of GP offer teleconsu-ltation	Spiked with COVID, reimbursement evolving	Declined post-COVID, still present	Common, multi-use, national and regional	High, growing, 30% + teleconsu-ltations

Commercial potentials and market dynamics

Across the six DigiH4A countries, hospitals, clinics, and healthcare professionals are the primary buyers and implementers of digital health solutions. Providers act as gatekeepers and integration leaders, aligning solutions with clinical workflows. Public-sector involvement is especially influential in Sweden, Denmark, and France, where large publicly financed hospital networks help set procurement standards and can accelerate national-level scale.

All countries operate comprehensive coverage systems through public schemes, private plans, or a mix. Germany, France, and Denmark rely on strong statutory systems that can enable broad reimbursement once pathways are defined. France, Sweden, and the Netherlands pair public coverage with meaningful private options, creating multiple routes to reimbursement and room for pilots and partnerships.

Each country blends public and private provision, but balances differ. Belgium skews toward private, non-profit hospital ownership. Sweden and France combine a predominantly public hospital system with a sizable private primary-care segment. In Sweden, there is a large presence of private actors in primary care, but services remain regionally funded and reimbursed. The Netherlands features a large private GP sector alongside publicly regulated hospitals. Germany and Denmark also mix ownership models across primary and specialist care, which expands entry points but requires product and contracting flexibility.

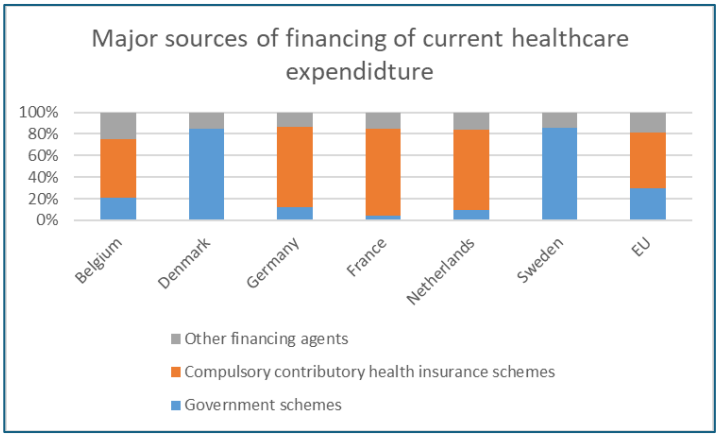

Figure 3: *Eurostat (2022). Healthcare expenditure statistics by function, provider and financing scheme.*

Openness to digital health and purchasing dynamics also vary. Germany offers scale but tends to adopt cautiously. France is driven by institutional B2B demand, with consumer uptake most visible in remote care. Belgium is hospital-led, concentrating decisions among large institutions and networks. The Netherlands broadens procurement beyond providers to include payers and municipalities, creating partnership opportunities but also more complex navigation. Denmark is predominantly public and centrally coordinated but with local autonomy, favouring larger, transformational contracts. Sweden is highly regionalised with active public and private purchasing, rewarding solutions adaptable across settings.

Insurance frameworks shape viability, taking into consideration multiple factors such as cost–benefit analysis. Germany's dual model is extensive but can be procedurally complex for novel tools. France's statutory-plus-private mix allows flexible reimbursement scenarios. Belgium's mandatory public system provides clear coverage foundations but may move cautiously on new categories. The Netherlands' model supports experimentation and public–private mixes, including employer-linked demand. Denmark and Sweden are largely tax-funded, with selective growth of private cover for value-added services. Across all countries, early collaboration with payers or public authorities, often via pilots, helps establish evidence and pave the way to reimbursement.

For country-specific market access and reimbursement steps, please see the SME "country sheets" and the WP1 report.

Table 2: *Commercial potential summary*

Country	User openness	Main buyers of health services & products	Hospital market size	Insurance & Reimbursement	Commercial Potential Summary
Germany	66% SHI-insured (statutory health insurance) open to digital	Hospitals, doctors, pharmacies	1,900 hospitals (with strong fragmentation between urban/rural areas)	Dual system (87-89% public), reimbursement evolving	Large, structured market, wide reach
France	High B2B focus, strong B2C in teleconsultations	Public/private hospitals, private insurers	~3,000 facilities (1,342 public)	Statutory + private, reimbursement	Large complex market, multiple pathways

				for some digital services	
Belgium	50% search health info online, 40% use tech monitoring	Hospital networks, care institutions	103 hospitals	Mandatory public, limited private, clear coverage	Small, focused, easier institutional entry
Netherlands	88% of care users consider it desirable to handle some care tasks online	Providers, insurers, municipalities	120 hospitals	5 major private groups, employer-based growing	Innovative, dynamic, mix public-private
Denmark	70% digital contact w/GP; 80% trust digital	Government, regional public hospitals	21 regional hospitals	85% public funded, limited private	Digitally mature, decentralised but with large contracts
Sweden	High telemedicine use; 20-30% revenue from B2C teleconsultation	Regional authorities, private clinics	85 hospitals (70 public)	85% public, 15% private, employer ins. increasing	Advanced, scalable, public-private mix

Pathway to market entry: the initial engagement process

Common points

Across all six countries, initial entry is supported by engagement with innovation hubs, national portals, or specialised clusters. These organisations offer strategic guidance, local adaptation support, and connections to funding and early-adopter networks. Engagement with regional stakeholders is often necessary where healthcare delivery and innovation ecosystems are locally structured. Early regulatory alignment with EU medical device requirements and national HTA expectations is essential before wider adoption and reimbursement.

Differences in the initial engagement process

To analyse the main differences in the initial engagement process across countries, TRL-like scales were used to assess different criteria. The scales used are available in the 2.1 appendix and annexes document.

Table 3: Initial engagement complexity across six countries

Country	Entry Complexity	Decentralisation Level	Regulatory Burden
Germany	Medium to High	Medium to high	High
France	Medium to high	Medium to high	Medium to High
Belgium	High	Medium	Medium to High
Netherlands	Low to Medium	Medium	Flexible/modular
Denmark	Low to Medium	High	Low (initially)
Sweden	Medium	Medium/Medium to High	Medium

Evidence generation: similarities and differences

Similarities
All six countries require robust clinical or pilot evidence, cost-effectiveness evaluations, and budget-impact analyses for digital health products seeking market access or reimbursement.

Differences
Socio-economic evaluations are required in France, Belgium, and the Netherlands, but not in Germany, Denmark, or Sweden, adding an extra dimension of broader societal impact consideration in those countries. User acceptance studies are only mandated in the Netherlands and Denmark, reflecting a particular emphasis on end-user engagement and adoption in these markets. Interoperability requirements for evidence are present in France, Belgium, and the Netherlands, but are not currently a prerequisite in Germany, Denmark, or Sweden—highlighting varying expectations for technical integration and compatibility across the region.

__Table 4:__ Evidence requirements by country

Dimension	Germany	France	Belgium	Netherlands	Denmark	Sweden
Clinical trials/pilot	✅	✅	✅	✅	✅	✅
Cost-effectiveness	✅	✅	✅	✅	✅	✅
Budget impact	✅	✅	✅	✅	✅	✅
Socio-economic evaluation	❌	✅	✅	✅	❌	❌
User acceptance	❌	❌	❌	✅	✅	❌
Interoperability	❌ (evolving to ✅)	✅	✅	✅	❌	❌

It's interesting to note that both MedTech Europe and COCIR call for harmonised technical standards and clinical-evidence requirements, as underscored in the March 2025 Joint Discussion Paper *'Future governance of medical technologies in Europe'*.

Application submission and reimbursement processes

Across all six DigiH4A countries, market access begins with the submission of applications and supporting documentation to national agencies or regulatory bodies. The only exception is Denmark, as no centralised reimbursement body exists yet. These authorities assess compliance with national regulations, quality standards, and alignment with healthcare priorities. Successful application is a prerequisite before any consideration for reimbursement or wider market uptake.

Table 5: Central bodies involved in application and approval

Country	Central Body Involved
Germany	BfArM (DIGA)
France	CNEDIMTS, ANSM, HAS
Belgium	NIHDI, FAMHP
Netherlands	ZIN, NZa, Digizo (or invidual insurers)
Sweden	No centralised body for reimbursement Läkemedelsverket for Medical Device Approval, Inera and TLV for digitalisation
Denmark	No centralised body for reimbursement Danish Medicines Agency for Medical Device Approval

Common elements across countries include payer communication, tariff-setting (where relevant), and compliance with EU-level requirements for safety, data protection, and usability. The sequence, decision-makers, and timelines vary by governance model: centralised systems offer clearer national routes, while decentralised systems rely more on regional pathways or contracting with payers.

Both MedTech Europe and COCIR, when interviewed for this report, called for streamlined, pan-European reimbursement pathways to reduce duplication of effort and lower barriers for SMEs.

National specificities: unique features and approaches

Each country profile provides a detailed overview of national specificities. At a high level, some countries emphasise structured fast-track or staged pathways; others favour iterative, collaborative evaluation. Some centre on interoperability and IT standards, while others rely more on strong regional innovation cultures. Financing tools and support schemes also differ.

Table 6: National specificities across the six countries

Country	Financing & Support	Regulatory/Strategy Highlights	Key Specific Feature
Germany	Strong national R&D/startup funding + DiGA fast-track	DiGA framework, fast-track process, DIPAs (digital nursing applications)	Clear and structured regulatory path (DiGA)
France	National innovation tools aligned with doctrine + public funded schemes	Digital Health Doctrine, convergence platform	Nationally coordinated digital health vision
Belgium	Regional innovation + tax incentives	Multilingual compliance, integrated care	Localisation focus (language + care path)
Netherlands	Broad public funding schemes + Integrale zorgakkoorden	Polder model, DigiD, bundled payments	Stakeholder collaboration + iterative evaluation
Denmark	Innovation Fund, MedCom IT standards	Interoperability focus, strong governance	Mandatory IT standards with centralised control
Sweden	National strategy + local innovation funds and ecosystem support	Vision eHealth 2025 + medtech funding programs	National vision + regional/local innovation culture

Key market barriers and obstacles

There are several obstacles to market access across the six countries. The table below summarises key barriers; detailed explanations are provided in In-depth country profiles section. TRL charts used are available in the 2.1 appendix and annexes document.

