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# Innovation Capability of Biomedical Engineering Enterprises Through Collaboration with Universities and R&D Institutions

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***Abstract:***

***Purpose:*** *To examine the innovation capability of biomedical engineering enterprises in relation to cooperation with universities and R&D institutions.*
***Design/Methodology/Approach:*** *The study combines a literature review with a descriptive analysis of 80 complete questionnaires from biomedical engineering enterprises in Poland's Silesian Voivodeship. Data were collected through computer-assisted web interviewing (CAWI) supported by telephone contact. Reported percentages describe innovation activity, research cooperation, technological outcomes, financing, support needs and green transformation plans, with multiple-response items interpreted separately from the single-response cooperation-frequency item.*
***Findings:*** *Product innovations new to the enterprise predominate (76.3%), whereas innovations new to the international market are uncommon (3.8%). Medical universities in the Silesian Voivodeship are the most frequently reported research partners (71.3%). Cooperation commonly involves recurring grant projects (45.0%) and publicly co-financed joint R&D (61.3%). Reported technological outcomes include ready-to-implement devices (26.3%) and software modules or AI algorithms (25.0%). Own funds alone finance development activity in 51.3% of firms. Planned green transformation activity is reported by 77.5%.*
***Practical Implications:*** *The reported patterns suggest scope for strengthening durable research partnerships, simplifying grant procedures and improving access to regulatory advice and clinical testing environments.*
***Originality/Value:*** *The paper brings together theoretical perspectives and descriptive sector evidence on research relationships, technological outcomes, financing and planned environmental investment. The descriptive findings characterise reported patterns rather than establish causal effects.*

***Keywords:*** *Absorptive capacity, knowledge transfer, biomedical engineering, regional ecosystems, green transformation.*

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## 1. Introduction

Innovation is widely recognized as a fundamental driver of competitiveness and long-term growth in knowledge-intensive industries. Among these industries, biomedical engineering occupies a unique position due to its integration of engineering, medicine, biology, and information technologies in the development of healthcare solutions.

Rapid scientific advances, increasing healthcare demands, and stringent regulatory requirements have intensified the need for continuous innovation within biomedical engineering enterprises. As a result, firms are increasingly seeking access to external sources of knowledge and expertise to complement their internal research and development (R&D) activities.

The traditional model of innovation, in which firms relied primarily on internally generated knowledge, has gradually been replaced by more collaborative approaches. According to Henry W. Chesbrough (2003), the growing distribution of knowledge across organizational boundaries has led firms to adopt open innovation strategies that combine internal capabilities with external ideas, technologies, and competencies.

Within this framework, innovation is no longer perceived as an isolated organizational activity but rather as a process emerging from interactions among multiple actors in innovation ecosystems.

The growing importance of external knowledge sources has also been emphasized in the concept of absorptive capacity developed by Wesley M. Cohen and Daniel A. Levinthal (1990). The authors argue that a firm's ability to recognize the value of external knowledge, assimilate it, and apply it for commercial purposes constitutes a critical determinant of innovative performance.

Consequently, collaboration with universities and research institutions provides firms not only with access to new scientific discoveries but also with opportunities to strengthen their absorptive capacity and enhance their innovation potential.

A complementary theoretical perspective is provided by the Triple Helix model proposed by Henry Etzkowitz and Loet Leydesdorff (2000). This framework conceptualizes innovation as an outcome of dynamic interactions among universities, industry, and government. In knowledge-based economies, universities increasingly perform entrepreneurial functions beyond their traditional missions of teaching and research.

They actively participate in technology transfer, patenting, spin-off creation, and collaborative R&D activities, thereby becoming key actors in innovation systems. The Triple Helix model suggests that closer interactions among academic institutions, enterprises, and public authorities stimulate knowledge creation and facilitate the commercialization of scientific research.

Within this context, university-industry collaboration has attracted significant scholarly attention. As noted by Markus Perkmann and Kathryn Walsh (2007), organizations increasingly rely on interorganizational networks as a source of innovation. Such collaborations may take various forms, including joint research projects, university-industry research centers, contract research, consulting arrangements, and personnel mobility.

