

INVESTMENT POTENTIAL OF MEDTECH STARTUPS: HOW REGULATORY BARRIERS, REIMBURSEMENT, AND SCALABILITY SHAPE INVESTOR DECISIONS

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Abstract: The investment potential of medtech (medical technology) startups is shaped by a complex interplay of regulatory, financial, and technological factors. Although prior studies have explored startup valuation and innovation dynamics, limited attention has been paid to how certification, reimbursement, and scalability jointly influence investor decisions in emerging markets. This study addresses this gap by analyzing Polish medtech startups using sector analysis and survey data from 33 investors. The findings reveal that public reimbursement significantly enhances the investment attractiveness of medtech startups' offerings, while regulatory certification (CE/FDA) acts as both a barrier to entry and a source of competitive advantage. Scalability and global expansion potential emerge as decisive factors, alongside positioning in high-innovation segments such as AI, ML, and telemedicine. By integrating these determinants into a comprehensive framework, the study advances the scholarly understanding of investment decision-making in medtech. It provides actionable insights for investors, inventors, entrepreneurs, and policy makers looking to foster innovation-driven healthcare ecosystems.


Keywords: investment attractiveness, medtech startups, public reimbursement, regulatory barriers, scalability

JEL Classification: M13, O32, L26, I15, G24

Introduction

Globally, the medtech market is valued at approximately € 606 billion, with the United States and Europe accounting for 46.6% and 26.4% of this share, respectively

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(MedTech Europe, 2023). Poland's medtech sector is in its infancy but is expanding, driven by rising health expenditures. Between 2014 and 2023, Poland's health spending nearly doubled to 7.1% of GDP (GUS, 2023), fostering medtech growth.

Certification processes such as CE marking in the EU and FDA approval in the U.S. are essential for market entry but impose significant costs and time-to-market delays. These requirements act as barriers for early-stage firms while simultaneously serving as quality signals that strengthen competitive positioning once achieved (FDA, 2018; FDA, 2020). Similarly, public reimbursement, understood as eligibility for coverage by the national health system, directly influences revenue predictability and market access.

Finally, AI, ML, and telemedicine solutions attract more investor interest than traditional devices (Koalicja AI w Zdrowiu, 2024; Mejtoft et al., 2022).

Existing research provides partial insight into these dynamics. Studies on entrepreneurship and early-stage finance emphasize life-cycle stage and risk-return profiles (Wilson & Silva, 2013; Jędrzejczyk, 2023), while innovation management literature highlights clinical evidence, regulatory compliance, and business model design (Mejtoft et al., 2022). However, an integrated perspective that combines regulatory barriers, reimbursement, scalability, and technological segmentation in the context of investor decision-making remains underdeveloped, particularly in emerging EU markets.

This study addresses this gap by analyzing the investment potential of Polish medtech startups through a mixed-method approach centered on survey data from 33 investors. The research adopts an exploratory approach aimed at identifying key determinants of investor preferences rather than testing strict causal relationships. Consequently, five guiding research questions were formulated: RQ1: How does public reimbursement influence the perceived attractiveness of investment in medtech startups? RQ2: In what ways does the life cycle stage affect investor evaluation? RQ3: How do regulatory and certification requirements shape investor perceptions of risk and competitive advantage? RQ4: How do scalability and globalization potential influence investor interest? RQ5: Which technology domains attract the greatest investor attention and why? By addressing these research questions, the paper contributes to theory, advances understanding, and offers actionable guidance to investors, entrepreneurs, and policymakers.

Theoretical overview

Investment attractiveness of startups: conceptual foundations

In entrepreneurship research, investment attractiveness reflects growth, risk, and execution; key determinants include team, novelty, scalable model, competitive edge, and market fit (Jędrzejczyk, 2023; Lobakhina et al., 2019). At the same time, information asymmetry and uncertainty decrease as ventures progress through their life cycle, making the stage of development a critical screening criterion for investors (Wilson & Silva, 2013; Łuczak, 2018).

Research on commercialization and pricing strategies emphasizes that technological superiority alone rarely guarantees revenue generation without complementary capabilities such as disciplined pricing, effective go-to-market channels, and robust sales operations (Simon & Fassnacht, 2019). Consequently, scalable, software-based models offer predictable improvements in unit economics and attract investors (Wilson & Silva, 2013; Simon & Fassnacht, 2019).

