HEALTHTECH INSIGHTS

STARTUP MARKET ACCESS READINESS

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Author and Contact

Siro Gottardi, siro@peakspirit.ch
Matthias Mettler, matthias@health-trends.ch
Jade Sternberg, jadesternberg@gmail.com

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Special thanks go to our partners, who provided us with significant support in the development of the database.

Swiss Healthcare Startups

digitalswitzerland

About This Report

The HealthTech sector in the DACH region (Germany, Austria, Switzerland) is experiencing dynamic growth, driven by demographic change, digital transformation, and increasing demand for innovative healthcare solutions. Startups play a vital role in this development by addressing medical, procedural, and systemic challenges with digital tools and new technologies. However, they face a complex and heavily regulated environment – making early, structured market validation a decisive success factor.

This report presents the results of an empirical study involving 46 HealthTech startups across Europe, with a particular focus on the DACH region. It examines how these ventures approach market validation, what methods they use, how deeply they validate their assumptions, and what resources they allocate to the process. The findings reveal a clear discrepancy between the strategic importance of market validation and the actual efforts made to carry it out. Although a majority of startups analyzed recognize its relevance, only around 40% achieve a robust validation maturity. This gap is especially evident among Digital Health and In-vitro Diagnostics (IVD) ventures, which often operate with lighter regulation constraints but still show lower validation depth compared to medical device startups.

The report identifies critical weaknesses in several key validation areas, including reimbursement strategies, legal and regulatory requirements, competitive intelligence, and clinical workflow analysis. Many early-stage startups invest less than €10,000 and fewer than three months into their validation activities – an investment level that is unlikely to be sufficient given the complexity of healthcare markets. Notably, the study finds a moderate positive correlation between validation depth and fundraising success, underlining the importance of thorough validation for investor readiness. In addition to presenting these empirical findings, the report offers concrete guidance for startups and ecosystem actors. It recommends that early-stage ventures start with a high-level validation across several segments and countries before committing to deep-dive analyses. Five core dimensions are identified as critical: Understanding existing workflows, mapping reimbursement and payer structures, refining the value proposition and pricing strategy, conducting in-depth competitive analysis, and incorporating early user feedback. Collaborations with academic institutions, hospitals, industry partners, and insurance providers are strongly encouraged to enhance data quality, credibility, and market insights.

The structure of the report follows a clear, logical progression: It begins with a contextual introduction that outlines the importance of market validation in the HealthTech domain. This is followed by a description of the HealthTech ecosystem in the DACH region, highlighting national characteristics and structural differences in Switzerland, Germany, and Austria. The third chapter discusses key validation concepts, methods, and common challenges. The heart of the report is the empirical study itself, which presents the dataset, evaluates the validation maturity of participating startups, and interprets results across categories such as financial stage, business model type, and market traction. Therefore, the final three chapters provide practice-oriented recommendations to startups, present the results of the empirical study in detail and reflect on the systemic underinvestment in market validation across the ecosystem – calling for a more structured and collaborative approach to ensure the viability and long-term success of startups.

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1 | Introduction

Innovations in healthcare are widely regarded as a key lever for addressing the demographic, societal, and economic challenges of our time. In the DACH region (Germany, Austria, Switzerland), HealthTech startups are gaining momentum by developing digital and technological solutions that span the entire patient journey, from prevention and diagnosis to treatment and aftercare. However, this dynamic industry operates within a highly complex environment shaped by strict regulations, long development cycles, and demanding reimbursement structures. Against this backdrop, one factor emerges as particularly critical: structured market validation.

Market validation is a decisive success factor in the innovation process of HealthTech startups. It refers to the systematic assessment of whether a planned solution addresses a relevant and recurring problem for clearly defined user groups, and whether these stakeholders are willing to adopt and finance the product. Within the heavily regulated healthcare landscape, where time-to-market can span several years and development costs can reach millions, early and data-driven validation is essential for avoiding strategic missteps and ensuring efficient allocation of resources.

Despite its importance, recent empirical findings from a study of 46 HealthTech startups reveal substantial deficits in validation efforts – particularly among Digital Health and In-Vitro Diagnostics (IVD) startups. While these companies sometimes benefit from lower regulatory hurdles compared to medical device hardware manufacturers, they tend to invest significantly less in validating their market assumptions. This discrepancy suggests a critical gap between perceived and actual readiness for market entry.

The aim of this contribution is therefore to examine the current state of market validation in the HealthTech sector in Europe, identify key methods and success factors, and provide actionable recommendations for startups and ecosystem stakeholders. Ultimately, this report seeks to offer practice-oriented and evidence-based insights into how HealthTech startups can better assess their market opportunities and improve their chances of success.

2 | The HealthTech Ecosystem in the DACH Region

2.1 Switzerland

Switzerland is currently undergoing a comprehensive digital transformation of its healthcare system. More than 350 HealthTech startups are active along the entire patient pathway. The HealthTech market in Switzerland is mainly concentrated in the cantons of Zurich, Basel, Geneva and Vaud (digitalswitzerland, 2023; Health-Trends, 2023).

Despite the strong momentum, challenges remain, particularly with the nationwide introduction of the electronic patient record (EPR) and the lack of clear reimbursement pathways for digital solutions. In contrast to other European countries, Switzerland does not yet have a separate reimbursement pathway specifically created for digital health applications, as has been introduced in Germany under the name DiGA, short for Digital Health Applications. Instead, digital health solutions in Switzerland must be integrated into existing remuneration systems (Eichenmann et al., 2024).

Public interest in data sovereignty is also growing: 68% of the Swiss population would like to own and control their personal health data (digitalswitzerland, 2023). National initiatives such as the Swiss Personalized Health Network (SPHN) and the Swiss Health Data Space aim to improve interoperability, transparency and patient empowerment.

2.2 Germany

Germany has taken significant regulatory steps to accelerate Digital Health adoption and therefore drive HealthTech innovation in a broader sense. The Digital Healthcare Act (DVG) and the Hospital Future Act (KHZG) provide the framework for targeted investments in digital infrastructure. A notable innovation is the DiGA Fast Track, which allows Digital Health applications to become eligible for reimbursement following evaluation by the Federal Institute for Drugs and Medical Devices (BfArM) (Scaler8, 2023).

Germany also hosts numerous leading innovation clusters such as the Medical Valley in the Nuremberg–Erlangen region, home to over 500 medical technology companies and numerous hospitals and academic institutions. It serves as a vibrant hub connecting start-ups, corporates, and researchers (de:hub, 2022).

2.3 Austria

Austria’s HealthTech ecosystem is also evolving rapidly, with Vienna as a key innovation center. The Health Hub Vienna (HHV) acts as a neutral, open innovation platform that connects startups, established enterprises, academia, and public sector institutions. Its core mission is to foster the development of patient-centered solutions and to transform the healthcare system through collaborative projects and knowledge sharing (Health Hub Vienna, 2025).

Currently, Austria lacks a standardized framework for reimbursing Digital Health applications (DiGAs); reimbursements are granted on a case-by-case basis under specific provisions of the General Social Insurance Act (ASVG) (Quickbird Medical, 2024). In 2024, the Austrian Federal Ministry of Social Affairs, Health, Care and Consumer Protection initiated the development of a uniform evaluation process for DiGAs, aiming to establish clear reimbursement criteria by 2026.

2.4. DACH Countries Similarities and Differences

While the three countries of the DACH region share many structural similarities in their healthcare systems, there are already significant differences in the reimbursement of Digital Health solutions, as outlined in the previous sections. These discrepancies become even more pronounced when factoring in therapy area, reimbursement pathway, degree of digitalization, and the nature of the startup - be it hardware, diagnostics, or software-based. This underlines the critical importance of thorough market research and validation for a successful market entry - not only across fundamentally different countries, but even within seemingly similar markets like Germany, Austria, and Switzerland.