Table 7: Market barriers across Europe

Country	Regulatory Complexity	Reimbursement Delay	Funding Gaps	Interoperability Challenges	Market Fragmentation
Germany	High	High	Medium	Medium	Medium
France	High	Medium	Low to medium	Medium	Medium
Belgium	High	High	Medium	Medium to high	High
Netherlands	Medium	Low to medium	Medium to high	Medium	Low to medium
Denmark	Medium	N/A*	Medium	Low	Medium to High
Sweden	Medium	Medium	Medium	Medium	High

Key comparative observations

- Germany and Belgium also show significant hurdles, especially in regulatory, reimbursement, and fragmentation areas.
- Denmark and the Netherlands are distinct for having only “Medium” or “Low” barriers for most factors, except for some market fragmentation.
- Sweden has moderate obstacles overall, with high market fragmentation being the greatest challenge.

- France occupies a middle position with largely "Medium" ratings across most domains.

Accessing the digital health market remains complex across Europe, but the scale and nature of challenges vary significantly. Denmark and the Netherlands offer comparatively smoother entry, especially regarding interoperability and reimbursement. Germany, Belgium, and— to a lesser extent—France and Sweden present mixed landscapes requiring careful strategic planning.

Synthesis and comparative summary

The comparative analysis of digital health market access across the six DigiH4A countries reveals a highly advanced but nuanced landscape, with each country offering unique opportunities and challenges for SMEs and policymakers alike.

For **SMEs**, entry into the North Sea region's digital health markets is shaped by a combination of strong overall growth prospects (with expected annual market growth rates above 5% in all countries), established health insurance coverage, and high technology adoption among both patients and providers. However, practical barriers vary widely. For instance, countries like Denmark and the Netherlands present digitally mature and efficiently coordinated environments with clear procurement routes, but gaining initial access often requires strong evidence generation and navigation of public tender procedures. France, Germany, and Belgium, by contrast, feature complex regulatory and reimbursement climates, with decentralised, region-specific processes that demand substantial localisation efforts (such as multilingual adaptation in Belgium). The Netherlands, while innovative and dynamic, stands out for its consistently medium barriers in reimbursement, funding access, interoperability, and system fragmentation—underscoring the importance for SMEs to secure robust local partners and move iteratively, leveraging pilot projects where possible.

For policymakers and HTA (Health Technology Assessment) bodies, the diversity of governance models and digital maturity levels across these countries offers valuable lessons. Highly interoperable, well-integrated systems—like those in Denmark and the Netherlands—enable both efficiency and scalability, while the centrality of public sector procurement in Denmark and France demonstrates how coordinated strategies can accelerate digital transformation. Conversely, persistent barriers such as regulatory complexity, slow reimbursement pathways, and fragmented stakeholder landscapes (especially in Germany, Belgium, and the Netherlands) highlight areas where targeted policy reforms or support schemes could significantly improve SME access and digital health diffusion.

Key recommendations moving forward

- **SMEs** should invest early in understanding local entry pathways, develop strong clinical and economic evidence, and tailor their offerings for both public and private procurement practices. Leveraging innovation hubs, regional clusters, and early advisory engagement is critical.
- **Policymakers** should streamline regulatory and reimbursement processes, improve interoperability requirements, have clearer and homogeneous guidelines, and build centralised, transparent portals for digital health onboarding. Fostering cross-country

knowledge sharing, especially evidence of standards and pilot program funding, can help lower SME barriers.

While there is clear momentum for digital health across the North Sea region, the market's promise will only be fully unlocked through pragmatic approaches that bridge clinical, economic, and regulatory expectations—tailoring support for innovative SMEs and leveraging policy levers to streamline adoption at scale.

In-depth country profiles

This second section provides a country-by-country analysis for the six countries participating in the DigiH4A project. Each profile begins with an "ID card" summarising the key features of the national context, followed by a more detailed overview based on desk research and interviews.

The following table gives an overview of the SMEs interviewed for this analysis, highlighting the digital health solutions they have developed and the specific pathologies or issues they address in their respective countries. It is important to note that while their experiences offer valuable insights into opportunities and challenges in digital health market access, they may not fully represent the entire landscape in their countries. The perspectives gathered are, by nature, subjective and shaped by each SME's unique context and focus.

Please keep in mind that the insights and recommendations in this section are based on interviews with selected SMEs—two in each country. While these offer rich perspectives, they may not fully capture all aspects of the digital health environment or apply universally to all innovations. Readers should therefore interpret the findings as supplementary guidance rather than a definitive overview of market entry, regulatory processes, or commercialisation. For tailored advice, further research and consultation with local experts are strongly recommended.

Table 8: SME overview

Country	Pathology / Issue addressed	Name of solution	Classification Type	Product Claim	Status on reimbursement pathway
Germany	N/A	Anonymous SME (DiGA)	N/A	N/A	Reimbursed under DiGA
	Chronic pain	HELP Mee Schmerztherapie	CE marking	Pain management therapy	Not reimbursed
France	Chronic Obstructive Pulmonary Disease (COPD)	Biosency	IIa MD	Predictive algorithm detecting vital-sign deviations hourly to forecast health decline in COPD patients.	Reimbursed in FR
	Lower back pain	Axomove	I MD	Remote follow-up care for patients after hospitalisation for lower back pain	Reimbursed in FR
Sweden	Fall prevention and mobility monitoring in hospitals and care institutions	QUMEA	I MD	Fall prevention and mobility monitoring in hospitals and care institutions.	Reimbursed in CH, AT, DE, SWE, NO, FIN, IS, DK, AU
	Non-invasive heart failure monitoring platform	ACORAI	IIa MD	Non-invasive heart failure monitoring platform.	Not reimbursed
Denmark	Chronic back pain	Selfback	I MD	Self-management solution for people with back pain.	Not reimbursed on national scheme but reimbursed by a health insurance fund in DE
	Solution for hospital beds, monitoring mobility, respiration and heart rate	Ably Medical	I MD (2024) IIa MD (undergoing CE Certification)	Sensor-based solution integrated into hospital beds (mobility, respiration, heart rate monitoring).	Not reimbursable in DK
Netherlands	Mental Health	Minddistrict	MDD transitioning to IIa	Reduction of stress and fatigue.	Not via a fixed reimbursement title
	Home-monitoring platform	Chipmunk Health	Not MDR	Home monitoring platform for GP and chronic patients.	Not via a fixed reimbursement title
Belgium	Cardiac arrhythmias	Fibricheck	IIa MD	Detection and monitoring of cardiac arrhythmias, especially atrial fibrillation.	Reimbursed in BE, NL, UK, US, etc.
	Remote monitoring for cancer	Resilience Pro	IIa MD	Remote monitoring for cancer patients.	Reimbursed in FR

Belgium

Market overview and entry context

Belgium has a population of 11 million (as of January 2024) and is characterised by a unique federal structure that strongly shapes its healthcare and digital-health ecosystem. The country comprises three regions and three language communities, with healthcare responsibilities shared between the federal state and these federated entities. This creates a highly decentralised environment in which regions have autonomy over areas including innovation funding, while central authorities provide overall policy direction and regulation.

Belgium has a high standard of living, and healthcare represents a substantial share of public spending: in 2022, 10.9% of national GDP was dedicated to health. Most of this expenditure (77.6%) is publicly financed, while out-of-pocket payments and voluntary insurance account for 17.9% and 4.5% respectively. Although the health system is traditionally provider-driven, citizens are increasingly engaged digitally: 50% seek health information online, and 40% regularly use health-monitoring technologies.

The country is transitioning from a growth phase towards digital-health market maturity. Belgium has reached a 100% eHealth maturity score, driven by widespread use of EHRs, e-prescriptions, and secure digital-health exchange platforms. Key policy initiatives—including the eHealth Action Plan 2022–2024, the Belgian Integrated Health Record (BIHR), and participation in EU4Health—reinforce this trajectory. Regional hubs such as Leuven, Ghent and Brussels are especially active in fostering digital innovation.

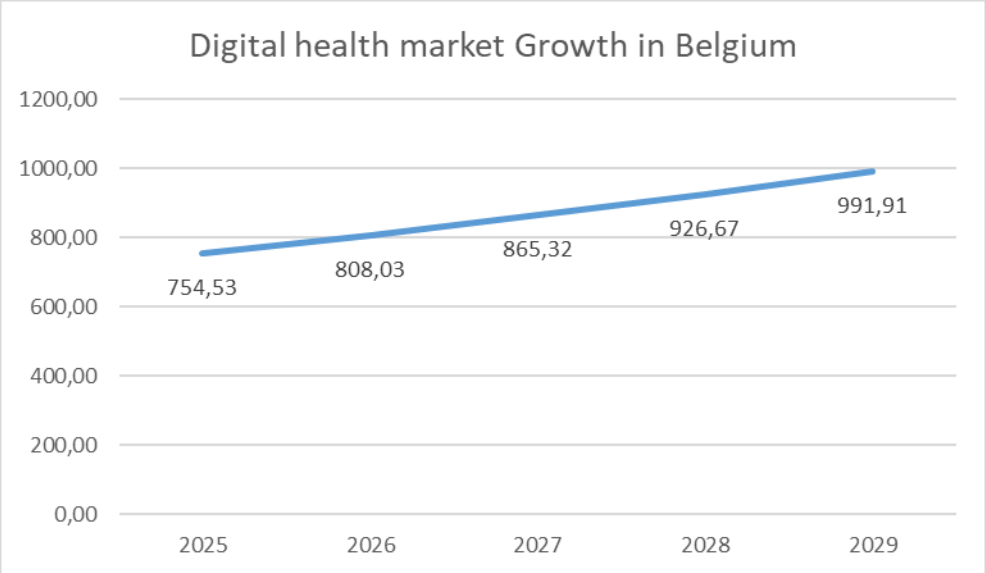

Figure 4: *Digital health market growth in Belgium*

According to a 2025 *Chambers and Partners* report, Belgium's digital health market is expected to generate €754.53 million by the end of 2025 and grow to €991.91 million by 2029, representing a CAGR of 7.09%.

SMEs such as Fibricheck highlight that although Belgium offers strong infrastructure, navigating the federal system requires significant adaptation. They emphasise that *"every process step—registration, reimbursement, training—takes extra time and effort due to language and documentation requirements. Everything must be more than translated; it must be localised for each language community."* This complexity is compounded by differing expectations and workflows across regions, and by reliance on intermediary bodies for regulatory and reimbursement advice, which increases administrative overhead compared with other markets.

Commercial opportunities and user landscape

Belgium's digital-health sector is dynamic, with between 200 and 300 medtech and e-health companies nationally. The majority are SMEs, including start-ups and university spin-offs concentrated in major academic cities. Belgium is particularly strong in cardiovascular devices, diagnostics, orthopaedic technologies, and health IT.