Regulatory barriers and market authorization in medtech

Market access in medtech is conditioned by conformity assessment and authorization procedures, most notably CE marking in the EU and FDA approval in the United States, which require evidence of safety and clinical effectiveness (FDA, 2018; FDA, 2020; FDA, 2023). For early-stage companies, these processes involve significant capital costs, extended time-to-market, and complex quality system requirements (Maresova & Kuca, 2014). At the same time, certification serves as a credible quality signal that facilitates adoption by providers and payers and raises entry barriers for imitators, consistent with Porter's framework on industry structure and mobility barriers (Porter, 2006; Maresova & Kuca, 2014).

In the domain of digital health and software as a medical device, its classification and adequate documentation remain critical, reinforcing the dual role of regulation (FDA, 2020; Maresova & Kuca, 2014).

Public reimbursement and Health Technology Assessment (HTA)

In public health systems, reimbursement drives demand and stability by moving solutions from out-of-pocket niches to mainstream adoption (AOTMiT, 2023). Consequently, solutions with reimbursement potential offer investors greater revenue visibility and a shorter path to scale, aligning directly with the objective of assessing investment attractiveness in medtech startups.

Scalability and globalization potential of medtech startups

Scalability, which means growing revenue faster than costs, underpins technology investments. Studies on early-stage digital companies indicate that projects combining knowledge intensity, modularity, and data-driven feedback loops transition more rapidly from validation to replicable commercialization (Griva et al., 2023). In medtech, scalability is accelerated by modular architectures, software components, standardized implementation pathways, and channel partnerships; however, regulatory readiness and robust evidence packages remain prerequisites (Mejtoft et al., 2022).

Expansion into well-funded markets expands TAM and accelerates organizational learning across payer regimes (Wilson & Silva, 2013; Simon & Fassnacht, 2019). Strategic commercialization research consistently shows that the ability to sequence regulatory approvals (e.g., CE, FDA), access distribution networks, and maintain pricing discipline supports scaling and sustainable competitive advantage (Mejtoft et al., 2022; Simon & Fassnacht, 2019).

Technological segmentation and innovation intensity

The medtech spans devices, in vitro diagnostics, and digital health. Recent waves focus on AI/ML, telemedicine, and data-intensive applications (FDA, 2020; Mejtoft et al., 2022; FDA, 2023). At the clinical-industry interface, physician-industry collaboration, when ethically managed, accelerates the co-creation of solutions with measurable health outcomes (Chatterji et al., 2008). Analyses of European market structure suggest that regulatory classifications and evidence requirements shape entry dynamics and competitive intensity (Maresova & Kuca, 2014).

From an investment perspective, high-innovation segments such as AI/ML and telemedicine combine superior clinical or operational impact with software-like economics, enabling rapid scaling and defensible pricing positions (Mejtoft et al., 2022; Simon & Fassnacht, 2019).

Startup life cycle and investor preferences

The startup life cycle organizes investor preferences by risk profile, capital requirements, and information availability. Pre-seed/seed stage prove concepts, early growth/growth validate scaling, later stages prepare investors exits (Wilson & Silva, 2013; Cegielska & Zawadzka, 2017; Sipari, 2017; Merelä, 2021). Financing instruments evolve accordingly, from FFF, angels, and accelerators to VC rounds and, eventually, PE or debt (Merelä, 2021; Lemley & McCreary, 2021).

Valuation at early stages employs hybrid qualitative–quantitative methods (Berkus, Scorecard, DCF variants including VCM and FCM) that incorporate scenario analysis sensitive to regulatory and reimbursement milestones (Gemzik-Salwach, 2014; Babiarz, 2016; Wieczorek & Woźniak, 2019; Montani, 2020; Mańkowska, 2022). For investors, the stage of development thus serves as a synthetic indicator of execution risk and proximity to regulatory and payer pathways, explaining the preference for ventures in the commercialization or expansion phases (Wilson & Silva, 2013; Łuczak, 2018).