3 | Market Validation for HealthTech Startups: Relevance, Methods, and Success Factors

Market validation is a critical phase in the innovation process of HealthTech startups. It refers to the systematic assessment of whether a planned product addresses a real market need and whether defined user groups are willing to adopt or pay for it. The aim of market validation is to provide evidence that a product solves a relevant and recurring problem for a clearly defined group of stakeholders and that there is a willingness to adopt and pay for the solution (Ries, 2011; Blank & Dorf, 2012). Within the highly regulated and complex healthcare sector, market validation plays a particularly important role: strategic missteps at this stage are costly to correct later, especially given the regulatory, interoperability, and data protection barriers (EIT Health & McKinsey, 2020).

3.1 Purpose, Importance, and Market-Specific Conditions

Market validation is considered solid when both the problem-solution fit (PSF) and early indicators of product-market fit (PMF) are supported by concrete data – such as letters of intent, pilot project collaborations, or behavioral usage data from minimal viable product (MVP) tests (Y Combinator, 2022; Haarmann & Holler, 2024). This is particularly crucial in the healthcare domain: due to heavy regulation and the associated requirements in product and service development, the time-to-market takes considerably longer than in many other industries. The average time-to-market is around three years for Software as a Medical Device (SaMD) and up to seven years for medical hardware, with development costs reaching up to USD 54 million for Class III devices in the U.S. (Sertkaya et al., 2022; Silvestrini, 2023; Haarmann & Holler, 2024).

Comparable timelines and cost structures apply within the DACH region, although there are no corresponding overviews. The following statements are based on empirical values from corresponding investor programs such as Innosuisse or from typical budget plans of HealthTech startups in funding applications, especially in Swiss or German e-health programs (e.g. Digital Health Applications – DiGA Fast-Track): While simple Digital Health applications may reach market readiness within 6 to 12 months, medical products – depending on their risk classification – often take 3 to 7 years. From the authors' own market experience, it can be deduced that market validation efforts in early stages typically cost between € 50,000 and € 150,000, while advanced phases involving pilot trials and regulatory studies can push costs to € 500,000 or significantly more, especially when international approvals are pursued.

These figures underline the importance of early, structured validation to avoid expensive misallocations. A well-evidenced validation process enables startup teams to make informed go/no-go decisions even before regulatory constraints (e.g. design freeze) lock in product development paths. In addition, HealthTech founders must also account for complex value chains: while consumers may directly purchase Digital Health tools (e.g., apps), medical-grade solutions are often financed by third parties such as hospitals or insurers. This creates triadic decision-making structures involving patients, physicians, and payers, all of whom have divergent roles and incentives. Effective validation must therefore involve all key stakeholders and define tailored value propositions for each (Yock et al., 2015, p. 159).

3.1 Validation Methods

Startups typically apply a mix of qualitative and quantitative approaches that align with the phases of the lean start-up methodology (Ries, 2011):

- Customer Discovery Interviews: In-depth interviews with clinicians, patients, or administrators reveal user needs, usage contexts, and system constraints. However, recruiting these stakeholders can be extremely difficult: a Swiss study by Haarmann & Holler (2024) showed an average response rate of only 9% from healthcare professionals.
- Concept Testing and Surveys: To assess PSF and PMF, concept descriptions or prototypes are shown to potential users, who give feedback on relevance, usage intent, and pricing expectations. Net Promoter Scores (NPS) and referral willingness are often used as additional indicators.
- Sean Ellis Test: A pragmatic and widely adopted method where MVP users are asked how disappointed they would be if they could no longer use the product. A result of over 40% "very disappointed" is considered a strong indicator of PMF (Ellis, n.d.; Haarmann & Holler, 2024). In HealthTech, this test must be adapted (e.g., with smaller test groups or realistic pricing brackets).
- Willingness-to-Pay (WTP) Analysis: Particularly relevant in healthcare, where the end-user (e.g., patient) often isn't the paying entity. Validation must therefore include physicians, hospital buyers, and payers, and must test stakeholder-specific pricing expectations (Yock et al., 2015).
- Behavior-Based Metrics: Early indicators such as retention rates, pre-sales, and referral rates help to assess product traction. Especially in digital settings, these KPIs can often be gathered during MVP stages (Haarmann & Holler, 2024).

3.3 Success Factors and Challenges

A robust market validation depends on three core principles:

1. Early Hypothesis Testing: Validation must start before product development progresses too far. PSF analysis should precede PMF assessment: no product can achieve market fit if it fails to solve a real problem (Haarmann & Holler, 2024).
2. Stakeholder-Centric Design: The fragmented roles in healthcare markets (e.g., user ≠ buyer) require deep understanding of stakeholder needs and incentives. Tailored value propositions and revenue models are essential (Yock et al., 2015).
3. Objective Measurement: Bias is common, especially when founders conduct interviews themselves. Standardized tools, third-party moderation, or quantitative testing increase result validity (York & Danes, 2014).

Market validation is therefore not a one-time effort, but an iterative process of testing, learning, and adapting. In the capital-intensive and regulation-heavy HealthTech space, solid validation determines not just product-market success, but also investor confidence and survival. Successful teams combine qualitative research with quantitative metrics and use structured processes to inform strategic pivots, long before regulatory constraints limit flexibility. Hence, by investing early in validation – even at five- or six-figure costs – startups can reduce the risk of failure, enhance stakeholder engagement, and increase their likelihood of developing meaningful solutions that make it to market.

4 | Practical Recommendations for Startups and Stakeholders

4.1 Best Practices for Successful Market Validation

Thorough market validation is essential for any startups aiming for a successful market entry and sustainable growth. However, for early-stage startups with limited funding, conducting extensive analysis across multiple countries and customer segments is often impractical due to the significant resources required. Instead, a focused approach is crucial. We recommend initially validating three to six segments across two to three countries, with plans to expand to five countries and their respective customer segments after securing the first investment round.

For example, a software solution designed to optimize surgical workflows might initially focus on both outpatient and inpatient settings in Germany, France, and the US, with plans to expand validation efforts to the UK and Switzerland at a later stage. This phased approach ensures efficient resource allocation, as conducting such an analysis requires significant effort.

4.1.1 Key Aspects of Market Validation

Successful market validation involves a structured approach to understanding each target segment and country. The following five areas are critical:

a) Standard of Care, Processes, and Existing Workflows

- Identify how the target institutions currently operate.
- Understand the people, tools, and materials involved in existing processes.
- Assess the time and costs associated with current workflows.
- Recognize the biggest unmet needs, as these are fundamental in shaping a compelling value proposition and pricing model.
- Processes vary significantly by country, institution type, and use case, a factor that must be deeply analyzed.

b) Payer, Reimbursement, and Business Case

- Determine who will pay for the solution and through which channels.
- Many countries offer 20+ different reimbursement or market entry pathways. These must be screened to identify the most accessible option.
- Identify “low-hanging fruit” reimbursement models that enable faster adoption and scaling.
- In some cases, institutions or private investors are incentivized to invest from their own budgets without relying on special reimbursement pathways. These opportunities should not be overlooked, which is why it's crucial for startups to understand the business case that drives their customers to invest in their solution.

c) Value Proposition and Pricing

- These two factors are interlinked and depend on a thorough understanding of the current standard of care and the internal processes of the customers.

- The value proposition should be fine-tuned based on the most pressing unmet needs identified.
- Cost analysis and the identification of unmet needs will inform a value-based pricing approach.
- It is important to ensure the pricing model aligns with customers' willingness and ability to pay.

d) Competitive Intelligence and Market Potential

- Competitive Intelligence:
    - Startups often underestimate entry barriers, assuming superior technology alone will secure adoption.
    - Even indirect competitors with existing contracts can block access to institutions, regardless of technological superiority.
    - An in-depth competitive analysis is essential to understanding real barriers to entry.
- Market Potential:
    - Startups should conduct both top-down and bottom-up market size estimations and validate their estimations through expert feedback

e) Product Development and Early Testing

- While this report focuses more on commercial aspects, early product validation is another crucial area.
- Startups should actively test prototypes or minimal viable products (MVPs) with potential users to gather real-world feedback.
- Unlike desk research, physical product testing provides deeper insights into user adoption challenges and necessary improvements.