In 2025, the digital-health sector is projected to generate revenues of approximately $828 million, growing at more than 7% annually and expected to exceed $1 billion by 2029. Growth is even faster in the connected-care market, forecast to surpass $1 billion by 2030. Hospitals and healthcare institutions are the principal buyers, with 103 recognised hospitals forming a significant market base.

Despite plentiful innovation, accessing buyers remains challenging. Both Fibricheck and Resilience consistently report that Belgium's fragmented procurement landscape requires institution-by-institution engagement, often beginning with pilot collaborations. Scaling demands repeated negotiation with each hospital, as centralised purchasing power is limited. Evidence from abroad is rarely accepted without adaptation to Belgian clinical settings.

Fibricheck recounts that *"even a mature solution widely validated in other countries still depends on building trust with Belgian clinicians and demonstrating clear value in daily practice. Local procurement norms and unwritten expectations add further hurdles, making in-person stakeholder management as important as the product itself."*

SME entry barriers and processes

Entering the Belgian digital health market is notably complex. SMEs often find they are required to work with local partners — especially academic or clinical stakeholders — to both navigate the multi-tiered system and achieve integration into care pathways. The sales cycle is lengthy, often exceeding twelve months, and procurement mechanisms vary significantly among hospitals and care organisations.

Although there is a degree of central coordination, structural decentralisation means that applicants must also be ready to engage with multiple federal and regional agencies. Legal and regulatory requirements are high, reflecting both the evolving stringency of EU legislation and the complexities imposed by Belgium's federal structure. Documentation is required in all three national languages (Dutch, French, and German), further increasing entry barriers.

Describing the entry process as *"maze-like"*, Resilience shares experiences of prolonged, bureaucratic, and incremental pathways, where communication must pass through intermediary organisations, response times are variable, and there is often little transparency about decision-making or timelines. Fibricheck also stated that *"Direct answers are hard to*

come by; most technical and regulatory questions are routed through layers of intermediaries, and feedback is rarely clear or actionable. Internal expertise and persistent local presence remain critical, as expert advisors for digital health regulation are scarce and expensive."

Table 9: *Market entry conditions (Belgium)*

	Entry Complexity	Decentralisation Level	Regulatory Burden
Belgium	High	Medium	Medium to High

Evidence generation requirements

Gaining market or reimbursement access in Belgium requires robust local evidence. SMEs must deliver clinical trials or real-world pilot data, ideally partnering with Belgian institutions. Cost-effectiveness is typically required (at minimum through literature review), with international data permissible only if its relevance to Belgium can be justified. Budget impact and broader socio-economic considerations are standard. Technical compliance—especially conformity with national data-exchange standards—is mandatory and must be formally declared.

Importantly, user acceptance from providers or patients is not a formal initial requirement, though it may become significant at later stages.

Both interviewed SMEs emphasise that, irrespective of prior international trial success, *"Belgian authorities and hospitals want to see your solution deployed and proven here—data from abroad may be helpful, but it is never enough for reimbursement."* Local RCTs, pilots, and direct cost-effectiveness analysis are required for critical milestones. Even the best algorithms or devices must prove real-world use, safety, and impact in local workflows. *"Integration into care pathways and technical interoperability are both formally assessed, and user acceptance, while not initially required, can become crucial post-market."*

Table 10: *Country-specific evidence requirements (Belgium)*

Dimension	Belgium
Clinical trials/pilot	✅
Cost-effectiveness	✅
Budget impact	✅
Socio-economic evaluation	✅
User acceptance	❌
Interoperability	✅

Application submission and reimbursement pathway

In Belgium, reimbursement applications are coordinated through national bodies: the National Institute for Health and Disability Insurance (NIHDI) for reimbursement which the 1.1 report of the DigiH4A program describes as "*Relatively centralised, NIHDI determines eligibility, pricing, and reimbursement*". On the other hand, the Federal Agency for Medicines and Health Products (FAMHP) for regulatory checks and CE-marking. As the same 1.1 report describes it: applications proceed through staged recognition, with escalating evidence demands for functionality, safety, and clinical value before national reimbursement is granted. Pricing and coding are set centrally once a positive decision is reached. Procurement is often hospital-led; multi-site networks and consortia can accelerate uptake. Pilots generate local evidence but must align with national criteria to secure payment continuity.

Both Fibricheck and Resilience describe this process as *"administratively demanding and slow,"* requiring products to be integrated into validated Belgian care pathways, often via pilot studies. The pathway lacks transparency, with slow feedback cycles and non-specific timelines for decision-making. Companies report challenges in interpreting requirements and a general absence of direct feedback, contrasting with more straightforward systems in certain neighbouring countries. Preventive and innovative solutions, in particular, face unclear or non-existent reimbursement routes—prompting some SMEs to sell directly to patients or via insurers in the interim.

Main obstacles encountered for SMEs

Belgium's landscape introduces several challenges: complex and fragmented regulation, lengthy and opaque reimbursement timelines, limited funding for scaling, technical barriers around interoperability, and pronounced market fragmentation. SMEs must contend with overlapping federal and regional authorities, divergent technical standards, and frequent shifts in EU regulation interpretation.

Fibricheck remarks that a key barrier is the lack of direct dialog with central authorities, forcing them to *"submit into a black box and await an uncertain outcome, often after major investment."* Reimbursement structures remain biased towards acute, billable interventions rather than digital prevention or remote monitoring—with innovation usually tested via short-term pilot agreements, not integrated into long-term funding streams.

Table 11: *System-level barriers to digital health adoption (Belgium)*

	Regulatory Complexity	Reimbursement Delay	Funding Gaps	Interoperability Challenges	Market Fragmentation
Belgium	High	High	Medium	Medium to high	High

Incentive, support and SME-targeted opportunities

Belgium's innovation ecosystem offers agencies in each region (e.g., VLAIO in Flanders, Innoviris in Brussels, AEI/WALInnov in Wallonia), facilitating access to grants and tax incentives for R&D. Living labs, robust academic-industry collaboration, and validated platforms (like mHealthBelgium) support both the piloting and certification of digital health solutions. Participation in local clusters and platforms is considered vital for both visibility and

engagement with hospitals or insurers—regional networking can make the difference between pilot inclusion and being left out of procurement conversations.

Multilingual documentation and fully localised offerings are essential, with digital solutions and all supporting info required in Dutch, French, and German. Integration into local care pathways is a critical differentiator for successful reimbursement.

Experience from the two SMEs that were interviewed suggests that leveraging EU networks and local industry associations can help provide context and introductions, but building proof points and ongoing partnerships with regional agencies and local hospitals is seen as the most effective strategy for adaptation and growth.

Conclusion and recommendations

Belgium presents a compelling yet complex landscape for digital health SMEs, characterised by a robust healthcare infrastructure, high public funding, and a strong appetite for innovation—offset by significant regulatory, linguistic, and operational challenges. The federal structure, decentralised procurement processes, and stringent evidence requirements create a high-friction environment where success depends on deep local adaptation, persistence, and strategic partnerships.

Key takeaways for both Fibricheck and Resilience include the necessity of localised evidence generation, multilingual documentation and engagement, and relationship-driven commercialisation rather than relying on centralised procurement. While Belgium's reimbursement pathways remain opaque and slow—particularly for innovations outside established frameworks—SMEs can pragmatically sustain momentum by leveraging every available billing or reimbursement code, including temporary or experimental lines, to finance pilots until national coverage is attainable. In parallel, invest early in full multilanguage deployment—extending beyond patient-facing interfaces to back-office and administrative modules—for the country's three language communities, and place extra emphasis on persistent local engagement, where personal relationships often outweigh pure technical compliance in driving procurement. Regional grants, accelerators, and living labs can further build credibility and unlock pilot opportunities, but direct reimbursement remains uncertain, making parallel business models (B2B, B2C, and insurer partnerships) essential to bridge lengthy approval timelines.

The experiences of companies underscore that success in Belgium requires patience, local advocacy, and continuous adaptation—not just in product development but in compliance, clinical validation, and stakeholder engagement. For SMEs willing to invest in long-term relationship-building, to rigorously exploit interim reimbursement mechanisms, and to operate fluently across Belgium's multilingual, fragmented system, the market offers access to a sophisticated healthcare ecosystem with strong potential for scalable digital health adoption. However, those seeking rapid, streamlined entry may find regulatory and commercial hurdles prohibitive without substantial local support, strategic flexibility, and a willingness to iterate.

Ultimately, Belgium's digital health market rewards resilience, local expertise, and iterative, evidence-backed engagement—augmented by smart use of interim reimbursement codes, comprehensive multilingual capability, and high-touch stakeholder relationships—making it a viable but demanding opportunity for SMEs equipped to thrive in a high-regulation, relationship-centric environment.

Denmark

Market overview and entry context

Denmark, with a population approaching 6 million, stands as one of Europe's most digitally advanced healthcare systems. Over 85% of health expenditure is publicly funded, and digital health is a clear policy priority—evident from continuous public policy planning (notably through its national strategy for digitalisation).

The national system, characterised by a strong welfare model, is **decentralised**: five regions (four in 2027) manage hospitals and specialist services, while 98 municipalities handle primary, social, and rehabilitation care. Each region is responsible for managing its own procurement, innovation, and pilot projects, creating a landscape that is collaborative in ambition but complex in execution. National agencies and councils (e.g., the Danish Health Data Authority, Board for Health Apps, and Digital Health Denmark starting in 2026) set polices and standards, but do **not act as one-stop "gatekeepers"**—procurement decisions remain regional/municipal.

Danes are digitally literate: over 90% have a digital ID (NemID/MitID), and digital channels underpin both public and private sector health strategies. Denmark has 21 hospitals with emergency function, 98% EHR usage, and near-complete EMR/telemedicine penetration. Primary care and hospital IT systems are to some extent integrated.

SMEs (SelfBack, Ably Medical): Both highlight that "*Denmark's health tech promise is real*". There is universal IT use, strong integration, and a receptive population. But there is no unified entry path: approval and reimbursement are split, and each region sets its own criteria. Advanced digitalization means high entry standards and heavy buy-in needed from local IT/security, which slows and complicates SME market entry.

Commercial opportunities and user landscape

Denmark's digital health sector offers a fertile but demanding environment for innovation. The field is populated by several hundred digital health SMEs, many spun out of prominent clusters such as Danish Life Science Cluster, DigitalLead, and Health Tech Hub Copenhagen. These organisations are at the centre of a network that extends across Scandinavia and northern Europe, supporting frequent cross-border pilots with several European countries.