Synthesis, research gaps, and rationale for research questions

Reimbursement shapes funded demand and revenue visibility, providing investors with a critical signal of risk reduction and scalability potential (AOTMiT, 2023). Scalability and globalization link technical merit to investable growth through replicable deployments, software leverage, and cross-market expansion (Simon & Fassnacht, 2019; Griva et al., 2023; Mejtoft et al., 2022). Technological segmentation matters because high-innovation domains (AI/ML, telemedicine) combine clinical impact with favorable scale economics (Chatterji et al., 2008; Mejtoft et al., 2022). Finally, the life-cycle stage integrates risk, capital needs, and proximity to regulatory and payer milestones (Wilson & Silva, 2013; Łuczak, 2018).

Despite these insights, the literature reveals research gaps relevant to this study. First, most prior works examine regulatory, reimbursement, scalability, and technological segmentation factors in isolation, whereas investor decisions in payer-driven systems result from their combined configuration. Second, in the context of Poland

and the CEE region, there is a lack of integrated analyses linking entrepreneurial dynamics with HTA and regulatory frameworks. Third, few studies operationalize investor preferences into structured rankings of startups based on these combined determinants. Therefore, the main objective of this study is to evaluate the investment attractiveness of investment in Polish medtech startups included in the 2024 Top Disruptors in Healthcare report and to identify the determinants that shape investor decision-making in this sector (Koalicja AI w Zdrowiu, 2024). The research aims to explore whether and how factors such as reimbursement, regulatory certification, scalability, technological segmentation, and life-cycle stage shape investor evaluations, using descriptive evidence.

Research design

The study employed a survey-based quantitative analysis. The core empirical component consisted of a CAWI (Computer-Assisted Web Interviewing) survey targeting investors and investment analysts active in the medtech sector. The CAWI method ensured structured responses from dispersed participants. The process covered objective setting, questionnaire design, CAWI data collection (Microsoft Forms), and data analysis (Microsoft Excel). The survey was conducted in January 2024 and formed the primary source of empirical evidence for answering research questions.

Sampling strategy

Convenience sampling targeted active medtech investors. This approach was justified by the specialized nature of the target population and the need to ensure that the respondents had relevant expertise.

The final sample comprised 33 respondents, including individual investors, venture capital professionals, business development managers, and analysts. All participants confirmed their active involvement in medtech-related investment activities, ensuring the relevance and credibility of the data collected. Although the sampling strategy relied on convenience methods, the pool represents a diverse set of actors actively engaged in medtech investment in Poland. Recruitment used networks, referrals, and sector-specific social media. All respondents confirmed active involvement in medtech-related investment activities, ensuring the relevance of their perspectives despite the absence of statistical representativeness. Non-probabilistic sampling limits generalizability. Nevertheless, the composition of the sample reflects heterogeneity in roles and investment strategies: 41% of the respondents were investment analysts or professionals from investment institutions, 22% were individual investors, 13% were business development managers, and 9% were startup founders, with the remaining respondents (15%) being board members, M&A specialists, and business angels. Investment focus varied, with 30% concentrating exclusively on medtech, 42% treating it as one of their main areas, and 27% considering it a minor component of their portfolio. The objectives of investing activity ranged from return maximization (42%) and portfolio diversification (30%) to strategic technology acquisition (18%) and ESG-aligned innovation (9%). This diversity

provides a credible basis for an exploratory analysis of investor preferences in the medtech domain. We included fully completed and consistent responses from active medtech investors.

Operationalization of variables

Each research question was operationalized through specific survey items:

For RQ1 (Reimbursement): Measured by Likert scale ratings (1-5, where 1 indicates the least importance and 5 the greatest importance) of public reimbursement and binary responses regarding willingness to invest in startups without reimbursement potential.

For RQ2 (Life-cycle stage): Captured through ranking of preferred development stages (Pre-seed, Seed, Early Growth, Growth, Late Stage) and Likert scale importance ratings.

For RQ3 (Regulatory barriers): Assessed using Likert scale importance ratings of certification importance (CE/FDA) and perceived capital barriers associated with regulatory compliance.

For RQ4 (Scalability and globalization): Evaluated through Likert scale importance ratings of scalability and selection of preferred expansion regions (EU, US, other markets).

For RQ5 (Technological segmentation): Measured through Likert scale importance ratings, selection of the most attractive technology domains (AI, telemedicine, biotechnology, etc.), and agreement with statements on innovation-driven investor interest.