4.1.2 Key Challenges in Market Validation

We identified three core challenges that startups often face when validating their markets:

Challenge 1: Structuring the Market Validation Process

- Market validation requires assessing multiple interdependent factors (e.g. clinical pathways, pricing, reimbursement), making it difficult to structure.
- We recommend organizing an internal workshop to map out the market validation process and priorities.
- If no team member has expertise in market validation, consider consulting an expert.
- We suggest desk research and expert interviews as primary validation methods for B2B companies. In addition, pilot projects can also contribute to market validation insights.

Challenge 2: Accessing the Right Experts

- Structured expert interviews provide in most cases far more valuable insights than surveys or desk research alone and are crucial for success
- The biggest challenge is gaining access to key stakeholders, such as:
    - Physicians, nurses, and procurement teams
    - Hospital directors, insurers, and specialists
    - Innovation managers, business development professionals, and decision-makers in pharma, MedTech, or other organizations
- Cold outreach is often necessary. Startups should:

- Aim for at least 3-5 expert interviews per segment (totaling 18-30 for six segments).
- Leverage existing networks but recognize that cold outreach is often inevitable.
- Work with an experienced partner if the team lacks business development skills.

Challenge 3: Data Analysis and Developing a Market Entry Strategy

- Once validation data is gathered, synthesizing insights into a clear go-to-market strategy can be challenging.
- In many cases, data does not provide a definitive answer. When this occurs:
  - Testing multiple market entry strategies may be necessary.
  - Conducting another small round of validation could help clarify direction.

4.1.3 Final Recommendations: High-Level vs. In-Depth Validation

Successfully validating HealthTech markets is a complex, resource-intensive process. We recommend startups focus on high-level validation across multiple segments first, rather than conducting an in-depth validation of a single segment upfront. A high-level validation typically provides 70-90% of the key insights needed for early decision-making. This enables startups to:

- Identify priority markets and focus areas.
- Develop a structured, expert-validated go-to-market strategy.
- Secure stakeholder buy-in, including from investors.

Once key segments are identified, startups can then proceed with in-depth validation where necessary to fine-tune their approach and maximize market entry success.

4.2 Cooperation with Universities, Hospitals and Other Stakeholders

Collaboration with key stakeholders is a critical enabler for effective market validation in HealthTech. Yet, this area remains severely underprioritized. A lack of awareness for the topic of market validation and limited access to relevant experts often hinder the ability to answer core validation questions with the necessary depth. Educational institutions like incubators and accelerators that support startups in the HealthTech sector must place greater emphasis on market validation and address its critical role in shaping viable business models. Training programs should actively raise awareness among future entrepreneurs about the risks of insufficient market validation and prepare them to tackle these challenges early on.

To address this, we recommend building a targeted business development network that includes experts from hospitals, clinics, insurers, business development, representatives of end customers, e.g. patient experts, and market validation. Collaboration with academic institutions and universities offers not only methodological expertise and research capacity but also increases credibility and participation rates among healthcare professionals during early-stage user studies. Clinical partners enable real-world testing environments, strengthening the evidence for both problem-solution fit and product-market fit.

Involving additional ecosystem actors – such as payers, regulatory bodies, or industry associations – helps startups better understand reimbursement and regulatory pathways, data protection requirements, and the structure of healthcare markets. These stakeholder relationships are not just a source of insights and access; they significantly improve data quality, speed up validation processes, and ultimately increase the likelihood of successful market entry and scale-up.

5 | Study on Market Validation in the HealthTech Sector

5.1 Description of the Sample

The underlying dataset of the conducted market study consists of 46 HealthTech startups, with 31 based in Switzerland, 5 in Denmark, 3 in Germany, and the remaining startups primarily located in other European countries. A online survey was conducted in the fourth quarter of 2024 to assess their perspectives on market validation, the tools they use to validate different market segments, the sophistication of their methods, and the resources they allocate to market validation.

Among the participating startups, 19 had been working on their ideas for less than two years, while the rest had been developing their concepts for a longer period. In terms of industry focus, 16 teams operate in the medical device hardware sector, while 18 are in Digital Health, of which 9 develop Software as a Medical Device (SaMD), and the other 9 focus on non-medical device-regulated software. Additionally, 7 teams specialize in In-vitro Diagnostics (IVD), and 5 are engaged in Other Life Science Technologies.

Regarding market maturity, 15 startups had already launched at least one product, while the remaining companies were still in the pre-launch phase. Among them, 12 planned to launch their first product within the next year.

In terms of funding stages, 14 startups were bootstrapped, 25 were in the pre-seed or seed stage, and 7 had progressed to series A or beyond.

This diverse sample of life science and HealthTech startups provided valuable insights into different approaches to market validation across various sub-sectors.

5.2 Results and Interpretation

Most startups recognized market validation as a highly important topic, with 84.7% agreeing on its significance. In addition, a notably higher proportion of medical device hardware startups (93.8%) stated that market validation should either be a priority from the start or remain a high priority at all times. In contrast, startups in Digital Health, In-Vitro Diagnostics, and Other Life Science Technologies showed a more varied perspective: 52% of these companies either did not rank market validation as highly important or considered it a priority only at a certain stage.

This disparity between medical device hardware startups and those in different health technology sectors is particularly interesting, given that many key aspects of market validation – such as reimbursement strategies, identifying the most pressing unmet clinical needs, defining a strong value proposition, and pricing considerations – are crucial across almost all types of HealthTech startups.

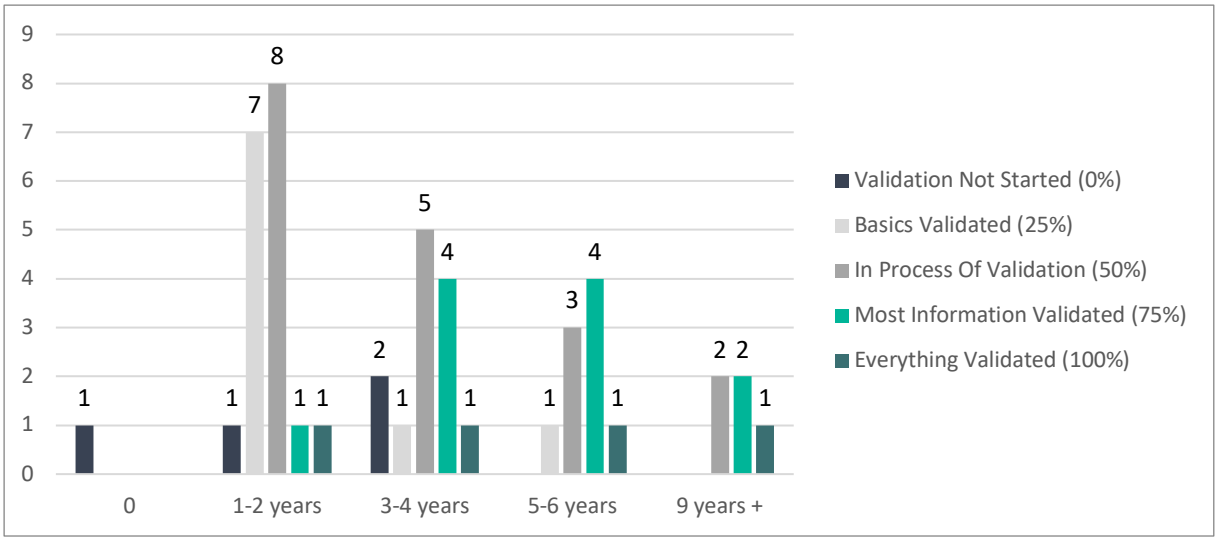

Figure 1: Distribution of Startups by Startup Age and Perceived Validation Stage

As can be seen in Figure 1, which shows the number of startups by their age and their self-assessed progress in market validation, a significant number of teams which have been working on their ideas for more than two years are still at 50% or less in their market validation process. This trend may reflect the complexity of navigating a sustainable market validation strategy. Additionally, it could indicate that market validation is often neglected or perceived as a "nice to have" rather than a fundamental necessity in the development process.