The Danish market is fundamentally defined by public sector procurement. The five regional health authorities, responsible for hospitals and specialist care, and 98 municipalities, in charge of rehabilitation and elderly services, represent the main commercial entry points. While private healthcare is gaining momentum among actors like pension funds (PFA, PensionDanmark), private hospitals (Aleris, Capio), and insurers, the private market remains a small proportion of overall health spend—less than 15%. Remote patient monitoring, mHealth, sensor integration, digital rehabilitation, and teleconsultations stand out as notable commercial verticals.

For SMEs, opportunities in Denmark consistently start as small pilots. As Ably Medical explains, *"hospitals and municipalities want proven value in real Danish settings, not just international certifications."* Even after successful demonstration, SMEs find that progress must often be restarted in each new region or municipality. SelfBack highlights that *"the*

process resets in every new region"; there is rarely a single successful deal that unlocks scaling nationwide. The advanced digital maturity of Denmark, while attractive, can make expansion harder, as major institutions already have robust, publicly-funded solutions and set a high bar for technical and clinical fit. SME experience suggests smaller, less digitalised markets sometimes present easier pilot partnerships, as institutional alternatives are still being developed.

SME entry barriers and processes

For SMEs looking to access the Danish health market, entry is defined by highly individualised and resource-heavy negotiations. Each procurement or pilot—whether with a region or a municipality—requires a bespoke approach covering local regulatory, clinical, contract, and IT requirements. *"You must align on regulatory, clinical, procurement, and IT requirements for each entry,"* notes an Ably Medical representative. No single, unified HTA, reimbursement, or payer process exists, and there is no rapid fast-track.

Technical integration with Denmark's established public EMR and IT systems is a significant barrier. Ably Medical reveals, *"every region and even some hospitals have unique templates, and you must adapt every time."* Security practices, GDPR compliance, and local technical documentation all present recurring demands, consuming major SME resources.

While Denmark's innovation clusters and public programs—such as Innobooster grants—are invaluable for introductions, pilot access, and early networking, SMEs like SelfBack and Ably Medical describe support as *"light touch."* These avenues are far less involved when it comes to helping close deals or manage regulatory complexity, meaning SMEs typically take on most of the adaptation, compliance, and relationship-building work.

Bottom-up advocacy by clinicians proves crucial: pilots often materialise thanks to committed hospital staff championing innovations internally. Wider implementation can also follow when intergovernmental agreements across state, regions and municipalities create the conditions for scale that clinician led advocacy cannot achieve.

Table 12: *Market entry conditions (Denmark)*

	Entry Complexity	Decentralisation Level	Regulatory Burden
Denmark	Low to Medium	High	Low

Evidence generation requirements

Danish buyers exert typically high evidence standards. Entry requires clinical or real-world pilot data, and—according to SMEs—international certifications or validations are almost never enough. Each region or municipality expects clinical, usability, and health economic evidence to be tailored to Danish care contexts and workflows. SelfBack emphasises the need to view evidence generation as *"a continuous activity, not a one-off box tick,"* with every deployment demanding new rounds of privacy, clinical, and economic documentation.

Cost-effectiveness modelling is another gate; models must convincingly demonstrate value for the Danish health system, but assessment processes differ locally, and what's considered cost-effective in one place may not be enough elsewhere. User acceptance and

interoperability—although sometimes less formalised than in France or the Netherlands—are scrutinised by every major buyer; solutions that do not fit with established digital workflows are at significant risk of rejection or project stalling.

Table 13: Country-specific evidence requirements (Denmark)

Dimension	Denmark
Clinical trials/pilot	✅
Cost-effectiveness	✅
Budget impact	✅
Socio-economic evaluation	❌
User acceptance	✅
Interoperability	❌

Application submission and reimbursement pathway

Denmark has no central reimbursement channel for digital health. SMEs must approach each region or municipality directly and respond to localised calls for proposals, public tenders, or bespoke partnership opportunities. The 1.1 report of the project describes it as having a "*strong decentralisation… reimbursement decisions at regional or municipal level; national bodies provide guidance but lack binding authority*". The same report summarises that entry typically runs via regional public tenders, with conformance to national standards and MDR/IVDR expected. Funding and adoption are decided locally; strong clinical fit, workflow integration, and documented outcomes drive awards. Central guidance harmonises requirements, but vendors should plan for region-specific procurement cycles and integration work. Framework agreements can streamline subsequent call-offs.

Approval and procurement in one setting do not guarantee entry elsewhere—Ably Medical and SelfBack both note the need to repeat documentation, negotiation, and evidence-building efforts for each new buyer.

Routine reimbursement remains rare. Most digital products receive only project-based or discretionary funding, sidestepping any unified, top-down national funding flow. Companies face delays and resource strain as a result, and sustaining parallel business models—such as Software as a Service (SaaS), direct sales, or exporting—is often necessary to remain viable during slow procurement cycles.

Table 14: Denmark's central governance structure

	Central Body Involved
Denmark	No single national body From 2026, a new entity will be formed: Digital Health Denmark (Digital Sundhed Danmark)

Main obstacles encountered for SMEs

- Lack of standardsed, national HTA/reimbursement framework—everything is local.
- Public procurement/funding heavily dependent on budgets and priorities at the regional and municipal level.
- Onerous IT/security and integration requirements consume SME resources.
- Difficult to transition from isolated pilots to mainstream adoption—no *"scaling pipeline."*
- Local context trumps international evidence or regulatory status.

Table 15: System-level barriers to digital health adoption (Denmark)

	Regulatory Complexity	Reimbursement Delay	Funding Gaps	Interoperability Challenges	Market Fragmentation
Denmark	Medium	N/A*	Medium	Low	Medium to High

**No single route for reimbursement*

Incentive, support and SME-targeted opportunities

While Denmark offers strong R&D funding, e.g., Innobooster grants, and innovation tax credits (similar to SkatteFUNN in Norway), support for procurement, market scaling, or real-world validation is less direct:

- Living labs (e.g., Test & Development Denmark), clusters, and health innovation partnerships facilitate networking and early-stage validation.
- Clusters are influential for pilot access, networking, and building trust with clinicians/hospitals.
- Real leverage comes from clinician-championed pilots: *"Bottom-up entry through clinician advocacy beats top-down committee approval for pilots and first deployments."*
- Data privacy, cybersecurity, and local language adaptation are non-negotiables—national templates would help but are not in place yet.

Conclusion

Denmark offers a sophisticated, digitally mature health ecosystem with high public investment and a policy commitment to data-driven care. Yet market entry and scaling for digital health SMEs remain challenging due to regional fragmentation and demanding technical, security, and regulatory requirements. In this context, it is often advantageous to postpone Danish entry until certification and clinical evidence are secured in more centralised markets (e.g., DiGA, NICE), using those validations to build credibility with Danish stakeholders.

Success is predicated on close local partnerships, bottom-up clinician engagement, and strong adaptation to variable regional processes. Trusted medical voices frequently open doors more effectively than innovation managers, so prioritise clinician champions and emphasise in all communications that your solution supports—not replaces—clinical staff, with clear benefits for workforce sustainability and patient safety. Engage national clusters such as Health Tech Hub Copenhagen and the Danish Life Science Cluster for networking and visibility, but set realistic expectations: no single organisation can shortcut the

fragmented system. Prepare for bespoke integrations and GDPR reviews at each site; every region or institution may impose unique technical, security, and legal requirements that necessitate tailored implementation.

Both SelfBack and Ably Medical underscore that flexibility, persistence, and localised evidence are vital, while parallel business models (direct sales, SaaS, exports) help sustain operations as pilots progress and regulatory uncertainty drags on. Denmark's market rewards resilience, strong clinical engagement, and stepwise, locally validated growth—augmented by prior external certifications, pragmatic use of cluster networks, clinician-led adoption strategies, and site-specific integration and compliance planning. Those seeking quick, unified entry or blanket reimbursement should be prepared for a lengthy, resource-intensive journey.

France

Market overview and entry context

France, with a population of more than 68 million, presents a robust and rapidly evolving environment for digital health. The healthcare landscape is anchored by a strong public sector and a formalised digital health strategy driven by both national and regional authorities. Digital transformation is high on the agenda, particularly given that by 2030, one in three French citizens will be over 60.

A report from 2020 by Institut Montaigne, in collaboration with McKinsey & Company, emphasises the critical role of digital health in addressing challenges such as the rise of chronic diseases, demographic shifts, economic pressures, and new health and social issues. Based on an analysis of over 500 studies, the report estimates that accelerating the adoption of e-health solutions in France could generate an annual value between €16 and €22 billion over the next five to ten years. This potential is distributed across five key transformation areas: patient empowerment, digitalisation and data exchange, telemedicine, automation, and decision support, which collectively outline the future of the healthcare system.

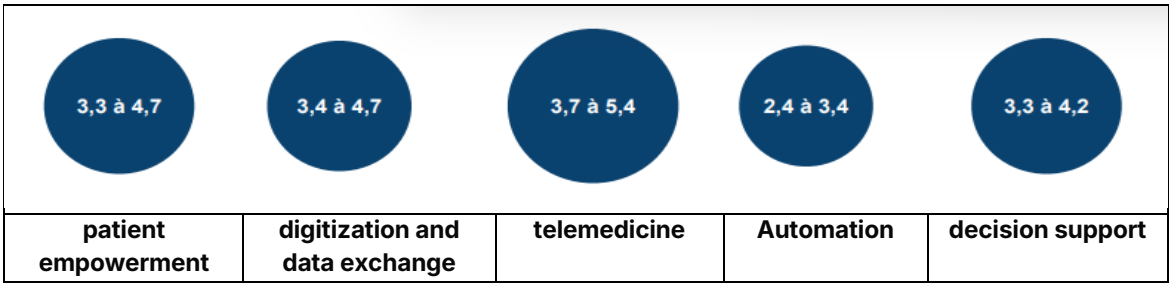

Figure 5: *Key Digital Health transformation areas in France (Institut Montaigne, 2020)*

Healthcare spending is substantial, with €122 billion dedicated to hospital treatment and a further €21 billion to the medical device sector. Growth is steady: medtech and digital health have each seen notable increases in investment, supported by public programs and an uptick in private funding after 2023. Over 450 digital health organisations and nearly 1,400 medtech companies are active, with a growing share offering solutions on the market.

Market access opportunities arise from both the public and private sectors: 17 regional health authorities and over 2,900 public and private hospitals form the backbone of public procurement, while 272 private insurers cover a highly insured population. Employers frequently influence access to private care, and supplemental insurance is nearly universal.