Ethical and methodological considerations

The study adhered to the principles of research integrity and respondent confidentiality. Participation was voluntary and the respondents were informed about the academic purpose of the research and the anonymity of their responses. No personally identifiable information was collected.

Methodologically, the use of a convenience sample introduces limitations regarding generalizability; however, this approach was deemed appropriate given the niche nature of the medtech investment community and the exploratory character of the study.

Research results

We analyzed CAWI data from 33 Poland-based medtech investors. All participants confirmed their involvement in investment activities within the sector, ensuring the relevance of their perspectives.

Public reimbursement and investment attractiveness (RQ1)

We tested whether public reimbursement increases investment attractiveness. The findings strongly support this assumption. Reimbursement was identified as a key factor by 32 out of 33 respondents, and its importance was rated at an average

of 4.09 on a five-point Likert scale, with the most frequent responses being 5 (very important) and 4. Furthermore, two-thirds of the respondents (67%) declared that they would not invest in a startup that does not include the public payer in its business model, while only one-third expressed conditional openness to such investments. Although reimbursement was most frequently ranked third among the most important determinants (42.4%), its near-universal recognition and high mean score confirm its strategic role in reducing revenue risk and enabling scalability.

Life-cycle stage as an investment criterion (RQ2)

The second RQ referred to the assumption that the life-cycle stage of a startup plays a critical role in the investor assessment. The data confirm this relationship. Thirty-one respondents indicated the stage of development as an important factor, and in ranking tasks, it most often appeared in second position (30.3%), followed by fourth (21.2%). Investors preferred the growth (39%) and early growth (33%) stages, which together accounted for nearly three-quarters of responses. The seed stage attracted 18% of preferences, while the pre-seed and late stage options were marginal (6% each). Thus, investors prefer post-validation ventures and avoid the riskiest early and lowest-return late stages.

Regulatory barriers and certification (RQ3)

The third RQ was proposed to examine whether regulatory and certification barriers restrict early growth but enhance competitive positioning once achieved. The results corroborate this dual effect. The importance of CE and FDA certification was rated on an average of 4.36, with 20 respondents assigning the maximum score of 5 and eight assigning 4. At the same time, the perceived capital intensity of regulatory compliance, including certification, clinical trials, and intellectual property protection, was rated at 4.03, indicating that these requirements are widely regarded as significant financial barriers. Respondents also acknowledged the strategic value of regulation in limiting market access for substitutes, with a mean score of 4.12 on this dimension.

Scalability and globalization potential (RQ4)

The fourth RQ aimed to explore whether scalability and globalization potential are the primary drivers of investor interest. The survey results provide compelling support for this claim. Scalability achieved the highest importance rating among all determinants, with a mean of 4.61 and the modal response at the maximum value of 5. Additionally, when asked about preferred regions for international expansion, respondents overwhelmingly indicated the United States and the European Union as priority markets, while other regions such as the United Kingdom, the Middle East, and East Asia were mentioned less frequently, and China, Africa, and Canada were not considered strategic destinations. These preferences underscore the centrality of scale economics and access to large, well-funded healthcare systems in shaping investment decisions.

Technological segmentation and innovation intensity (RQ5)

The fifth RQ investigated whether startups operating in high-innovation segments such as artificial intelligence and telemedicine attract greater investor attention than those in traditional domains. The evidence confirms this expectation. When asked to identify the most attractive technology domains, the respondents most frequently selected AI/machine learning (28 indications) and telemedicine (21), followed by biotechnology (12). Furthermore, agreement with the statement that high-innovation scalable segments generate greater investor interest averaged 4.48 on a five-point scale, with the majority of responses clustered at 4 and 5. The technological area was also the most frequently top-ranked determinant in the overall hierarchy of factors, occupying first place in 36% of cases. The figure below sums up the distribution of ranks attributed by the respondents to the determinants investigated within the RQs.