These partnerships enable firms to access specialized scientific expertise, state-of-the-art research infrastructure, and highly qualified human capital, while universities benefit from exposure to practical challenges and opportunities for knowledge application.

The relevance of collaborative innovation is particularly pronounced in the biomedical engineering sector. The development of advanced medical devices, diagnostic systems, biomaterials, rehabilitation technologies, and digital health solutions requires multidisciplinary knowledge that frequently exceeds the capabilities of individual organizations.

Furthermore, biomedical innovation is characterized by high development costs, long commercialization cycles, complex validation procedures, and strict regulatory oversight. Under such conditions, collaboration with universities and R&D institutions becomes an essential mechanism for reducing uncertainty, accelerating technological development, and improving innovation performance.

Recent studies focusing on medical device innovation emphasize the strategic importance of industry-academia-government collaborations. Such partnerships enable participants to leverage complementary resources and competencies, coordinate scientific and technological efforts, and address complex healthcare

challenges more effectively (Tanaka and Lopez, 2024). Moreover, collaborations facilitate the integration of scientific research with practical applications, increasing the likelihood that new technological solutions will successfully reach the market and create value for patients and healthcare systems.

Despite the acknowledged benefits of collaboration, several challenges may limit its effectiveness. Differences in organizational culture, divergent objectives, intellectual property concerns, communication barriers, and varying expectations regarding project outcomes can hinder knowledge exchange and collaborative performance (Perkmann and Walsh, 2007). In addition, not all firms are equally capable of transforming external knowledge into successful innovations, highlighting the importance of organizational capabilities that mediate the relationship between collaboration and innovation outcomes.

Although extensive research has examined university-industry collaboration and innovation management, relatively little attention has been devoted specifically to the mechanisms through which cooperation with universities and R&D institutions enhances the innovation capability of biomedical engineering enterprises. Given the strategic importance of biomedical technologies for healthcare improvement and economic development, a deeper understanding of these relationships is both theoretically and practically relevant.

Therefore, the objective of this paper is to investigate how collaboration with universities and R&D institutions contributes to the development of innovation capability in biomedical engineering enterprises. Particular attention is devoted to knowledge transfer processes, absorptive capacity, joint R&D activities, and innovation outcomes, including new product development, technology commercialization, and technological competitiveness.

By integrating insights from open innovation theory, absorptive capacity theory, and the Triple Helix framework, the study seeks to provide a comprehensive understanding of collaborative innovation in the biomedical engineering sector.

## 2. Literature Review

### 2.1 Innovation Capability in Biomedical Engineering Enterprises

Innovation capability is generally understood as an organization's ability to continuously transform knowledge and resources into new products, services, processes, or organizational solutions that create value and sustain competitive advantage. Recent studies emphasize that innovation capability is a multidimensional construct comprising technological, organizational, managerial, and relational dimensions. In knowledge-intensive industries, innovation capability depends not only on internal resources but also on the ability to acquire, integrate, and exploit externally generated knowledge (Sancho-Zamora *et al.,* 2021).

The biomedical engineering sector represents a particularly demanding environment for innovation. Enterprises operating in medical devices, digital health, biomaterials, artificial intelligence applications, and rehabilitation technologies face high technological complexity, rapid scientific advancements, lengthy product development cycles, and strict regulatory requirements.

Consequently, innovation capability in biomedical engineering extends beyond technological expertise and encompasses the ability to coordinate multidisciplinary knowledge originating from engineering, life sciences, medicine, and computer science.

Recent evidence suggests that innovation capability in health technology sectors increasingly depends on participation in collaborative innovation ecosystems rather than solely on internal R&D activities (Liu *et al.,* 2022; Tanaka and Lopez, 2024). Open and collaborative innovation models have become particularly important for addressing complex healthcare challenges and accelerating the translation of scientific discoveries into commercial applications.

## 2.2 Open Innovation and Collaborative Knowledge Creation

The concept of open innovation has become one of the dominant perspectives in innovation management research. Contemporary literature argues that organizations can no longer rely exclusively on internal knowledge generation because relevant expertise is increasingly distributed among multiple actors within innovation ecosystems (Yeung *et al.,* 2021). Open innovation therefore emphasizes purposeful inflows and outflows of knowledge across organizational boundaries to accelerate innovation processes and improve commercialization outcomes.