Biosency and Axomove both emphasise the duality of the French system—a single national digital health doctrine but strong regional differences in adoption and procurement priorities. As one respondent put it, *"You have to recognize that success in Paris doesn't mean instant access in Marseille or Lyon; every region, even every hospital, may have their own requirements and pilots."* Navigating through both national and local layers is essential, and many point to the need for robust regulatory intelligence and early local engagement. The interplay of strong national direction and regional pragmatism means that both compliance and relationships must be managed in parallel.

Commercial opportunities and user landscape

The French market is dynamic, with public hospitals serving as major buyers. Digital solutions are increasingly accepted over 90% of citizens report using digital health tools, and half are aware of France's national Mon Espace Santé platform, which streamlines patient data and interaction with the healthcare system.

Biosency remarks that *"the landscape is open to new digital health models, but it is relationship-driven. Pilots are almost always needed for access, and public buyers especially expect rigorous evidence and localization. In the private sector, things can move more quickly, but competitive referencing and detailed proof of value are still prerequisites."* Access can be facilitated by alliances with innovation clusters, but procurement and evaluation cycles tend to be long.

SME entry barriers and processes

Entry to the French market requires aligning with relevant regulations (such as MDR for medical devices) and national digital health priorities. Initial consultation with regional clusters or public innovation hubs is commonly the first step, helping SMEs understand if their technology qualifies as a medical device and which evidence-generation and compliance tasks need to be addressed.

Both Axomove and Biosency, which have navigated this process report that *"Regulatory preparation needs to be meticulous. The French system expects exhaustive documentation—technical, clinical, and cybersecurity. Delays are common if even small details are missing, and often, documents need to be adapted to French standards, not just translated."* Local pilot partnerships are seen as non-negotiable for gaining initial traction, and regional authorities wield significant influence, which means repeated, localised engagement.

Table 16: Market entry conditions (France)

	Entry Complexity	Decentralisation Level	Regulatory Burden
France	Medium to high	Low to medium	High

Evidence generation requirements

French reimbursement authorities expect high standards of proof: robust clinical data, cost-effectiveness analyses, health economic impact, and real-world outcomes are crucial. Documentation must be ready for review by national authorities and tailored to French language and technical conventions.

Biosency highlights, *"Even with existing international evidence, you must prove local impact, often via French hospitals or care networks. Integration with national interoperability and cybersecurity frameworks is seen as baseline, not a differentiator. The pathway to reimbursement is majorly tied to your ability to produce evidence relevant to French payers and providers, and to adapt rapidly to feedback from regulatory and health authority reviews."*

Table 17: Country-specific evidence requirements (France)

Dimension	France
Clinical trials/pilot	✅
Cost-effectiveness	✅
Budget impact	✅
Socio-economic evaluation	✅
User acceptance	❌
Interoperability	✅

Application submission and reimbursement pathway

Digital health SMEs in France typically begin by assessing their readiness with tools like the 'Convergence' self-assessment platform. From there, application files are submitted to relevant national bodies (e.g., CNEDiMTS, the Ministry of Health, or health assurance funds), supported by direct pilot partnerships. The 1.1 report of the DigiH4A project describes the situation in France as "*Strong regulatory and institutional framework… HAS and CNEDiMTS provide transparent, criteria-driven assessments. Fast-track innovations lowered initial barriers.*". The same report summarises it, saying that it is possible to submit for clinical and medico-economic assessment to access public reimbursement routes, with a fast-track option enabling temporary coverage during evidence build-up. Interoperability and cybersecurity conformity are important enablers for procurement and scaling. Complementary insurers can cover non-listed features or bridge gaps during transitional phases. Post-listing, tariffs/codes define routine payment and support nationwide diffusion.

Interviewed SMEs describe the process as *"structured on paper but often iterative and slow in practice. Submissions are detailed and feedback can mean returning to collect more evidence or documentation. Temporary funding programs like PECAN or the Forfait Innovation can support initial implementation, but permanent reimbursement comes only after extensive validation."* Navigating between temporary and standard reimbursement is a major hurdle.

Main obstacles encountered for SMEs

SMEs consistently identify the following pain points:

- Regulatory burden—preparing compliance files takes significant time and resources, and requirements are subject to ongoing changes.
- Regional fragmentation—gaining 'national' access requires piecemeal, region-by-region advocacy and often separate pilots.
- Procurement timelines—public sector decisions take many months, and feedback from each pilot must be processed and incorporated.

- Financial and partnership complexity—securing the right grants, partners, and professional support is possible but often feels opaque.

Table 18: System-level barriers to digital health adoption (France)

	Regulatory Complexity	Reimbursement Delay	Funding Gaps	Interoperability Challenges	Market Fragmentation
France	High	Medium to high	Low to Medium	Medium	low

SMEs reflect that, *"It's easy to underestimate the interpersonal and administrative effort needed—there's no shortcut around documentation, pilots, and constant adaptation to feedback."*

Incentives, support & SME-targeted opportunities

France offers a patchwork of support, including grants through national and regional innovation programs (France 2030, Stratégie d'Accélération en Santé), living labs, incubators, and funding agencies. While these resources are valuable, SMEs say *that "finding, applying, and qualifying for the right support takes commitment and time—external expert help and trusted cluster partnerships make a big difference."*

Conclusion and local recommendations

France presents a fertile yet highly structured ecosystem for digital health SMEs, combining a centralised vision with decentralised implementation. Strong public welfare, broad insurance coverage, and robust innovation funding create significant opportunity, but administrative, regulatory, and regional hurdles demand meticulous preparation, local alliances, and flexible, stepwise execution. Success hinges on arriving *"France-ready":* not just with innovative technology, but with regulatory and reimbursement dossiers that are meticulously prepared and locally adapted for ANSM, HAS, and payers—where superficial translation will not suffice.

To turn potential into progress, map financing instruments early and intentionally—spanning regional grants and national innovation calls—and enlist cluster advisors to navigate eligibility, timelines, and co-funding requirements. Expect iterative rounds of evidence requests from both authorities and clinical partners and build time and budget slack for additional analyses, endpoints, and real-world data generation. Pair the centralised policy environment with strong regional execution by cultivating relationships with CHUs, GHTs, and purchasing groups to manage decentralised procurement, integration, and GDPR processes.

Given elongated decision cycles, maintain commercial flexibility with parallel models—B2B sales to hospitals, SaaS offers to private providers, and partnerships with insurers—to sustain momentum while reimbursement pathways evolve. For those ready to adapt, invest, and iterate on the basis of France-specific evidence and partnerships, the market remains a compelling landscape for digital health innovation at scale.

Germany

Market overview and entry context

Germany, with a population of more than 80 million, features one of Europe's most established and well-funded healthcare systems, combining statutory and private insurance models. It was the first of its kind in Europe. The landscape for digital health is defined by a strong federal agenda—epitomised by the Digital Health Applications (DiGA) Fast-Track and the DIPA (Digital Nursing applications) managed by the Federal Institute for Drugs and Medical Devices (BfArM). This program offers a clear, regulated route for CE-marked digital health solutions to reach prescription and reimbursement within the statutory health insurance system.

Despite this pathway, providers and innovators operate within a moderately decentralised setup due to the federated system including 16 states. While federal law and agencies outline the broad regulatory and reimbursement frameworks, there is significant operational diversity on the ground, as funding, procurement, and often local adoption still involve state and institutional actors. Companies highlight that each journey—regulatory, procurement, or integration—demands close attention to both the centralised rules and the daily realities of decentralised implementation.

The experiences of entrants such as HELP, one of the companies interviewed for this report, underscore this complexity. As a young start-up, HELP notes that while there are clear opportunities enshrined by federal initiatives, various regulatory and procedural hurdles mean systems remain particularly challenging for small and innovative players—not just for large firms with established infrastructure. The anonymous SME interviewed confirms that the national framework provided a *"clear map",* but day-to-day adoption is constrained by provider capacity (e.g., therapist shortages) and limited time to learn new tools, which slows real uptake even when patients are motivated.

Commercial opportunities and user landscape

Germany's digital health market is internationally regarded for its regulatory innovation and for opening new commercial pathways. Public and private payers are receptive to high-quality, validated solutions, and the DiGA directory is regularly updated with digital applications that have proven to be safe, to show clinical benefit with scientific evidence.

Business models in Germany are largely centered around three approaches: business-to-business (B2B), business-to-consumer (B2C), Business-to-Government (B2G) and payors/employer collaborations (B2B2C). The primary avenue to scale lies in securing reimbursement under the statutory health insurance, but parallel opportunities exist in working directly with private payers who may have greater flexibility or faster adoption cycles.

For companies focusing on more immediate commercial traction, non-DiGA models through direct-to-consumer or through employer partnerships remain relevant—especially while waiting for the outcome of the rigorous public reimbursement process.

Importantly, firms such as HELP stress the critical importance of resourcing: specifically, ensuring access to sufficient long-term funding before and during the DiGA process. The demands of evidence generation, combined with potentially unpredictable timeframes for

review and approval, can represent a major barrier to market entry, especially for start-ups. Furthermore, the anonymous SME highlights that patients are generally not the barrier; they are motivated and willing to adopt. Bottlenecks arise with therapists (shortages, high time pressure for training). This SME also notes that building a network of therapists can accelerate adoption and sometimes *"bypass"* physician bottlenecks withing legal pathways.

SME entry barriers and process complexity

Successfully bringing a digital health solution to the German market is a staged process that requires early engagement with national regulators and industry bodies. The first formal step is typically CE-marking, establishing basic eligibility for further review. Next, companies must prepare a comprehensive submission for BfArM if pursuing the DiGA pathway, which demands extensive documentation on clinical safety, efficacy, positive care outcomes, and compliance with data protection and security standards.

The bar for clinical and economic evidence is particularly high, with a growing preference for real-world data generated within the German context to support claims. Companies must often undertake local pilot studies or proof-of-concept projects with providers and insurers to build the necessary evidence base.

Once the application is filed, interactions with both public and private health insurers become critical. Companies need to demonstrate market demand and solution value based on robust, local pilot results or market studies. Reimbursement negotiations, especially for price and inclusion in covered services, require patience and are often the result of significant negotiation and additional documentation.

Through its own journey, HELP reflects on this environment as one where assumptions about simplicity are to be avoided. The company describes the necessity of expert navigation, careful budgeting, and ongoing relationship-building at each step of the process. The anonymous SME notes that every product change must be reported to BfArM via the portal; fees and processing overhead add up, even for items like changing minimum OS versions. BfArM flags only significant changes for deeper review, but the cumulative admin load is material. This SME also explains that insurer reluctance to reimburse can persist post-listing, adding negotiation steps and delaying revenue.