5.2.1 Analyzing the Link Between Validation Depth and Investment Levels

In our study, we assessed the tools and methodologies startups use to validate their target segments, including conversations, social media testing, focus groups, in-depth desk research, competitor analysis, structured interviews, and more. We defined a metric called "validation depth", ranking the thoroughness of each startup's validation process. The authors developed this metric based on their experiences with HealthTech startups. More sophisticated methods, such as structured interviews with industry experts, were scored higher compared to more basic approaches, such as casual conversations with potential customers.

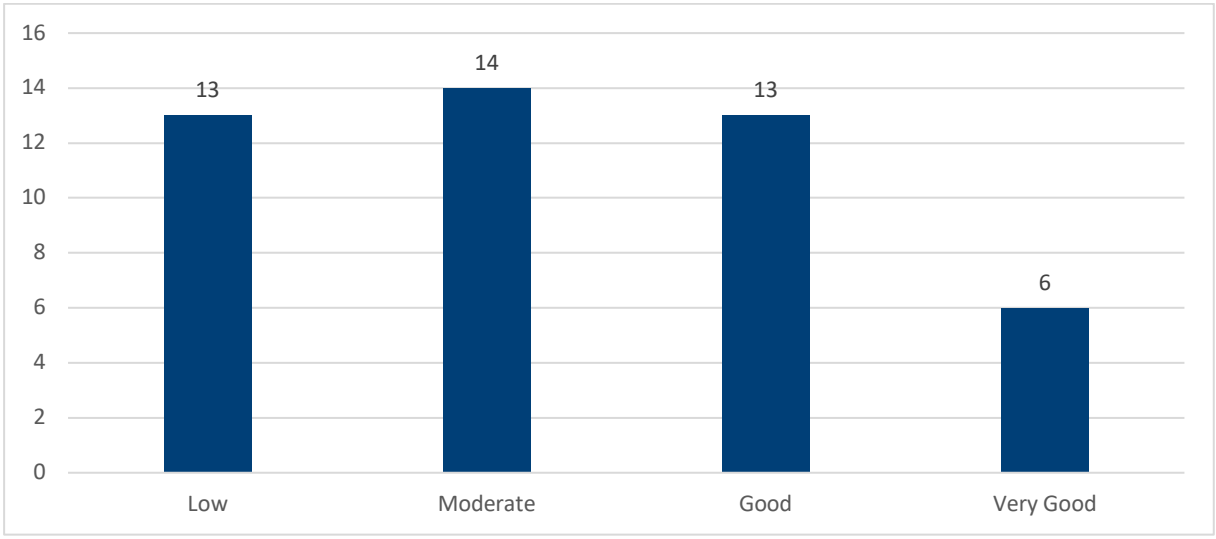

Figure 2: Distribution of Startups in Different Levels of Validation Depth

As depicted in Figure 2, our findings show that only 19 startups (41%) achieved a level of market validation that we would consider as "good" or "very good", while the majority (59%) remained at a low or moderate level. While validation needs may vary based on the type of project and the maturity of the startup, it was surprising that more than half of the surveyed teams had not reached a level of validation that could be considered good.

Based on our validation depth metric, we also found that IVD and medical device hardware startups were the only two groups where the majority of startups achieved a good or very good validation level. In contrast, Digital Health startups showed significantly weaker validation performance. This is particularly surprising given the sector's strong reliance on data-driven decision-making and regulatory compliance. All analyzed areas are subject to regulation, and with medical device regulation (MDR), hardware MedTech startups may in some cases be even more regulated than their Digital Health counterparts. Despite this, Digital Health startups often struggle with monetization, especially in markets like Switzerland, where viable business models remain unclear (e.g., see Health-Trends, 2023 or Eichenmann et al., 2024). Given these challenges, one would expect Digital Health startups to take a more structured approach to market access and prioritize validation efforts accordingly. However, our findings suggest that this is not yet the case.

Additionally, we observed a mild to moderate correlation between dilutive funding raised and validation depth (correlation coefficient = 0.30, p-value = 0.041). This correlation could be bidirectional:

1. Startups with sufficient funding may have more resources to invest in comprehensive market validation.
2. A strong market validation process may be a prerequisite for securing funding, as investors often require solid validation data before investing.

From our experience and discussions with venture capital experts, the second factor appears particularly relevant. Many investors assess market validation rigorously, and startups lacking sufficient validation data often struggle to secure funding.

5.2.2 Key Areas Researched in Market Validation

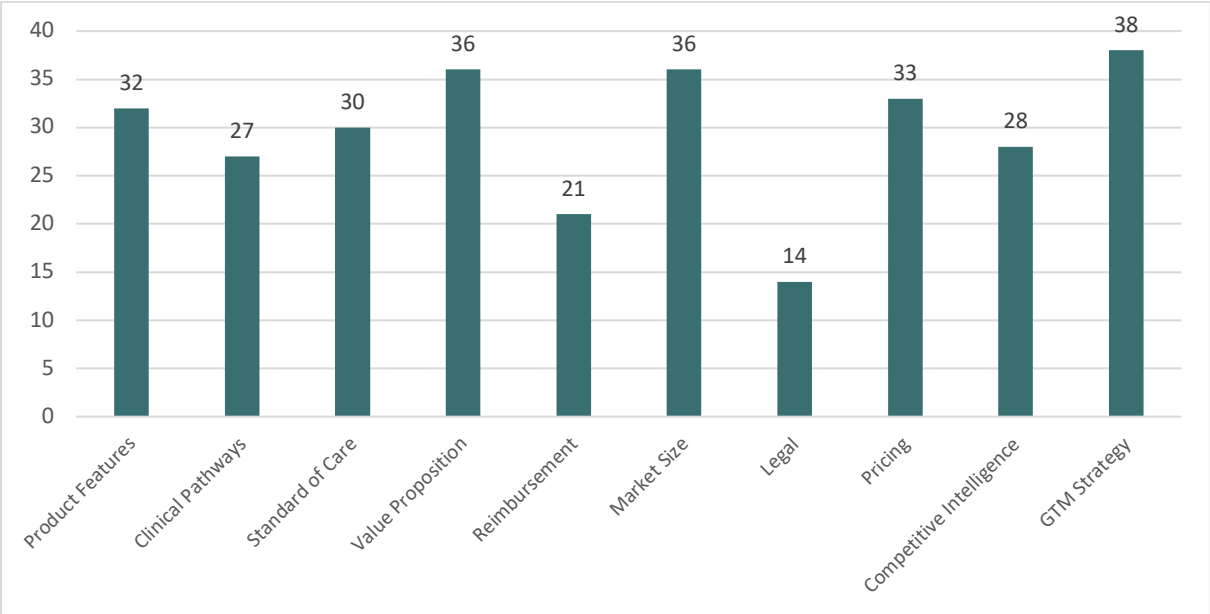

Figure 3: Distribution of Startups Focusing on Different Areas of Market Validation Research

As depicted in Figure 3, we examined 11 key areas of validation, including product features, clinical pathways, standard of care, value proposition, reimbursement, market size, legal aspects, pricing,

competitive intelligence, and go-to-market (GTM) strategy. While most startups validated most of these areas, four key aspects stood out as being significantly under-researched: legal aspects, reimbursement, competitive intelligence and clinical pathways.

Legal aspects: Legal considerations were explored by just 30.4% of startups. Given the strict compliance requirements in medical and Digital Health markets, overlooking this aspect can lead to delays, legal risks, and unexpected costs.

Reimbursement: Only 45.6% of the startups actively researched reimbursement, which is strikingly low given its critical importance. Understanding who will pay for the solution is fundamental, yet we know that many startups assume that big pharmaceutical companies, insurers, or healthcare providers will cover costs without validating this assumption. As shown in Figure 4, our data reveals that reimbursement research is often deprioritized until startups secure a significant amount of dilutive investment. This creates a classic "chicken-and-egg" dilemma for startups: Many lack the expertise to conduct reimbursement research early on and wait until they have closed their first funding round to invest in it. However, investors are often reluctant to invest in startups that have not validated their reimbursement strategy, making this delay a critical obstacle to securing funding.