Within the healthcare and biomedical sectors, open innovation has gained particular importance due to the interdisciplinary nature of technological development. Research examining medical and pharmaceutical innovation demonstrates that collaborations among firms, universities, public research organizations, and healthcare institutions facilitate access to complementary expertise, specialized research infrastructure, and financial resources (Yeung *et al.,* 2021).

Public-private partnerships have been identified as especially relevant mechanisms supporting the sharing of knowledge, technology, intellectual property, and scientific competencies.

Moreover, recent studies conducted in healthcare innovation ecosystems indicate that collaborative innovation enables organizations to respond more effectively to technological uncertainty and rapidly changing societal needs. Knowledge co-creation, interdisciplinary research teams, and cross-sector collaborations have become essential elements of successful innovation strategies within the biomedical domain (Liu *et al.,* 2022).

From this perspective, collaboration with universities and R&D institutions can be viewed as an important mechanism through which biomedical engineering enterprises gain access to valuable external knowledge and strengthen their innovation capabilities.

### 2.3 University-Industry Collaboration as a Source of Innovation

University-industry collaboration (UIC) has attracted growing attention as a mechanism for knowledge transfer and innovation generation. The increasing importance of knowledge-intensive economies has significantly expanded the role of universities beyond their traditional missions of teaching and basic research.

Universities are now recognized as active contributors to innovation ecosystems through research commercialization, patenting, spin-off creation, and collaborative research activities (Sjöö and Hellström, 2019).

A systematic literature review conducted by Karolin Sjöö and Tomas Hellström (2019) identified several factors that facilitate successful collaborative innovation between universities and firms.

These include access to resources, effective organizational structures, boundary-spanning functions, previous collaboration experience, organizational culture, network centrality, and favorable environmental conditions. The authors argue that collaborative innovation emerges from the interaction of these factors rather than from any single determinant.

Similarly, a systematic review by Ankrah and Al-Tabbaa (2015) demonstrated that successful university-industry collaborations depend on trust, communication quality, strategic alignment, intellectual property management, and mutual commitment among partners. The review highlights the importance of governance mechanisms that facilitate knowledge exchange while reducing relational and organizational barriers.

Recent empirical evidence also supports the positive effect of university-industry collaboration on innovation performance. Using data from 285 biopharmaceutical firms, Mingyu Tian, Yiwei Su, and Zhong Yang (2021) demonstrated that university-industry collaboration enhances firm innovation performance by providing access to external scientific knowledge and complementary technological capabilities. Their findings additionally indicate that technological diversity strengthens the positive impact of collaboration on innovation outcomes.

These observations are particularly relevant to biomedical engineering enterprises, whose innovation activities frequently require multidisciplinary competencies, access to cutting-edge scientific discoveries, and close interactions with academic researchers and clinicians.

## 2.4 Role of R&D institutions in biomedical innovation systems

In addition to universities, public and private R&D institutions constitute crucial actors in biomedical innovation ecosystems. Research institutes, clinical research centers, government laboratories, and specialized biomedical organizations contribute significantly to scientific knowledge production, technology validation, and translational research.

Contemporary innovation literature increasingly refers to "knowledge co-creation" rather than unilateral knowledge transfer. According to the OECD (2019), collaborative research, co-patenting activities, spin-offs, researcher mobility, and joint research infrastructures have become major channels through which knowledge circulates between research institutions and industry. These interactions facilitate technological development and increase the likelihood that scientific discoveries will be transformed into commercially viable innovations.

Within biomedical engineering, R&D institutions often provide unique research facilities, specialized equipment, regulatory expertise, and access to clinical environments necessary for testing and validating innovative healthcare technologies. Collaboration with such institutions may therefore reduce technological uncertainty and accelerate technology commercialization.

Furthermore, recent studies on medical device innovation emphasize that effective cooperation among academic, industrial, and governmental actors improves coordination of resources, fosters scientific discovery, and supports technological development in healthcare systems (Tanaka and Lopez, 2024).