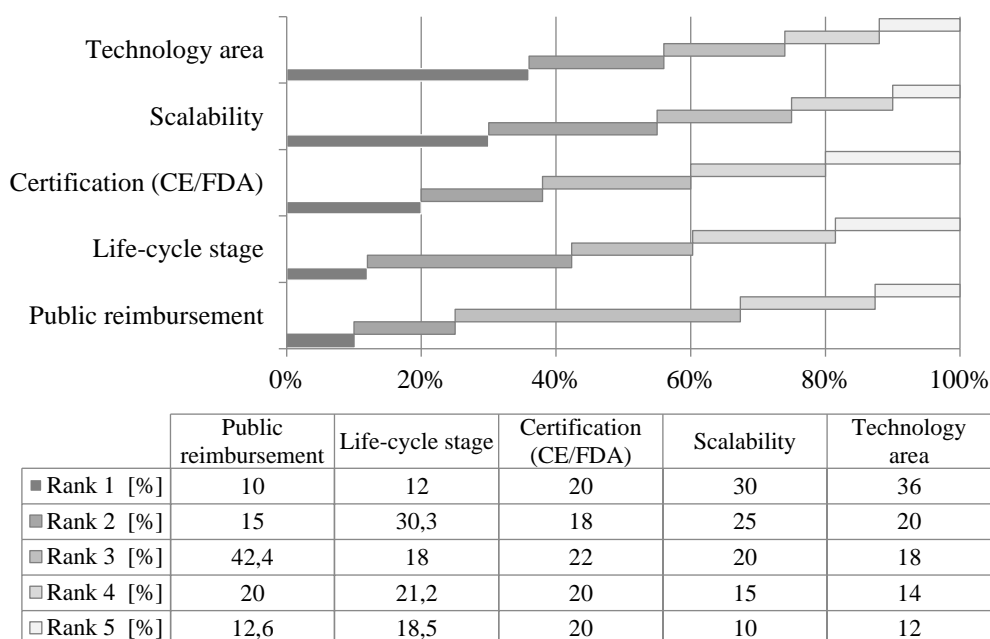


Figure 1. Rank distribution (1-5, with 1 for the least importance and 5 for the greatest importance) for key determinants of investment in medtech

Source: Own elaboration

Discussion

Public reimbursement emerges as a critical determinant of investment attractiveness, reflecting the payer-driven logic of healthcare markets. The life-cycle stage strongly influenced investor preferences, with a clear bias toward ventures that have

validated their business model and are positioned for scaling. Regulatory requirements were perceived as both a barrier and a source of competitive advantage, confirming their ambivalent role in shaping growth trajectories. Scalability and globalization potential dominate the hierarchy of determinants, while technological segmentation reinforces the premium placed on innovation and digital transformation.

The CAWI results reveal consistent patterns across the research questions. Reimbursement is widely seen as the key to investment attractiveness and is highly on importance, with two-thirds unwilling to invest where the public payer is absent from the business model. This reinforces the view that, in payer-centric systems, reimbursement transforms willingness to pay into funded demand and stabilizes cash flows, thus lowering revenue risk and shortening the path to scale (AOTMiT, 2023). Second, the life cycle stage is a decisive filter: preferences concentrate in post-validation phases (early growth and growth), consistent with declining information asymmetry and clearer unit economics as ventures mature (Wilson & Silva, 2013; Łuczak, 2018). Third, regulatory requirements are perceived ambivalently yet constructively: respondents rated the costs and capital intensity of certification as high while simultaneously attaching high value to CE/FDA authorization, which credibly signals quality and constrains non-certified substitutes (FDA, 2018; Maresova & Kuca, 2014). Fourth, scalability and globalization are top investor priorities associated with US and EU markets, settings where payer pathways, budget depth, and price points can support rapid diffusion. Finally, technological segmentation proved to matter with investors' attention centered on AI/ML and telemedicine, reflecting the combination of innovation intensity, software-type economics, and measurable clinical or operational results (Mejtoft et al., 2022; Koalicja AI w Zdrowiu, 2024).

In sum, these results validate that investor decision-making in medtech is shaped by the joint configuration of regulatory preconditions, payer status, scalability, stage, and technology domain, rather than by any single factor in isolation. The pattern is internally consistent; investors prefer opportunities where regulatory risk is either passed or credibly managed, where reimbursement amplifies addressable demand, where the business model enables replication across geographies, and where the technology sits in innovation-dense domains.

Positioning within and extending the literature

The findings align with HTA-driven market-access research, where clinical effectiveness, safety, cost-effectiveness, and budget impact gate diffusion (AOTMiT, 2023).