For most health technology startups, validating reimbursement on a per-country and per-market-segment basis is essential. Reimbursement structures can vary significantly within different customer segments in the same country (e.g. inpatient vs. outpatient reimbursement), and even more so between different countries and customer segments. Despite this, many startups incorrectly assume that if they understand reimbursement in one customer segment of their home market, the same principles will apply elsewhere. This assumption is often false and can lead to challenges in market entry, misalignment with payer expectations, and ultimately, the failure of the company.

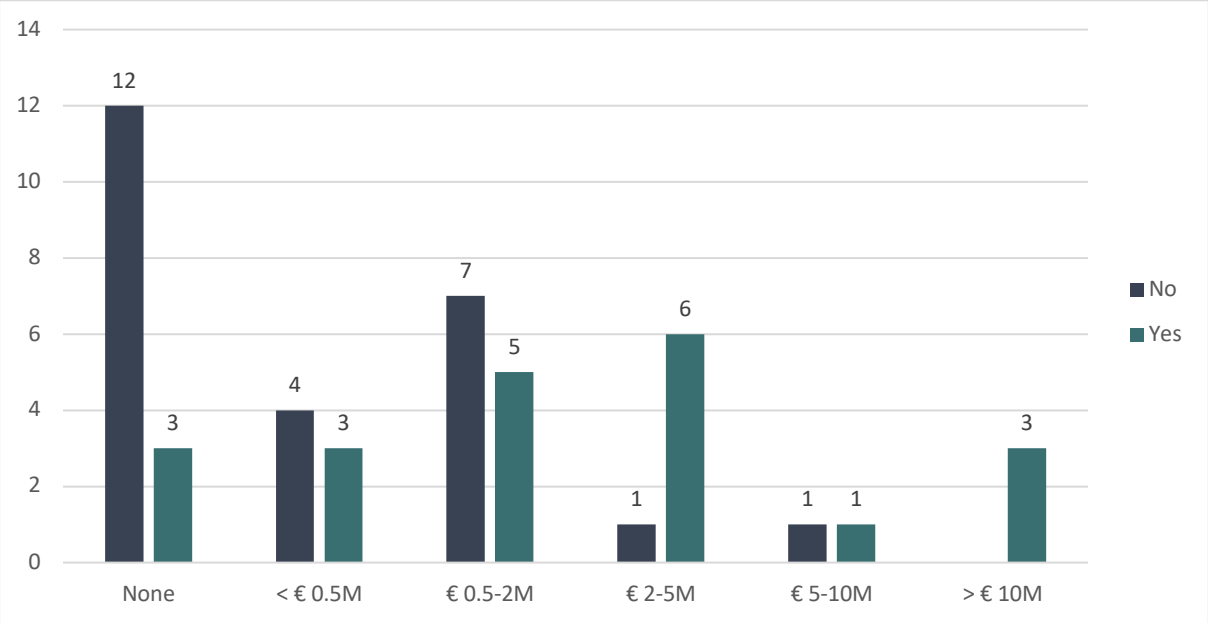

Figure 4: Distribution of Startups by Dilutive Funding Raised and Reimbursement Validation Focus

Competitive intelligence: Competitive research was conducted by 60.1% of the startups, but from our market experience working with numerous early-stage startups, we know that many do so superficially. From our experience, many startups are overconfident, believing they are the only "real" solution in their market. Instead of conducting in-depth analyses, they often limit their research to identifying competitor names and basic focus areas. A robust competitive validation should include assessments of competitors' team compositions, geographic expansion plans, partnerships, reimbursement strategies, and more.

Clinical Pathways: Clinical pathways were researched by only 58.7% of the startups. In some cases, this may be justified - such as for companies developing general-purpose solutions that do not need to integrate deeply into existing clinical workflows. However, clinical pathways remain one of the most neglected yet crucial validation areas. In our experience, many startups fail to fully understand current medical workflows and how their solution would be adopted in practice.

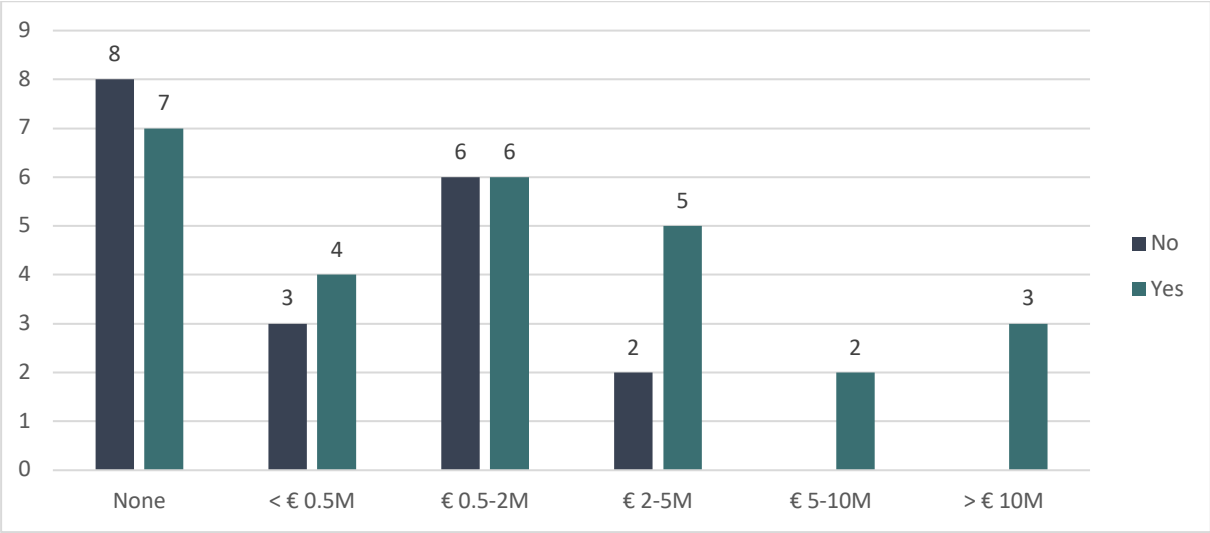

Figure 5: Distribution of Startups by Dilutive Funding Raised and Clinical Pathways Validation Focus

As depicted in Figure 5, our data further indicates a correlation between funding levels and the extent to which startups research clinical pathways. Our data on dilutive and non-dilutive funding, as well as funding needs, suggest that clinical pathways are typically researched only when teams have raised or are planning to raise a significant amount – typically in the multi-million range.

From our perspective, this aligns with a common underestimation of clinical pathway complexity among early-stage and low-funded teams. Clinical pathways may vary significantly across market segments and involve lengthy procedures, multiple stakeholders, and a very low willingness to adapt already implemented processes. Many early-stage teams fail to recognize the importance of understanding these aspects from the outset. However, a thorough clinical pathway analysis is crucial for both product development and market entry strategy. Without it, startups risk delays, unexpected barriers, and misalignment with real-world healthcare processes.

5.2.3 The Risk of Overgeneralization in Market Validation

In the previous sections, we highlighted that many of the key factors requiring validation for a successful market entry can vary substantially - not only between countries, but also across different market segments within the same country. Our findings indicate that a significant portion of startups are not validating their solution for each target country or market segment individually – 34.8% do not plan to validate for each country, and 30.5% do not plan to validate for each target segment.

From our experience, many startups begin with initial insights from a single country or healthcare setting and assume that their solution will perform similarly in other markets. Even when international expansion is part of their long-term roadmap, many teams fail to invest in further validation early on, which can lead to unanticipated regulatory, reimbursement, or adoption barriers – a massive overgeneralization.

In the following, we segmented the startups into distinct HealthTech categories (see Figure 6). The first group includes Digital Health solutions, which are further divided into “regulated” (e.g. Software as a Medical Device, such as a digital therapeutic app) and “not regulated” (e.g. a nurse coordination platform). The second group consists of diagnostic solutions, focusing on In Vitro Diagnostics (e.g. a novel

blood test). The third category is medical device hardware, referred to here as “hardware”, which includes products like implants. Lastly, we defined a category called “other technology”, which includes life science–related innovations that do not fall into the above categories, such as an app designed to improve research laboratory workflows.