## 2.5. Absorptive Capacity as a Mediator of Collaborative Innovation

The benefits obtained from collaboration do not result automatically from access to external knowledge. Organizations must possess internal capabilities enabling them to recognize, assimilate, transform, and exploit externally acquired information. This capability is generally conceptualized as absorptive capacity.

Recent studies continue to identify absorptive capacity as a central mechanism linking external collaboration and innovation performance. Monika Stelmaszczyk (2020) demonstrated that absorptive capacity positively influences product, process, and managerial innovation. Her findings further indicate that knowledge-sharing processes mediate the transformation of acquired knowledge into innovation outcomes.

Similarly, Rafael Sancho-Zamora and colleagues (2021) found that absorptive capacity positively influences innovation capacity, which subsequently improves organizational performance. Their study distinguishes between potential absorptive capacity, involving knowledge acquisition and assimilation, and realized absorptive

capacity, involving transformation and exploitation of knowledge. Both dimensions were shown to play important roles in fostering innovation.

More recent evidence suggests that absorptive capacity also serves as an important mediator between collaborative innovation activities and organizational performance. Organizations that systematically develop mechanisms for knowledge acquisition and utilization are more capable of translating collaborative relationships into measurable innovation outcomes (Mata *et al.,* 2023).

For biomedical engineering firms, absorptive capacity is particularly important because collaborative projects frequently generate highly specialized scientific knowledge that requires advanced technical competencies for successful implementation.

### 2.6. Triple Helix Perspective and Innovation Ecosystems

The Triple Helix framework remains one of the most influential theoretical approaches for understanding innovation ecosystems involving universities, industry, and government. Recent studies have extended this perspective by examining the dynamic evolution of innovation networks and the interactions among institutional actors.

Research by Josep M. Piqué, Jasmina Berbegal-Mirabent, and Henry Etzkowitz (2018) demonstrates that innovation ecosystems evolve continuously through changing relationships among universities, firms, and governmental organizations. Their findings suggest that innovation increasingly depends on network interactions, intermediary organizations, accelerators, and collaborative platforms that facilitate knowledge exchange among ecosystem actors.

More recent discussions also highlight the emergence of broader ecosystem approaches, including Quadruple Helix perspectives that incorporate civil society and users into innovation processes (Miller et al., 2021). Nevertheless, the Triple Helix framework continues to provide an effective foundation for analyzing collaboration among universities, research organizations, industry, and governmental stakeholders.

In the biomedical engineering sector, the Triple Helix perspective is particularly useful because healthcare innovation frequently requires coordination among academic researchers, technology developers, healthcare providers, regulators, and public funding agencies.

### 2.7 Research Gap

The reviewed literature consistently demonstrates that collaboration with universities and R&D institutions enhances innovation performance by facilitating knowledge

transfer, collaborative research, and access to complementary competencies. Recent studies highlight the importance of open innovation, absorptive capacity, and innovation ecosystems in explaining how external collaborations contribute to organizational innovation (Tian *et al.,* 2021; Sancho-Zamora *et al.,* 2021; Sjöö and Hellström, 2019).

Nevertheless, despite the growing body of research on university-industry collaboration, limited attention has been devoted specifically to biomedical engineering enterprises. Most existing studies focus on biotechnology, pharmaceuticals, or innovation in general, while the mechanisms through which collaboration with universities and R&D institutions shapes innovation capability in biomedical engineering remain insufficiently understood.

Therefore, further empirical investigation is required to explain how collaborative relationships influence knowledge transfer, absorptive capacity, technology commercialization, and innovation outcomes within biomedical engineering firms.

## 3. Research Methodology

The survey examined the capacity of biomedical engineering enterprises to transform scientific knowledge, technical competences and university R&D results into products, services and solutions for healthcare. Its geographical scope was the Silesian Voivodeship in Poland, as this region was an area of research interest throughout the entire project titled: "Developing the Potential of Silesian Biomedical Engineering in the Challenge of the Digital and Green Economy (BioMeDiG)."