The research results add two clarifications. First, investors simultaneously price in the capital drag associated with certification (mean perceptions of barrier height are high) and the moat-building effect once authorization is secured (high importance assigned to CE/FDA). Second, respondents perceive regulation to effectively limit substitutes, reinforcing the idea that compliance not only grants access, but also shapes the competitive set (FDA, 2018; European Commission, 2025).

Regarding the life-cycle stage, the concentration of preferences in early growth and growth phases fits the entrepreneurship and early-stage finance insights that risk and information quality evolve along the financing continuum (Wilson & Silva, 2013; Łuczak, 2018). The CAWI evidence adds a medtech specific layer: stage preferences appear intertwined with regulatory and payer milestones, suggesting that investors implicitly proxy readiness for certification and reimbursement through stage, consistent with applied commercialization work in medtech (Mejtoft et al., 2022).

The importance of scalability and globalization resonates with the research on strategy and commercialization that emphasizes replicable deployment, route-to-market design, and disciplined monetization (Simon & Fassnacht, 2019). The CAWI data refine this view by revealing a geographic hierarchy; the US and EU are favoured destinations, underscoring the interplay between scale economics and institutional environments with mature reimbursement and purchasing infrastructures. Finally, the focus on AI/ML and telemedicine echoes reports and scholarly discussions on innovation hotspots in European medtech, where patent intensity and data-rich applications drive momentum (MedTech Europe, 2023; Mejtoft et al., 2022; Koalicja AI w Zdrowiu, 2024). The survey expands this narrative by showing that investors do not treat ‘innovation’ as generic; they allocate attention to domains that combine measurable outcomes and software leverage, indicative of faster learning cycles and better operational leverage.

Conclusion

This study examined determinants of the attractiveness of medtech startups in Poland. The CAWI survey of 33 investment professionals confirmed that all five factors significantly influence investor decision-making. Reimbursement emerged as a critical determinant, reflecting the payer-driven logic of healthcare markets. The life-cycle stage strongly shaped preferences, with investors favoring ventures in early growth and growth phases. Regulatory requirements were perceived as both a constraint and a source of competitive advantage, while scalability and globalization potential dominated the hierarchy of determinants.

Findings add institutional factors (HTA, regulation) to startup attractiveness models. They demonstrate that investor assessments in medtech cannot be explained solely by generic risk-return considerations; they are conditioned by the interplay of regulatory readiness, payer status, and scalability. This layered perspective complements stage-based theories by showing that stage effects are mediated by progress toward certification and reimbursement milestones. Furthermore, the results bridge innovation management and market-access research, underscoring that value realization in medtech depends as much on evidence generation and coding readiness as on technological novelty.

For investors, the results suggest practical screening heuristics: prioritize ventures that are approaching or have achieved regulatory and reimbursement milestones, demonstrate credible scalability into US and EU markets, and operate in innovation-intensive domains where outcome evidence can be generated and monetized. For entrepreneurs and inventors, the findings highlight the need to sequence clinical

validation, regulatory filings, and payer strategy to compress time to revenue and de-risk fundraising. Building early relationships with HTA and notified bodies, as well as planning for international expansion, can significantly enhance the attractiveness to investors. For policymakers, the strong investor sensitivity to reimbursement and certification underscores the importance of transparent HTA criteria, adequate institutional capacity, and efficient regulatory pathways, which collectively shape the competitiveness of the domestic medtech ecosystem.

In Poland's emerging market, reimbursement readiness and regulatory credibility help offset ecosystem gaps, and the US/EU expansion also validates pricing and evidence. Two limitations of the study should be acknowledged. First, the sample was convenience-based and relatively small ($N = 33$), which constrains the generalizability of the findings beyond the expert population surveyed. Second, the study relied on self-reported preferences, which may diverge from actual investment behavior under deal-specific conditions. These limitations do not undermine the internal validity of the findings, but call for caution in extrapolation. Convenience sampling and descriptive statistics confirm the exploratory nature. Future research could address these limitations by combining survey-based evidence with transaction-level data on funding rounds, valuations, and post-authorization adoption trajectories. Comparative studies across EU markets with different HTA regimes and regulatory capacities would enrich our understanding of institutional effects on investor behavior. At the construct level, modeling interactions among regulation, reimbursement, and stage, such as whether reimbursement potential moderates the effect of stage on attractiveness, would provide deeper theoretical insight. Finally, examining how evidence-generation strategies (e.g., clinical endpoints, real-world data) mediate the link between the technology domain and investor interest would advance both academic and practical knowledge.