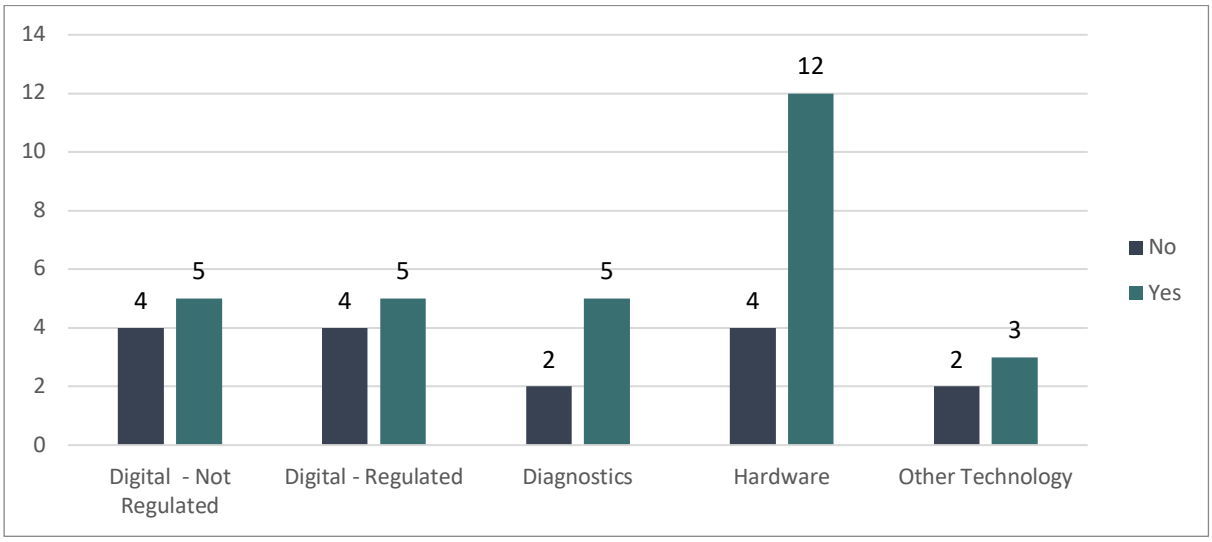

Figure 6: Distribution of Startups by Healthtech Category and Country-Specific Validation Approach

As illustrated in Figure 6, IVD and medical device hardware startups tend to adopt a more rigorous country-specific validation approach, aligning more closely with best practices we recommend for all HealthTech startups. In contrast, Digital Health startups appear less focused on understanding variations across different countries and are less likely to validate their solution beyond their initial target market. This lack of early validation may lead to delayed market entry, unexpected regulatory hurdles, and difficulties in securing reimbursement in new regions.

One possible explanation is that hardware and diagnostics teams often originate from academic environments, where they benefit from structured support systems - including, in some cases, guidance on market validation. In contrast, Digital Health teams are frequently bootstrapped outside of academic environments and may face greater barriers to accessing education and expertise in this area. Combined with the fundraising challenges in the Digital Health sector (and also in the other sectors), this limited access to resources and support may contribute to the insufficient emphasis on market validation - ultimately reflecting the broader difficulties faced by Digital Health startups. This, however, remains a hypothesis and should be further examined and validated through future research.

5.2.4 Budget and Human Resource Allocation for Market Validation

Figures 7, 8, and 9 highlight critical insights regarding the financial and human resources allocated to market validation across different HealthTech startups.

A key finding is that early-stage startups (seed and earlier), which are typically focused on securing their first major funding round, often neglect thorough market validation. From our experience, many of them lack a solid understanding even of their home market, leaving them underprepared for the challenges typical at their stage. As discussed earlier, our collaboration with investors confirms that one of the main reasons HealthTech startups fail to secure initial funding is their insufficient understanding of target markets, leading to weak business models.

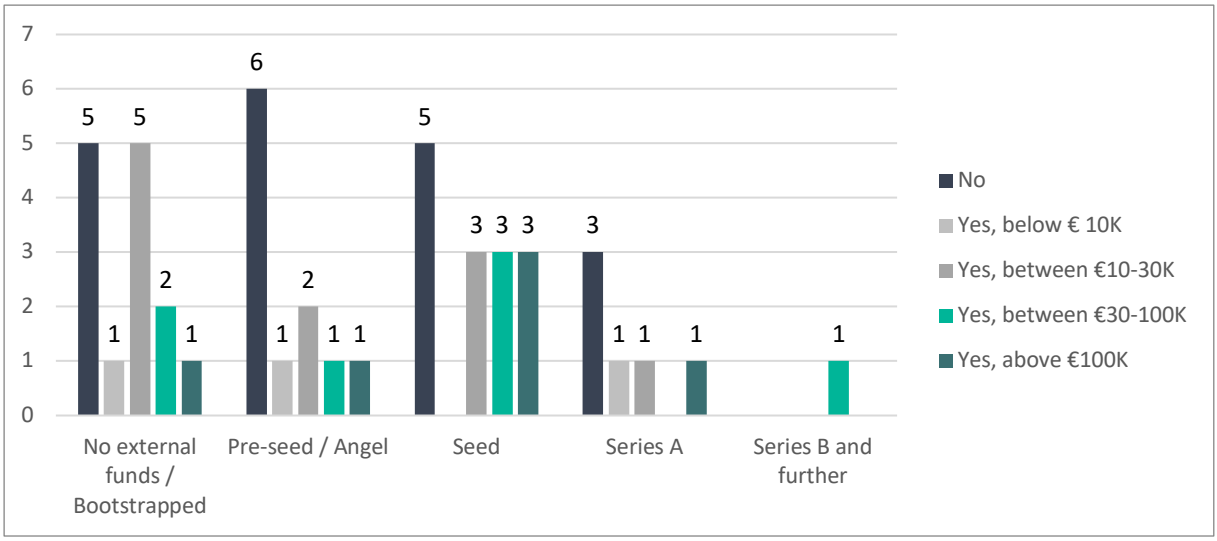

Figure 7: Distribution of Startups by Investment Round and their Planned Financial Investment in Market Validation

As illustrated in Figure 7, this challenge is evident:

- Among the 39 startups from the sample analyzed, that are in Seed stage or earlier, nearly half (18, 46.2%) have allocated either no budget at all or less than €10,000 on the topic, an amount likely insufficient for thorough validation.
- If startups choose to bootstrap their market validation, they must compensate for the lack of financial investment with substantial human resources. However, as insights from the data collected show, even then the start-ups in question do not invest more of their own time in validation. In our experience, it takes at least six months for an experienced market access expert to thoroughly validate a single market and develop a refined go-to-market strategy. However, our data show that more than two-thirds (34 out of 46, or 73.9%) of the startups spent less than three months on the process – insufficient to properly validate multiple target segments and countries.

Even among startups seeking €2-5M in funding, we found concerning trends:

- Half (4/8) had not allocated any financial resources to market validation.
- More than half (5/8) had allocated less than one month of human resources to the process.
- This underlines a major gap, even among startups with ambitious and capital-intensive business models.

Figures 8 and 9 reveal sector-specific differences in market validation investments:

- Medical Device Hardware startups allocate the most resources, with approximately 50% planning to invest more than €30,000, and also roughly 50% allocate over three months of human resources to market validation. However, the fact that the remaining 50% in this sector still fall below this threshold is concerning.
- The situation is far worse for Digital Health, IVD, and Other Life Sciences startups:
    - 90% (27/30) of startups in these sectors allocate less than €30,000 to market validation, an amount we consider to be the minimum necessary to properly validate different countries.
    - 60% (18/30) allocate less than €10,000, an amount unlikely to support meaningful validation.
    - 86.7% (27/30) allocate three months or less to market validation efforts, which is a very limited amount that may lead to incomplete validation.