The Silesian Voivodeship is one of Poland's leading regions in the medical, biomedical, and biotechnology sectors. Moreover, the voivodeship has strong academic and research centers that provide education in biomedical engineering.

Data were collected using computer-assisted web interviewing (CAWI) supported by telephone contact. The achieved sample comprised 80 complete questionnaires without missing data. Respondents represented positions involving innovation and business development, R&D management and technology, technology transfer, clinical research or regulatory affairs, as well as enterprise ownership and senior management. These organisational roles provided the enterprise perspective on cooperation with universities and R&D institutions.

The questionnaire covered enterprise characteristics; innovation and R&D activity; the type, geographical reach and intensity of university cooperation; formal and organisational cooperation arrangements; implementation outcomes; barriers to science–business relationships; competences and research infrastructure; the role of technology transfer centres and university special-purpose companies; financing and public support needs; cooperation and investment plans; and the contribution of innovation and knowledge transfer to business resilience and competitiveness.

The sample included microenterprises (32.5%), small enterprises (40.0%), medium-sized enterprises (15.0%) and large enterprises (12.5%). This article presents a descriptive analysis of the report's aggregate response distributions for innovation types, research partners, the frequency and forms of cooperation, technological outcomes, financing, non-financial support instruments and green transformation plans. Percentages are reproduced as reported.

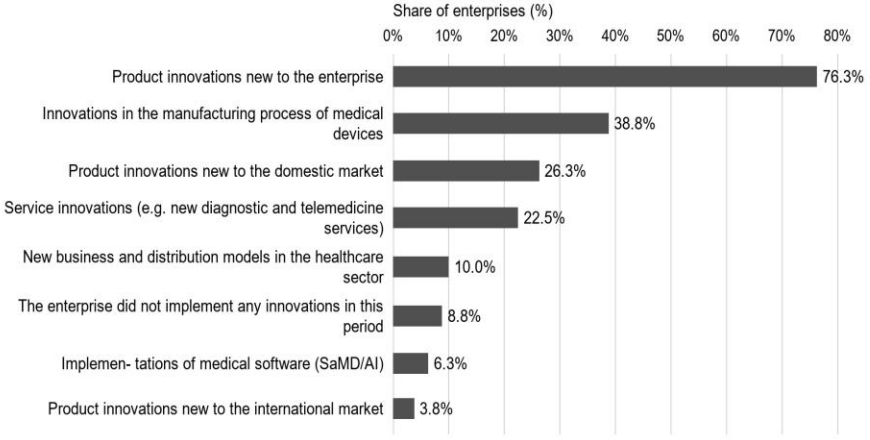
Multiple-response questions are interpreted as the shares of enterprises selecting individual categories, so their percentages may exceed 100% in total; the cooperation-frequency item records one predominant pattern, with a small rounding difference in its total. Results concerning the previous three years and plans for the next three to five years retain their respective questionnaire reference periods.

The analysis combines these descriptive findings with the theoretical perspectives reviewed in the article. Its purpose is to characterise reported patterns of research cooperation and innovation activity; the aggregate distributions are not used to estimate causal effects or test mediation relationships.

## 4. Research Results

This section presents the findings of a survey of 80 biomedical engineering enterprises in the Silesian Voivodeship, focusing on their innovation activity and cooperation with universities and R&D institutions. The analysis covers the types of innovations introduced, research partners, the frequency and forms of cooperation, and the technological outcomes reported by enterprises. It also examines sources of financing, non-financial support needs, and planned activities related to green transformation and sustainable development. Together, these findings provide a descriptive picture of the surveyed firms' innovation capabilities and their links with the regional research environment**.**

***Figure 1.*** *Types of innovations introduced to the market in the last 3 years*




***Source:*** *Authors' own study on the basis of primary research.*

The data presented indicate that the vast majority of the surveyed medical device enterprises engaged in innovation activity over the last three years. Only 8.8% of the entities reported no implementations at all, which means that more than 91% of firms introduced at least one type of innovation to the market. The percentages do not add up to 100%, as respondents could select more than one answer.