References

- AOTMiT. (2023). *Kwalifikacja świadczeń do koszyka świadczeń gwarantowanych*. <https://www.aotm.gov.pl/swiadczenia-opieki-zdrowotnej/kwalifikacja>
- Babiarz, A. (2016). Methods of valuing investment projects used by Venture Capital funds, financed from public funds. *Prace Naukowe Uniwersytetu Ekonomicznego we Wrocławiu*, 428, 11-28.
- Cegielska, E., & Zawadzka, D. (2017). Źródła finansowania startupów w Polsce. *Annales Universitatis Mariae Curie-Skłodowska, Sectio H, Oeconomia*, 51(6), 53-63.
DOI: 10.17951/h.2017.51.6.53
- Chatterji, A. K., Fabrizio, K. R., Mitchell, W., & Schulman, K. A. (2008). Physician–industry cooperation in the medical device industry. *Health Affairs*, 27(6), 1532-1543.
DOI: 10.1377/hlthaff.27.6.1532
- European Commission. (2025). *Single Market Compliance Space: Notified body list*. European Commission. <https://webgate.ec.europa.eu/single-market-compliance-space/notified-bodies>
- FDA. (2018). *Overview of regulatory requirements: Medical devices*. U.S. Food and Drug Administration. <https://www.fda.gov/training-and-continuing-education/cdrh-learn/overview-regulatory-requirements-medicaldevices-transcript>
- FDA. (2020). *What is digital health?*. U.S. Food and Drug Administration. <https://www.fda.gov/medical-devices/digital-health-centerexcellence/what-digital-health>
- FDA. (2023). *In vitro diagnostics*. U.S. Food and Drug Administration. <https://www.fda.gov/medical-devices/products-and-medical-procedures/invitro-diagnostics>