Table 19: *Market entry conditions (Germany)*

	Entry Complexity	Decentralisation Level	Regulatory Burden
Germany	Medium to High	Moderate	High

Evidence requirements and administrative burden

Germany's reputation for rigor extends deeply into evidence assessment and administrative procedure. Meeting DiGA requirements obliges companies to submit not only clinical trial data, but also real-world effectiveness information, patient safety documentation, and detailed explanations of data protection compliance in line with very strict interpretations of GDPR.

The administrative expectations—often involving repeated queries, documentation updates, and adaptations to new regulatory clarifications—can present substantial delays and require dedicated attention from SMEs. HELP's experience highlights the importance of both securing robust CE marking and planning for a patient, well-funded engagement with the approval authorities and payers.

Additionally, both public and private insurers may require further economic analyses, including cost-effectiveness and budget impact studies, before authorising broad reimbursement or forming commercial partnerships.

Table 20: Country-specific evidence requirements (Germany)

Dimension	Germany
Clinical trials/pilot	✅
Cost-effectiveness	✅
Budget impact	✅
Socio-economic evaluation	❌
User acceptance	❌
Interoperability	✅

Application submission and reimbursement pathway

The 1.1 report highlights that the reimbursement pathways follow *"Relatively centralised frameworks… national bodies such as BfArM determine eligibility… with national directories or formal inclusion lists."* The same report summarises that companies submit a standardised dossier covering safety, clinical benefit, and (where applicable) economic value to obtain national listing. Provisional inclusion may be possible while generating further evidence; full inclusion follows positive assessment. After listing, pricing and coverage are negotiated within statutory channels, while private contracts can complement. Hospital/insurer pilots help de-risk adoption but do not substitute for directory inclusion.

Systemic barriers and ecosystem gaps

Major challenges identified by stakeholders and participants include high regulatory barriers, lengthy approval timelines, and substantial upfront resource needs. SMEs repeatedly point to the absence of tailored support mechanisms for smaller, innovative teams, which often lack the financial depth of established companies to withstand prolonged development and evaluation periods.

The need for secure, long-term funding is particularly acute before entering and throughout DiGA development—the risks in process length and outcome are significant. As HELP suggests, more flexible and alternative reimbursement models, such as success-based

payments, would help encourage adoption and reduce pressure on innovator cash flow. Process unpredictability can also emerge when dealing with private insurers, where negotiation is less formalised and standards of evidence may vary from those set by the public sector and BfArM.

The anonymous SME highlights that BSI technical guidelines are perceived as disproportionately burdensome: examples cited include mandatory 30-minutes session logouts and two-factor authentications flows relying on health ID/ePA/eID methods that many (especially older) patients do not use-risking exclusion and lower uptake. There is also some concern that updates may increasingly require (re)certification under security rules; for teams releasing on ~14-week cycles, this is financially and operationally demanding. Finally, the anonymous SME notes that very few new DiGAs are entering while existing ones resist adopting the most onerous BSI requirements due to expected user loss.

Table 21: System-level barriers to digital health adoption (Germany)

	Regulatory Complexity	Reimbursement Delay	Funding Gaps	Interoperability Challenges	Market Fragmentation
Germany	High	High	Medium	Medium	Medium

Support structures and strategic guidance

Despite these obstacles, Germany features a developed infrastructure for digital health innovation. National and industry associations such as SVDGV (German Digital Health Association) offer policy guidance, networking, and regulatory advice. Public and regional grants, along with innovation funding, can provide critical support for pilot programs and initial evidence generation.

Collaboration across the ecosystem—between innovators, established companies, insurers, and care providers—is increasingly seen as vital to unlocking commercial opportunities and navigating the regulatory landscape.

HELP's version of best practice involves engaging experienced consultants who know the regulatory and commercial terrain, maintaining realistic expectations, and leveraging industry clusters for advice and connections. The anonymous SME recommends joining the manufacturer's association early to access working groups and peer guidance. It also notes that many certifications must now be secured upfront before application, creating substantial pre-submission costs. SMEs should confirm market demand first to justify these investments.

Conclusion

Germany holds a unique and ambitious place in digital health: the DiGA pathway has have a pioneer role and has drawn global attention for providing a national route to reimbursed, evidence-based digital therapeutics, yet entry is complex, documentation is exacting, and SME-specific supports are limited. Companies like HELP underscore the paradox—national reimbursement is a singular commercial prize, but reaching it demands early, expert navigation of DiGA fast-track rules, CE marking, and data-protection law; substantial financial runway; and the patience to steer through a rigorous, sometimes unpredictable system. Success therefore hinges on securing regulatory and reimbursement expertise from the

outset, generating German-language clinical and real-world evidence through local pilots with insurers and hospitals, and conducting detailed market and stakeholder research that respects Germany's evolving requirements and regional nuances rather than relying on simplifying assumptions.

To sustain momentum while statutory reimbursement is pending, build parallel business channels—direct sales to clinics, employer partnerships, and selective B2C offers—and advocate with payers and provider partners for alternative reimbursement approaches such as outcome- or success-based payments that can accelerate adoption and better share financial risk. Plan operations with compliance realities in mind: budget for BfArM change-request fees and security audits; consolidate releases to limit re-certification burden; and co-design authentication and session flows with older users to reduce drop-off and support equitable access. In short, Germany rewards resilience, planning, and strong stakeholder engagement; the system is most accessible to teams prepared to localise evidence, invest in expert guidance, diversify commercial paths, and master the formalities required to achieve reimbursement and scale.

The Netherlands

Market overview and entry context

The Netherlands is a densely populated country of a little over 18 million inhabitants, with near-universal health insurance coverage and a highly digital-literate population. Healthcare is organised as regulated competition among private insurers within a nationally defined benefit package, underpinned by strong primary-care gatekeeping and a long tradition of consensus decision-making: *"the polder model"*. Digital identity and data exchange are widely used, and providers across hospitals, GP groups, and community care have comparatively mature IT estates. Policy steers digital health to be *"part of care"*, not a parallel track: there is no DiGA-style app prescription pathway. Instead, digital interventions are expected to substitute or augment insured care, fit an Nsa performance rule, and be recognised in insurer-provider contracts. This makes pathway integration the precondition for sustainable reimbursement, and it also explains why pilots tied to concrete workflow changed are the usual on-ramp to scale. National initiatives such as Digizo.nl and its "Pas Toe" list aim to shorten the bridge from successful pilots to routine use by signalling which digital practices are ready for wider adoption, while the 2022-2027 Integral Care Agreement codifies the system's ambition to push *"self-care if possible, home if possible, digital if possible."*

During an interview conducted for the DigitalH4A project, Minddistrict, - an SME with around 100 employees, about three quarters based in the Netherlands- described how this context lands in practice for mental health. Their modular, research-based platform supports blended care in the GGZ (specialist mental health) sector. As the company puts it, reimbursement in the Netherlands is *"not via a fixed reimbursement title"*, but blended models are viable because *"shorter consultations are reimbursed more favourably, which allows providers to invest."* That logic aligns with the Dutch emphasis on efficiency and workload relief as the primary levers for commissioning digital tools. A second interview was conducted with Chipmunk Health – a Dutch start-up founded in 2018 and currently a team of about 10 people- shows how the same policy logic plays out in primary care, where ketenzorg contracting and GP-led chronic-care pathways are the natural economic home for remote monitoring that replaces routine quarterly visits with data-driven follow-up. The company's remote home-monitoring platform, which conveys readings from certified devices without manipulation and therefore is *"not classified as a medical device under MDR according to a notified body"*, integrates with GP workflow through a population-review dashboard for practice nurses, is being exercises in a living lab of about, 2,000 participants with field testing of new devices and a read-only mobile app. So far it has completed pilots with domotics and home-environment sensors. This highlights how Dutch pathway-first commissioning can support low-cost, high-volume models when operational fit at the practice level is strong and the intervention demonstrably saves staff time while avoiding unnecessary lab testing.

Commercial opportunities and user landscape

Commercial models in the Netherlands centre on B2B arrangements with providers and their insurer partners, sometimes complemented by B2B2C channels via employers or pharmacies while awaiting broader coverage. Minddistrict's core model is a SaaS license for care organisations, aligned in the Dutch market to the economics of blended care and insurer agreements. As the SME interviewed states, Dutch policy embeds digital within existing pathways, the most scalable wins typically occur when an intervention demonstrably shifts activity to lower-cost settings, shortens or partially digitises consultations, or enables remote

monitoring that averts avoidable contacts. The HartWacht telemonitoring program, illustrates how insurer-backed models can translate a validated service into multi-site deployment. Minddistrict's experience echoes this: the platform gains traction where provider teams can redesign workflows and contract those changes with their lead insurer, rather than trying to sell a stand-alone "app." Chipmunk Health follows the primary-care route. It is reimbursed via ketenzorg and can be declared by hospitals under the telemonitoring code. A CZ contract uses declining per-patient prices at scale and stays fully reimbursed for GP groups. The model works when inclusion in the chronic-care population is high enough to unlock efficiency.

SME entry barriers and processes

Despite the opportunity, SMEs face high entry complexity. Minddistrict emphasised *"high compliance costs and divergent requirements per country,"* noting that the firm receives no systematic external support on regulations and therefore built an internal compliance team of four Full Time Equivalent (FTE), bringing in outside legal expertise as needed. Even within the Netherlands, negotiations are decentralised and contract-based, which elongates timelines. Continuous product iteration—a normal reality for SaaS—collides with audit demands: *"continuous platform development during trials makes audits complex."* Structural differences across systems add friction to multi-country strategies, with the firm citing the Netherlands' blended-care economics versus Germany's more inpatient-focused logic as a concrete example. Finally, demonstrating preventive value is *"difficult"*, which complicates pure ROI cases when effects accrue outside a single budget holder or contract year. Chipmunk Health reports that reimbursement is workable but innovation readiness and adoption in practices are uneven, that stronger levers and accountability at practice level would help, that regulatory and standards work is handled internally with ISO work underway oriented to ISO 13485 despite the non-MDR classification, and that capability is built through co-creation with partners, a concluded collaboration with Philips, tight alignment with hardware suppliers, collaboration with Maastricht University, and participation in regional networks such as LIOF and BOM rather than formal innovation-management programmes.