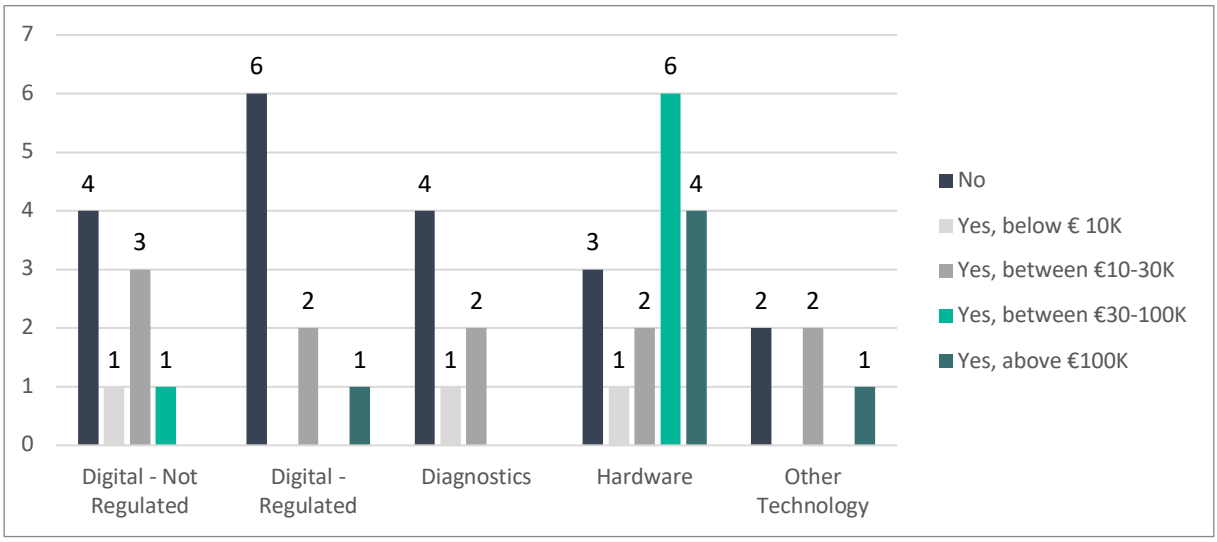

Figure 8: Distribution of Startups by HealthTech Category and Planned Financial Investment in Market Validation

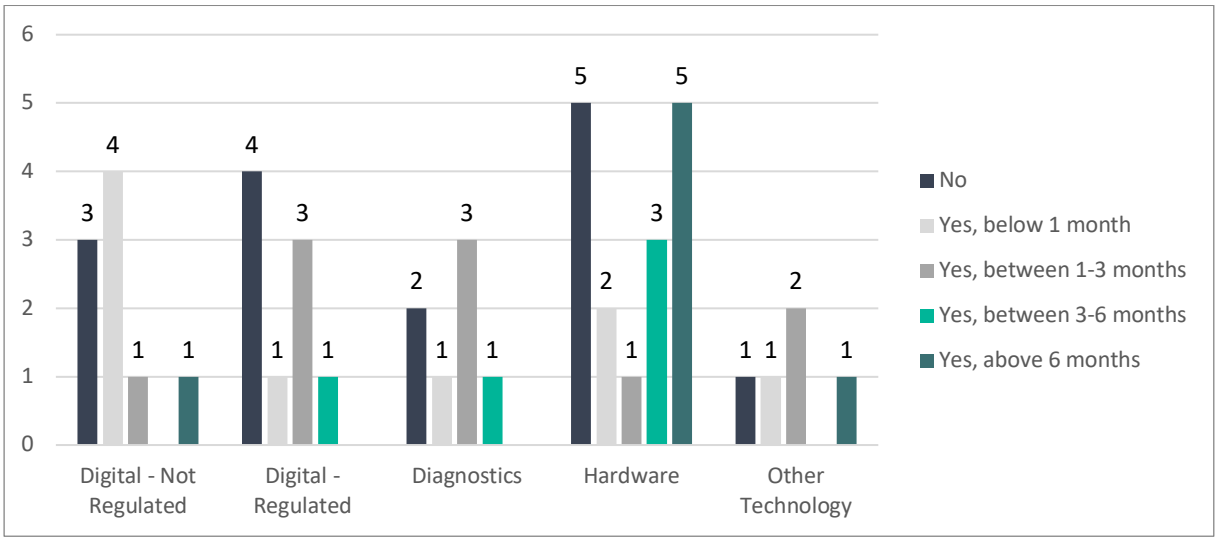

Figure 9: Distribution of Startups by HealthTech Category and Planned Human Resources Investment in Market Validation

These figures clearly suggest that market validation remains both underprioritized and underfunded. In this context, it is essential to raise awareness among founders about the importance of market validation - not only to enhance the success prospects of individual startups, but also to strengthen the overall HealthTech startup ecosystem. Given that millions in taxpayer funding are invested in grants supporting early-stage research, there is a compelling public interest in ensuring that these funds are allocated wisely. Even if the scientific output of grant-funded projects is of high quality, conducting research without proper market validation risks misalignment with real-world needs and may ultimately result in the failure of otherwise promising innovations.

5.2.5 Market Traction and Its Relationship with Market Validation

A critical measure directly linked to market validation is market traction: i.e., the ability of a startup to demonstrate that there is demand for its solution, typically through paying customers. However, in the HealthTech industry, generating early revenue is often not legally possible, as medical products must usually receive regulatory approval before being sold. This approval process can take up to several years, particularly for products that have the potential to pose significant risks to patients.

To provide a proxy for market traction, many startups in the sector rely on alternative indicators, such as Letters of Intent (LOIs), research collaborations with renowned institutions, or paid research pilot programs. In our study, we assessed what types of traction startups have achieved and ranked them based on our expert evaluation of their level of market traction.

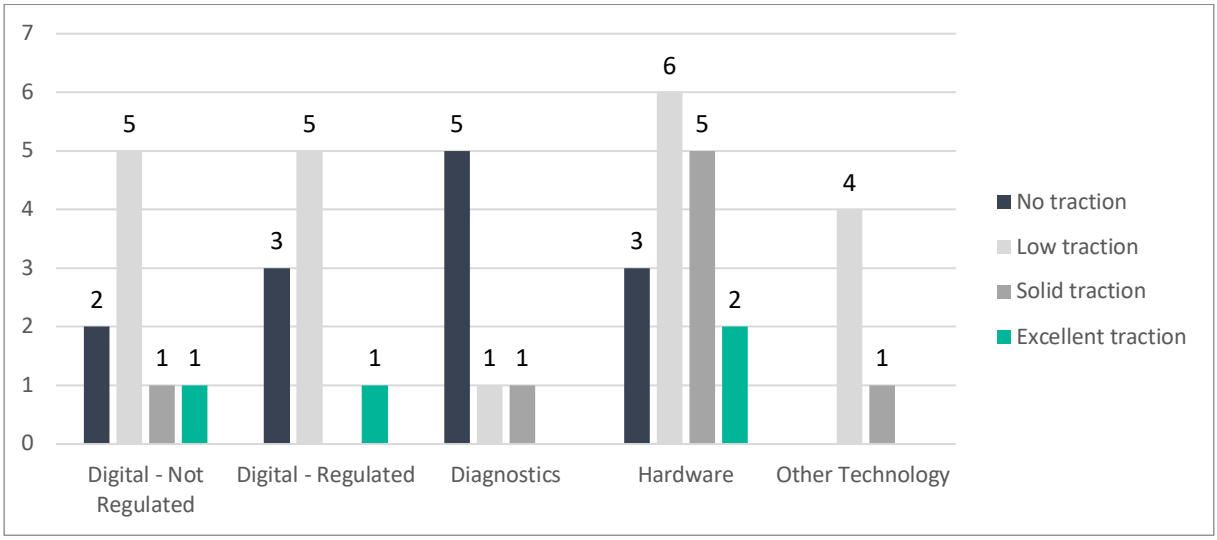

Figure 10: Distribution of Startups by Healthtech Category and Traction Generated

As illustrated in Figure 10, Medical Device Hardware startups exhibit significantly higher market traction than other HealthTech sectors. However, overall, most startups seem to struggle with market traction:

- 34 out of 46 startups (73.9%) were ranked as having low or no traction.
- This lack of traction is usually a major barrier to raising funding, as most investors require startups to demonstrate a clear level of market engagement.