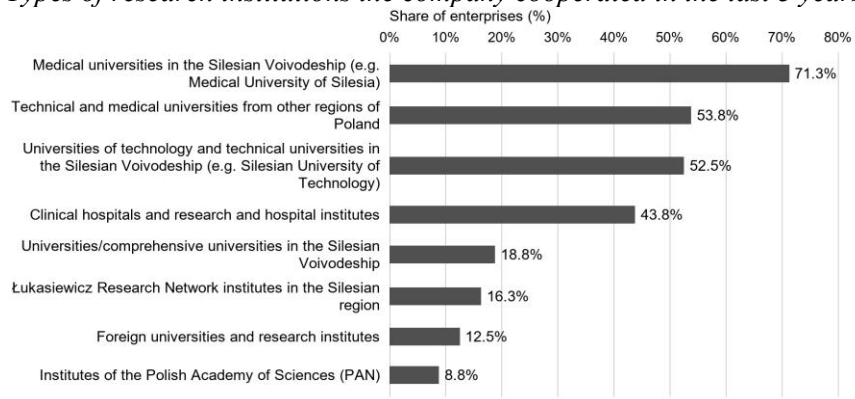
The dominant form of activity was product innovations new to the enterprise (76.3%), i.e. solutions that are new to the firm but not necessarily to the market. As the degree of novelty increases, the share of implementations falls markedly: product innovations new to the domestic market were reported by 26.3% of enterprises, and those new to the international market by only 3.8%.

This ratio (roughly 20 : 1 between innovations new to the enterprise and those new to the international market) points to the prevalence of imitative and adaptive strategies over the development of breakthrough solutions. This may result from the high costs of research and development, lengthy certification procedures for medical devices and the limited export potential of the surveyed entities.

Second place went to innovations in the manufacturing process of medical devices (38.8%), which highlights the important role of technological and organisational improvements aimed at enhancing quality, efficiency and the regulatory compliance of production. Service innovations, e.g. new diagnostic and telemedicine services, were implemented by 22.5% of firms.

New business and distribution models (10.0%) and medical software, including SaMD and AI-based solutions (6.3%), were introduced relatively rarely. The low share of digital innovations, despite their growing importance in healthcare, may reflect competence-related, financial and regulatory barriers. At the same time, it indicates an area of considerable untapped development potential for the sector under study.

***Figure 2.*** *Types of research institutions the company cooperated in the last 3 years*




***Source:*** *Authors' own study on the basis of primary research.*

The data presented indicate that the surveyed medical device enterprises maintain diverse relationships with the research and scientific community. The percentages do not add up to 100%, as respondents could indicate more than one type of institution; their total (277.8%) means that, over the last three years, the average enterprise cooperated with almost three different types of partners.

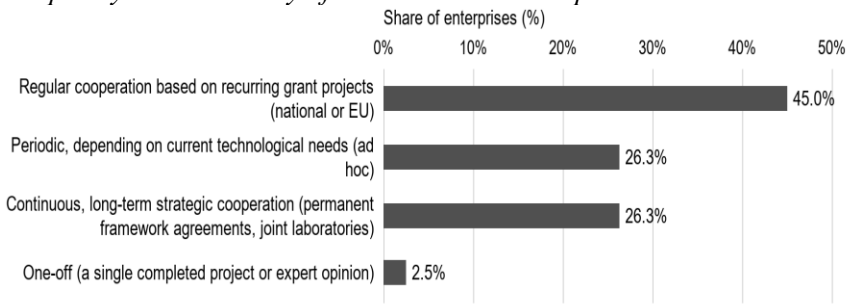
The most important partners are medical universities in the Silesian Voivodeship (71.3%), which confirms that the surveyed firms are strongly embedded in the regional healthcare ecosystem. At the same time, more than half of the enterprises (53.8%) cooperated with technical and medical universities from other regions of Poland, which shows that the search for expertise is not confined to the immediate surroundings.

The high share of universities of technology and technical universities in the Silesian Voivodeship (52.5%) reflects the interdisciplinary nature of the industry, in which the development of medical devices requires a combination of medical and engineering knowledge. Clinical hospitals and research and hospital institutes also play an important role (43.8%), which may be linked to the need to conduct the clinical investigations and evaluations required in the device certification process.