Table 22: Market entry conditions (Netherlands)

	Entry Complexity	Decentralisation Level	Regulatory Burden
Netherlands	Low to Medium	Medium	Flexible/modular

Evidence generation requirements

Evidence expectations in the Dutch setting prioritise practical demonstrations of clinical benefit, user acceptance, and budget impact within real care pathways. Minddistrict has *"extensively"* tested modules with Dutch university medical centres—citing collaborations with notorious academic hospitals on clinical effectiveness in fatigue, oncology, and MS—as well as studies on patient satisfaction, professional time use, and the effectiveness of blended care.

Economic arguments are anchored in efficiency and staffing relief, though the company notes that proving prevention-driven savings is *"harder to prove directly."* Their experience also highlights a recurring European challenge: evidence often does not travel. To pursue the German DiGA route, Minddistrict reports that *"multiple new studies had to be run… because Dutch results were not accepted,"* underlining why SMEs should plan for local evidence even when they already hold solid data from neighbouring countries. Chipmunk Health conducts

joint value work with CZ and practices showing time savings for practice nurses when routine controls shift to remote monitoring, an Eindhoven case where reduced HbA1c lab testing produced a positive business case from day one, and a Midden-Limburg trajectory that reaches break-even around 2027 if lab protocols do not change, with tariffs structured to keep payer impact non-negative while the living lab (~2,000 people) accelerates iteration and acceptance.

Table 23: Country-specific evidence requirements (Netherlands)

Dimension	Netherlands
Clinical trials/pilot	✅
Cost-effectiveness	✅
Budget impact	✅
Socio-economic evaluation	✅
User acceptance	✅
Interoperability	✅

Application submission and reimbursement pathways

To describe the reimbursement pathways in the Netherlands, the 1.1 reports explains that it is "*Hybrid… ZIN evaluates eligibility for the basic package; NZa oversees reimbursement; individual insurers retain discretion over contracts*".

The same report summarises this, saying that SMEs first need to align with national eligibility criteria for inclusion in the basic benefit package; then negotiate with individual insurers for contract terms and tariffs. Regional authorities and municipalities may co-fund or co-procure for public health and long-term care use cases. Pilots and outcomes-based agreements are common on-ramps to scaled reimbursement. Data-sharing, interoperability, and measurable outcomes are decisive in insurer decisions.

Minddistrict characterises its Dutch pathway accordingly: integration *"into GGs reimbursement through blended care,"* with revenues realised as providers reconfigure consultations and insurers accept the redesigned pathway. The firm contrasts this with Denmark, where its solution is purchased through central government procurement, and with Germany, where it has pursued DiGA while also relying on pilots with pension funds and clinics. That cross-country spread reveals the Dutch market's distinctive premise: there is room for digital health to scale, but the path runs through care redesign and contract language rather than a dedicated digital tariff.

On the other hand, Chipmunk Health contracts ketenzorg with regional GP organisations, is declared by hospitals under the telemonitoring code, expects other insurers to follow once concrete projects start, and is exploring WLZ for long-term care providers (VVT).

Table 24: The Netherlands' central governance structure

	Central Body Involved
Netherlands	ZIN, NZa, Digizo (or any other individual health insurers)

Main obstacles encountered for SMEs

The interview with Minddistrict underscores several obstacles that are highly relevant to Dutch entry. Compliance and audit work are costly and continuous in a SaaS context, made heavier by *"divergent requirements per country."* Trial and audit timelines are long, which creates financing and runway risk, particularly when evidence must be duplicated for different jurisdictions. Structural differences in how systems value digital pathways impede reuse of assets and playbooks. And while Dutch providers and insurers are receptive to blended care, budget-impact proof points are expected early, yet preventive gains—often the most meaningful in mental health—remain difficult to quantify within annual contract cycles. Chipmunk Health adds that practice-level adoption is the binding constraint, that substantial inclusion is needed to unlock efficiency and clinician time relief, and that limited use of public R&D funding to date –one subcontract under a municipal EU Horizon project and WBSO now under consideration- puts a premium on simple, scalable contracts and hands-on change support.

Table 25: System-level barriers to digital health adoption (Netherlands)

	Regulatory Complexity	Reimbursement Delay	Funding Gaps	Interoperability Challenges	Market Fragmentation
Netherlands	Medium	Low to medium	Medium	Medium	Low to medium

Incentive, support & SME-targeted opportunities

The Dutch incentive landscape is built to fold proven digital practice into routine care rather than fund apps separately. The 2022-2027 integrated care agreement sets a *"digital where appropriate"* ambition, while two levers matter most for SMEs: the Dutch healthcare authority's guidance that shows how teleconsultations, telemonitoring, and blended pathways can be paid under existing rules, and Digizo.nu, which accelerates spread by flagging ready-to-scale use cases and minimum interoperability.

Funding exists but is targeted. SET helped home-care providers adopt digital health; Health~Holland's Top Sector LSH co-finances R&D and evaluations and insurers run focused pilots that can scale when results are clear. Minddistrict's path – about thirty research consortia to build content and integrations – illustrates how subsidies bridge evidence and interfaces but never replace a commercial plan.

Navigation support should be used early. Zorg voor Innoveren orients on financing and regulation; early dialogue with ZIN aligns study designs; the annual digital health Monitor informs realistic uptake goals. Regional programs in Amsterdam, Rotterdam, Leiden, Utrecht, Brainport, and the North offer test beds to secure a first provider-insurer pair, agree KPIs, and produce real-world results that unlock replication.

Procurement rewards audit-ready integration: DigiD login where relevant, HL7/FHIR exchange, and clean EHR embedding. Minddistrict's bundling of modules and EHR partnerships fits this logic, yet a unified SME-friendly route through assurance and contracting is still missing and compliance remains costly.

Chipmunk Health's path shows that even with minimal subsidy uptake, WBSO (tax credit) can be considered to fund internal R&D, regional networks can open doors to commissioning partners and using existing national and regional platforms that already handle data and governance can speed onboarding of foreign devices and services.

Conclusion and recommendations

The Netherlands offers a supportive, evidence-first environment that can take an SME from pilot to scale when the product is woven into real pathways, integrates cleanly, and delivers measurable efficiency. SMEs should use early ZIN advice to scope evidence, secure a lead provider–insurer pair with pre-agreed KPIs, fund missing studies and integrations via Health~Holland or regional schemes, bundle features into audit-ready packages, and plan from day one for HL7/FHIR and DigiD alignment. Policy makers can accelerate this path by formalising a transparent fast-track from the current insurer pilot schemes into time-boxed, conditional reimbursement for vetted digital interventions, publishing a small set of reference KPIs and contracting templates for major pathways, expanding advisory capacity for regulatory and evidence *"gap checks"*, and harmonising procurement clauses on interoperability and privacy. Taken together, these steps would lower transaction costs without lowering the bar on quality—and would get proven digital care into routine Dutch practice faster.

Sweden

Market overview and entry context

Sweden, with its 10.6 million residents, is renowned for its advanced healthcare system and pioneering digital transformation. Healthcare is delivered via 21 autonomous regions and nearly 300 municipalities, combining national vision and local self-governance. Sweden allocates over 11% of its GDP to healthcare, and digital health is a clear policy priority—evident in universal electronic health record coverage, the integration of telemedicine, and widespread adoption of secure digital patient identification.

For SMEs considering entry, company experiences consistently highlight that Sweden's openness to innovation is partnered with rigorous expectations for evidence, technical fit, and security. As QUMEA recounted, *"Swedish health authorities are open to pilots, but expect a deep understanding of both healthcare structure and the realities of local implementation."* Each region, they noted, *"should be treated almost as a separate market, with its unique decision makers and priorities."*

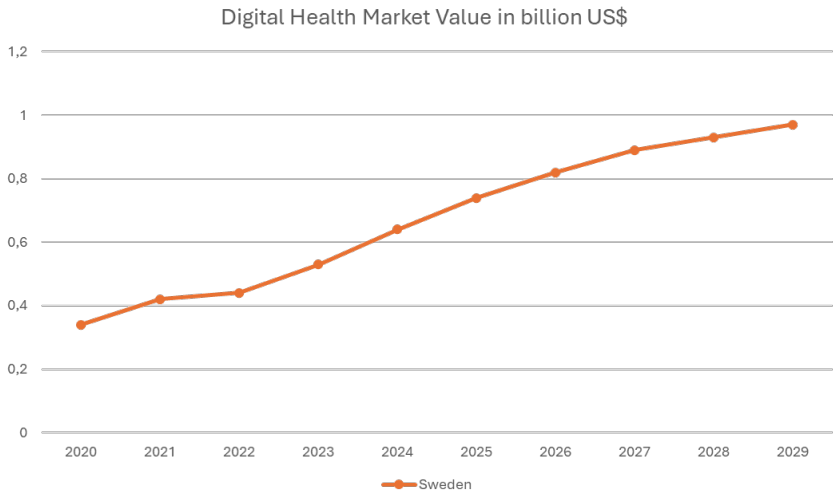

Figure 6: *Digital health market value in billion US$*

Commercial opportunities and user landscape

Sweden's patient and clinician communities tend to be digitally literate, creating favourable conditions for novel health technologies. Over 95% of Swedes use the internet daily, and public services like the national patient portal 1177 Vårdguiden facilitate wide access to digital health information of services – However, QUMEA experience shows that *"entry almost always begins as a structured pilot—often requiring a competitive application or being brokered by local healthcare innovation clusters."* From the SMEs' perspective, successful pilots are crucial not just as *"proof of concept"*, but as relationship-building mechanisms. *"A single well-documented pilot in a key region builds credibility nationally,"* QUMEA advised, *"but expect to iterate solutions based on local feedback and involve both clinical and administrative champions from the very start."* Furthermore, tailoring proposals to address region-specific health priorities—such as elder care, chronic disease burden, and rural access—is described as essential for gaining traction. Identifying regions and public or

private care providers with a track record of actual procurement and implementation of digital solutions is more vital than size of the region/care provider.

SME entry barriers and processes

Entering the Swedish system means not just having the correct CE mark or MDR compliance, but meeting nuanced, region-level procurement standards and IT security benchmarks. QUMEA report encountering *"high demands for interoperability and data protection, alongside layered procurement pathways that can vary enormously between regions."* In practice, this means *"the approach that worked in Stockholm might not meet requirements in Skåne, and timelines for procurement can stretch over a year."* ACORAI commented on the intense resource allocation needed, stating: *"Expect repeated technical and clinical workshops, and prepare for several rounds of administrative and end-user review."* Another cautioned about *"integration difficulties"*—IT departments and clinicians expect to see how the product will work with local existing systems, requiring technical pilots and documentation that clearly demonstrate workflow compatibility.