- Gemzik-Salwach, A. (2014). Wykorzystanie metody Dave'a Berkusa do analizy potencjału rozwojowego firm start-up w Polsce. *Acta Universitatis Lodzianensis. Folia Oeconomica*, 300(2), 111-122.
- Griva, A., Kotsopoulos, D., Karagiannaki, A., & Zamani, E. D. (2023). What do growing early-stage digital start-ups look like? A mixed-methods approach. *International Journal of Information Management*, 69, 102427. DOI: 10.1016/j.ijinfomgt.2021.102427
- GUS. (2023). Wydatki na ochronę zdrowia w latach 2021-2023. https://stat.gov.pl/files/gfx/portalinformacyjny/pl/defaultaktualnosci/5513/27/4/1/wydatki_na_ochrone_zdrowia_w_latach_20212023_2.pdf
- Jędrzejczyk, W. (2023). Determinants of the attractiveness of startups as innovative entities for external investors in Polish economic practice. *Procedia Computer Science*, 225, 3613-3620. DOI: 10.1016/j.procs.2023.10.356
- Koalicja AI w Zdrowiu. (2024). *Top Disruptors in Healthcare Report*. <https://aiwzdroziu.pl/>
- Lemley, M. A., & McCreary, A. (2021). Exit strategy. *Boston University Law Review*, 101(1), 1-101.
- Lobakhina, N., Surzhikov, M., Sedykh, J., & Zhuravleva, O. (2019). Analysis and evaluations of innovative startups pertaining to the attractiveness of investments. In: D. K.-S. Bataev, S. A. Gapurov, A. D. Osmaev, V. K. Akaev, L. M. Idigova, M. R. Ovhadov, A. R. Salgiriev, & M. M. Betilmerzaeva (Eds.), *Social and cultural transformations in the context of modern globalism* (Vol. 76, pp. 1982-1988). Future Academy. DOI: 10.15405/epsbs.2019.12.04.26
- Łuczak, K. (2018). *Wycena przedsiębiorstw typu start-up*. Uniwersytet Ekonomiczny.
- Mańkowska, N. (2022). Charakterystyka, źródła finansowania i wartość start-upów branży MedTech w Polsce. *Prace Naukowe Uniwersytetu Ekonomicznego we Wrocławiu = Research Papers of Wrocław University of Economics*, 66(4), 100-115.
- Maresova, P., & Kuca, K. (2014). Porter's five forces on medical device industry in Europe. *Military Medical Science Letters*, 83(4), 134-144.
- MedTech Europe. (2023). *The European medical technology industry in figures*. MedTech Europe. https://www.medtecheurope.org/wp-content/uploads/2023/10/the-european-medicaltechnology-industry-in-figures_2023.pdf
- Mejtoft, T., Lindahl, O., Öhberg, F., Pommer, L., Jonzén, K., Andersson, B. M., Eklund, A., Wåhlin, A., & Hallberg, P. (2022). Medtech innovation guide: An empirical model to support medical technology innovation. *Health Technology*, 12, 911-922. DOI: 10.1007/s12553-022-00689-0
- Merelä, J. (2021). *Optimizing value for funding rounds: Funding strategy for start-ups* (Master's thesis), <https://www.theseus.fi/handle/10024/498623>
- Montani, D. (2020). Startup company valuation: The state of art and future trends. *International Business Research*, 13(9), 31-45. DOI: 10.5539/ibr.v13n9p31
- Porter, M. E. (2006). *Strategia konkurencji*. PWE.
- Simon, H., & Fassnacht, M. (2019). *Zarządzanie cenami*. Wydawnictwo Naukowe PWN.
- Sipari, J. (2017). *Pre-seed funding for technology start-ups* (Master's thesis). <https://www.diva-portal.org/smash/get/diva2:1112285/FULLTEXT01.pdf>
- Wieczorek, S., & Woźniak, J. (2019). Sztuka wyceny przedsiębiorstw we wczesnej fazie rozwoju. *Kwartalnik Nauk o Przedsiębiorstwie*, 52(3), 89-99. DOI: 10.5604/01.3001.0013.4793.
- Wilson, K., & Silva, F. (2013). Policies for seed and early stage finance: Findings from the 2012 OECD financing questionnaire. *OECD Science, Technology and Industry Policy Papers*, No. 9. OECD Publishing. DOI: 10.1787/5k3xqsf00j33-en

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POTENCJAŁ INWESTYCYJNY START-UPÓW MEDTECH: JAK BARIERY REGULACYJNE, REFUNDACJA I SKALOWALNOŚĆ KSZTAŁTUJĄ DECYZJE INWESTORÓW?

Streszczenie: Potencjał inwestycyjny start-upów z sektora technologii medycznych (medtech) kształtowany jest przez złożoną interakcję czynników regulacyjnych, finansowych i technologicznych. W dotychczasowych badaniach analizowano wycenę start-upów i dynamikę innowacji, jednak niewiele uwagi poświęcono temu, w jaki sposób certyfikacja, refundacja i skalowalność łącznie wpływają na decyzje inwestorów na rynkach wschodzących. Niniejsze badanie wypełnia tę lukę, sondując polskie start-upy z branży technologii medycznych, wykorzystując analizę sektorową i dane z ankiet przeprowadzonych wśród 33 inwestorów. Wyniki wskazują, że refundacja publiczna planowanego do wprowadzenia na rynek wyrobu znacząco zwiększa atrakcyjność inwestycyjną, podczas gdy certyfikacja regulacyjna (CE/FDA) pełni podwójną rolę, stanowi barierę wejścia, ale także źródło przewagi konkurencyjnej. Skalowalność i potencjał globalnej ekspansji wyłaniają się jako czynniki decydujące, obok pozycjonowania wyrobu w segmentach wysokiej innowacyjności, takich jak sztuczna inteligencja, uczenie maszynowe, telemedycyna. Integrując te determinanty w spójne ramy, badanie wnosi wkład do rozwoju wiedzy na temat procesu podejmowania decyzji inwestycyjnych w sektorze medtech oraz dostarcza praktycznych wskazówek dla inwestorów, wynalazców, przedsiębiorców i decydentów, którzy dążą do wspierania ekosystemów opieki zdrowotnej opartych na innowacjach.

Słowa kluczowe: atrakcyjność inwestycyjna, start-upy medtech, refundacja publiczna, bariery regulacyjne, skalowalność

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