We know from our experience that market traction is closely tied to market validation:

- Effective market validation requires networking and industry engagement, which can, in turn, lead to market traction through partnerships, pilot programs, or customer commitments.
- Startups that invest in expanding their network and engaging with stakeholders are more likely to gain early traction, strengthening their position for future funding.

6 | Conclusion and Outlook

Our research highlights a significant gap in market validation efforts across HealthTech startups, with insufficient financial and human resources allocated to understanding target markets and reimbursement structures. While Medical Device Hardware startups demonstrate stronger validation efforts compared to other HealthTech sectors, it is shocking that even in this sector, only around half of the companies have invested the necessary resources into market validation. Given the highly regulated nature of this field and the complexity of market access, this lack of investment could pose significant risks to long-term success.

The situation is even more concerning in Digital Health, In-Vitro Diagnostics (IVD), and Other Life Science Technologies, where approximately 90% of startups fail to invest even the minimum amount, we consider necessary to properly validate different countries and market segments. This widespread neglect suggests that many startups may be advancing with limited understanding of how to enter and succeed in diverse healthcare markets, increasing their likelihood of failure.

Several factors may explain this chronic underinvestment in market validation:

- Scarcity of specialized know-how – The expertise required to conduct proper market validation is difficult to access, and most startups and supporting organizations lack this knowledge. Without in-house expertise or access to affordable guidance, startups struggle to navigate complex regulatory landscapes, reimbursement models, and healthcare ecosystem dynamics.
- Complexity of the topic – Market validation in HealthTech requires understanding country-specific regulations, reimbursement policies, and system variations. Without structured guidance and accessible resources, startups may delay or completely overlook this critical aspect of their business strategy.
- Scientific and technical focus of founding teams – Many founders come from research and engineering backgrounds, prioritizing technology development while lacking expertise in market access, commercialization, and regulatory strategy.
- High cost of market validation services – Many service providers charge high fees to validate individual countries, often making thorough multi-market validation unaffordable for startups. Since healthcare markets differ significantly between countries, this pricing structure creates a barrier to proper validation, forcing startups to rely on limited, often incomplete market insights.
- Neglect by the broader ecosystem – Historically, market validation has not been a central focus of incubators, accelerators, or investment programs, with more emphasis placed on technology development and fundraising rather than ensuring startups have a clear path to market adoption.

We suggest early-stage startups should adopt a focused approach, validating a few key segments and countries before expanding their efforts. A structured validation process - including understanding existing workflows, reimbursement pathways, competitive landscape, and expert insights - is critical for refining a strong value proposition. However, challenges such as accessing key stakeholders, structuring the validation process, and synthesizing data into a clear strategy must be carefully managed. By starting with high-level validation and progressively refining their market strategy, startups can optimize resources, attract investors, and increase their chances of successful market entry.

It is evident that market validation has been overlooked for far too long, leading to avoidable startup failures in the HealthTech sector. If the industry is to foster more sustainable, successful startups, all stakeholders in the ecosystem - including universities, venture builders, incubators, accelerators, startups, and investment firms - should begin prioritizing market validation immediately.

Investing in structured validation programs, expert guidance, and industry collaboration will be essential to equipping startups with the knowledge and resources they need to navigate the complexities of healthcare markets. By addressing this gap, the HealthTech ecosystem can significantly improve startup success rates, accelerate market adoption of innovative solutions, and ultimately drive better patient outcomes worldwide.

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About the Authors

Siro Gottardi is the CEO of Peak Spirit and a go-to-market and sales scale-up expert based in Switzerland, Europe. For many years, Siro has also supported multiple HealthTech startups as Chief Commercial Officer and Senior Business Developer, driving successful entries into European and North American markets. Siro is a startup coach in various incubation and acceleration programs across Europe. siro@peakspirit.ch

Matthias Mettler is a business economist and consultant. He is an expert on the Swiss Digital Health and healthcare innovation scene. He co-heads the healthcare sector and is an Associate Partner at Synpulse Management Consulting, where he works with his clients to shape the healthcare system of the future. He also runs Health-Trends, a leading think tank for HealthTech research in Switzerland. matthias@health-trends.com

Jade Sternberg is a Digital Health expert, working to create pilot projects between startups and hospitals. Passionate about healthcare, technologies and digitalization, she bridges the gaps between different stakeholder groups in the ecosystem to increase collaboration and innovation. She is a Board member of Swiss Health Data Space Association and an advisor for Kickstart. jadesternberg@gmail.com

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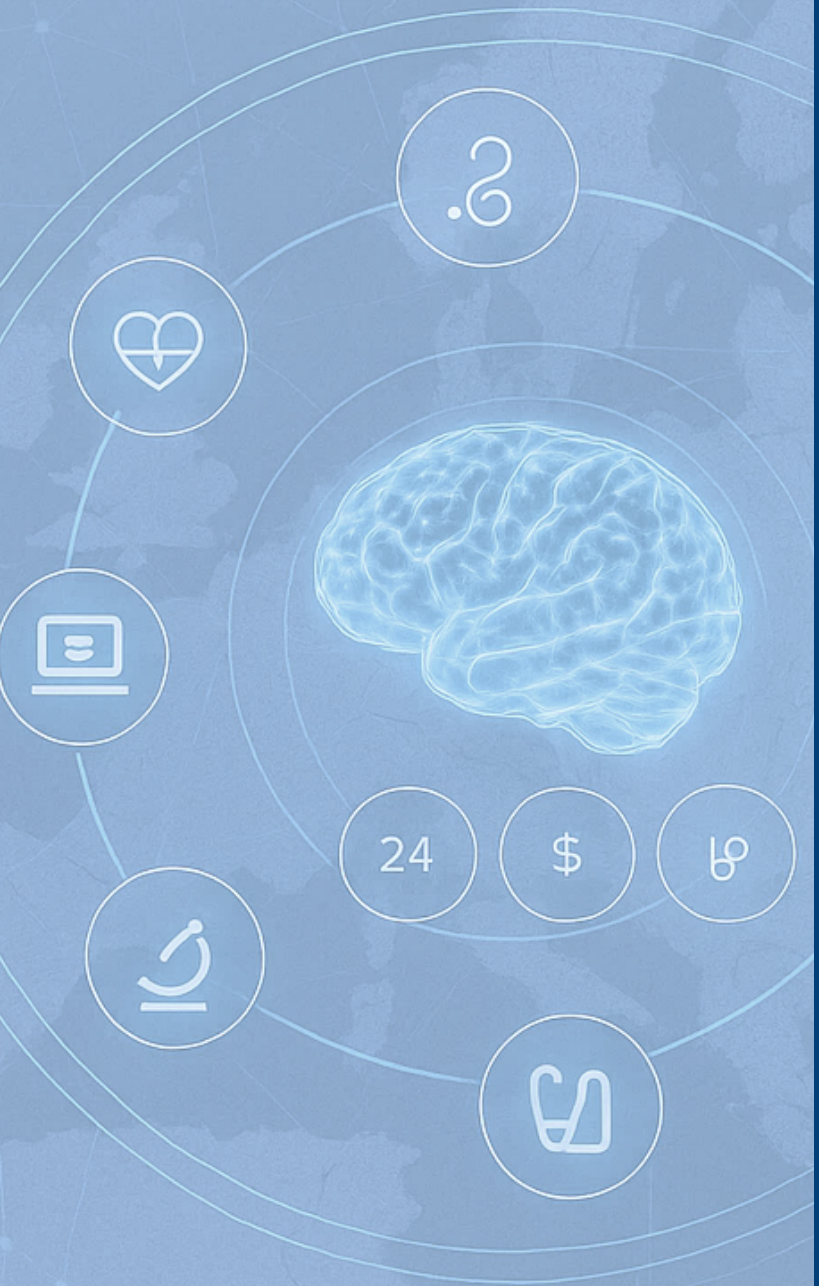

CONTACT US

info@peakspirit.ch
www.peakspirit.ch

Peak Spirit GmbH