Table 26: Market entry conditions (Sweden)

	Entry Complexity	Decentralisation Level	Regulatory Burden
Sweden	Medium	Medium to High	Medium

Evidence generation requirements

Swedish buyers value robust, practical, and locally generated evidence above all. *"You need well-documented Swedish outcomes,"* explained QUMEA. International case studies or generic clinical data carry less weight compared to clear results from Swedish pilots showing improved patient safety, cost reductions, staff satisfaction, or workflow efficiency. The validation process is iterative— after initial pilot results, companies are often asked for updates or further demonstrations. SMEs stressed the importance of *"transparently sharing all end-user feedback, including areas for improvement, and showing a willingness to co-develop your solution for local circumstances."* Technical interoperability, adherence to stringent data privacy rules, and demonstrated patient benefit are all equally scrutinised by Swedish evaluators.

Table 27: Country-specific evidence requirements (Sweden)

Dimension	Sweden
Clinical trials/pilot	✅
Cost-effectiveness	✅
Budget impact	✅
Socio-economic evaluation	❌

User acceptance	❌
Interoperability	❌

Application submission and reimbursement pathway

Sweden's decentralised reimbursement and procurement landscape means that each region runs its own pilot programs, innovation calls, and full procurements. The 1.1 report notes that there is a *"National evaluation via TLV/SBU with regional autonomy… each of 21 regions can decide whether to fund, leading to variability."* The same report recommends usage of national HTA guidance and reference assessments to support region-by-region funding decisions; reimbursement and procurement remain regional. Expect multiple tender rounds and local pilots to demonstrate value in target care pathways. Each municipality and region can procure a solution for up to 75.000 Euro, without a public tender for a duration of 1 year. Private hospitals and primary care offer an additional route for contracts, sometimes faster than regional pathways and with easier access to test and pilots with autonomous decision making. Interoperability with regional platforms and strong data-protection practices are prerequisites for scale.

QUMEA which has experience in this process describe how *"getting from pilot to paid contract is rarely automatic—companies have to proactively engage in follow-up, present cost-benefit analyses tailored to that specific region and often participate in further technical or economic evaluation rounds."* They highlighted the importance of *"targeting strong innovation regions first, building a local case study that's easy for other regions to adopt, rather than chasing fragmented pilots nationwide."* ACORAI also warned against the risk of *"pilot fatigue": "Without a clear scaling strategy and ongoing advocacy, pilots can remain isolated, never translating to system-wide reimbursement or widespread use."*

Main obstacles encountered for SMEs

The market presents several recurring challenges, as emphasised by those who have been through the process:

- **Fragmented procurement:** *"What you achieve in one region does not guarantee acceptance elsewhere—a new introduction often means starting again."*
- **Demand for Swedish evidence:** Despite any international accolades, local results are mandatory. *"Swedish clinicians and administrators want to see demonstrable improvement under Swedish conditions, using Swedish data."*
- **Integration hurdles:** IT systems, privacy legislation, and workflow design create complex practical requirements, and the bar for technical compliance is high.
- **Resource intensity and timelines:** Sales and procurement cycles are long and laborious. *"Budgets are set annually, and companies may need to build a Swedish presence for months or even years before seeing returns."*
- **Sustainability after pilots:** Without a structured commercialisation follow-up, it is not uncommon for even successful pilots to fail to progress to full-scale procurements or reimbursement.

Table 28: *System-level barriers to digital health adoption (Sweden)*

	Regulatory Complexity	Reimbursement Delay	Funding Gaps	Interoperability Challenges	Market Fragmentation
Sweden	Medium	Medium	Medium	Medium	High

Incentives, support and SME-targeted opportunities

Despite these challenges, Sweden's health innovation ecosystem is active and collaborative, providing meaningful support for digital health SMEs. Companies routinely engage with public innovation hubs, eHealth cluster organisations, and national development funds like Vinnova. SMEs say that introductions and guidance from these organisations are *"often decisive in navigating applications for pilot programs and identifying the right local clinical champions."* Participation in public-private accelerator programs, regional match-making and soft-landing events, and collaborative consortia offer additional stepping-stones to both early validation and system integration as well as finding local partners, eco-system structures and partners.

Conclusion and recommendations

Sweden offers a digitally mature health system with national ambition and strong regional autonomy, making it attractive yet demanding for SME entrants. High digital literacy, universal EHR use, and secure patient identification create favourable adoption conditions, but entry typically begins with structured, competitive pilots and proceeds through region-specific procurement pathways that can be lengthy and exacting. CE/MDR compliance is necessary but not sufficient; buyers prioritise Swedish-generated evidence, rigorous interoperability, and demonstrable fit with local workflows and data-protection requirements. Each region should be treated almost as its own market, with distinct decision makers, timelines, and IT standards, and the path from pilot to paid contract is neither automatic nor uniform.

Even though Swedes are highly positive to digitalisation in general, there is gap between the openness to new digital tools and solutions in private life versus the strong hesitation of the hospital staff for implementation of new digital solution in healthcare, even though it would improve quality of life for the patients and make care providing more efficient and cost effective.

To convert early wins into scale, co-create your value proposition with regional data, showing precisely how you address local priorities such as elder-care monitoring or staffing constraints; maintain active post-pilot visibility by offering hands-on support, gathering structured feedback, and preparing for iterative technical or clinical adjustments; and align commercial pushes with regional procurement calendars and annual budget cycles so tenders and negotiations land at the right moment. In sum, Sweden rewards SMEs that localise evidence, integrate deeply with regional systems, and sequence expansion deliberately—treat the market as a federation of opportunities, start where sponsorship is strongest, and pair technical diligence with disciplined, calendar-aware commercialisation to turn strong pilots into reimbursed, scalable deployments.

Practical recommendations and overall conclusion

General recommendations for Digital Health SMEs across Europe

Here are some keys recommendations for Digital Health SMEs that apply across the six member states studied across this report:

1. **Engage early with local stakeholders**
   - Connect from the outset with regional innovation hubs, care providers, hospitals and payers.
   - Leverage innovation clusters and national health-tech portals for networking, pilot sites and introductions
2. **Build and sustain Advocacy Networks**
   - Identify and nurture on-the-ground champions (clinicians, departments heads, business developers).
   - Maintain relationships through regular updates, joint workshops and co-development activities.
3. **Commit to continuous, iterative evidence generation**
   - Begin with small pilots and agile feedback loops; scale to formal clinical and economic studies.
   - Anticipate and budget for additional evidence requests or technical adaptations at every stage.
4. **Localise your solution and documentation**
   - Provide multilingual interfaces, user guides and regulatory submissions tailored to each region.
   - Incorporate local data – health system challenges, patient need, cost drivers – into your value case.
5. **Plan for prolonged timelines and resource needs**
   - Build in buffers for regulatory reviews, procurement cycles and integration work.
   - Secure robust, long-term funding and staffing to sustain operations through slow reimbursement phases.
6. **Integrate fundraising with the reimbursement and launch strategy**
   - Define the target reimbursement pathway early (evidence requirements, timelines, pricing/coverage milestones) and build a stage-gated fundraising plan around it.
   - Budget explicitly for clinical evidence generation, regulatory/quality activities, health-economic studies, and stakeholder engagement; align financing rounds to de-risked milestones (e.g., pilot completion, pivotal readout, submission/approval, first contracts).
7. **Leverage specialised expertise**
   - Engage experiences consultants or advisors to navigate complex regulatory, reimbursement and legal requirements.
   - Tap into local accelerator or public innovation programmes for policy insights and pilot funding.
8. **Diversify your revenue streams**

- Pursue parallel models (B2B hospital sales, insurer partnerships, B2C offerings, B2G government sales) to reduce dependence on any single reimbursement pathway.
- Be creative in identifying interim billing codes or customer streams to bridge funding gaps.
- Clarify where in the patient outcome value chain the cost lies and where the actual benefit will occur to understand product-market fit versus procurement and cost structure challenges.

9. **Communicate value to healthcare professionals**
    - Frame your solution as a tool that supports and augments clinicians' work, not as a replacement.
    - Emphasise evidence or improved patient outcomes, workflow efficiencies, and cost savings,
10. **Cultivate patience and resilience**
    - Expect multiple rounds of feedback, administrative hurdles, and local adaptations.
    - View market entry as a long-term investment in relationships and credibility, not a one-off transaction.

Recommendations for policymakers and general conclusion

This analysis of the North Sea region's digital health markets highlights both strong commercial upside and significant access challenges for SMEs—and points to clear levers for policymakers and HTA bodies to accelerate innovation diffusion.

Across all six countries, robust growth & high technology adoption and stable healthcare financing underpin a fertile environment for digital health solutions. Yet the journey from product to sustainable revenue is shaped by deeply country-specific factors:

- **Digitally mature systems (Denmark, Sweden)** offer streamlined procurement but demand rigorous local evidence and clinician buy-in.

- **Large, innovation-friendly markets (France, Germany)** reward persistence and regulatory diligence but require meticulous local adaptation and multi-layered pilot schemes.

- **Complex, decentralised landscapes (Belgium, Germany)** compel SMEs to master regional reimbursement codes, multilingual deployment and coalition-building within hospitals, insurers and clusters.

For SMEs, success hinges on three pillars:

1. Early, sustained engagement with local stakeholders—from innovation hubs and clinical champions to payers and procurement officers.
2. Continuous, iterative evidence generation—starting with small pilots, leveraging open feedback loops and scaling into formal studies that demonstrate clinical, workflow and economic value.

3. Parallel business and funding strategies—combining B2B hospital or insurer partnerships, B2C offerings and creative interim billing pathways to bridge long reimbursement cycles.

Policymakers and HTA bodies can unlock further value by:

- Streamlining and harmonising regulatory and reimbursement frameworks, with transparent timelines and unified submission platforms.
- Bolstering regional innovation hubs and clinician-led evaluation panels to reduce administrative friction and strengthen local validation.
- Fostering cross-border pilot collaboration, mutual recognition of evidence and shared data standards to lower entry barriers and scale successful models.

By aligning SME agility with targeted policy reforms—emphasising interoperability, multilingual guidance, outcome-based reimbursement pilots and centralised portals—Europe can accelerate digital transformation, improve patient outcomes and sustain workforce capacity. This coordinated approach will be essential as DigiH4A moves into WP3's cost–benefit analysis and the A2.2 seminar series, ensuring that both practical SME insights and policy imperatives inform future investment and regulatory strategies.