Enterprises cooperated much less frequently with general (comprehensive) universities in the Silesian Voivodeship (18.8%) and with Łukasiewicz Research Network institutes in the region (16.3%). The low share of the latter is all the more noteworthy given that these institutes are, by design, focused on applied research and technology transfer to the economy. The fewest enterprises indicated foreign universities and research institutes (12.5%) and institutes of the Polish Academy of Sciences (8.8%).

The results indicate that the cooperation network of the surveyed firms is based primarily on domestic, and in particular regional, medical and technical universities. Limited cooperation with foreign partners corresponds to the low share of innovations new to the international market and points to the untapped potential for internationalising the sector's research and development activities.

***Figure 3.*** *Frequency and continuity of research relationships with universities*




***Source:*** *Authors' own study on the basis of primary research.*

The data presented indicate that the research relationships between the surveyed enterprises and universities are predominantly recurrent and relatively durable. The percentages add up to 100% (the 0.1 percentage point difference is due to rounding), which means that each respondent indicated one predominant form of cooperation.

The most frequently indicated form is regular cooperation based on recurring national or EU grant projects (45.0%). This demonstrates the important role of public funding instruments in building science–business links, but at the same time it shows that the continuity of these relationships depends on the timing of calls for proposals and the availability of external funds.

One in four enterprises (26.3%) reports continuous, long-term strategic cooperation based on permanent framework agreements or joint laboratories, which should be regarded as the most advanced form of partnership and the least sensitive to external changes. Taken together, recurring and strategic relationships cover more than 71% of the surveyed entities.

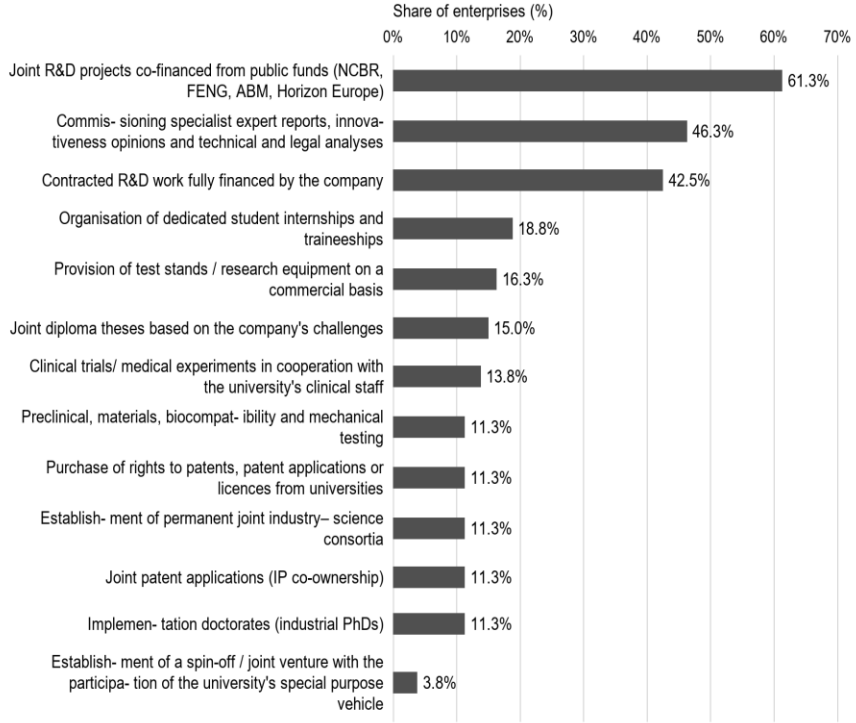
The same share of firms (26.3%) cooperates with universities periodically, depending on current technological needs (ad hoc). This model is reactive in nature and serves mainly to solve specific problems rather than to develop shared competences over the long term. One-off cooperation, limited to a single project or expert opinion, was indicated by only 2.5% of enterprises.

The results indicate that, in the sector under study, cooperation with universities rarely ends with a single contact. However, the predominance of the grant-based model over the strategic one suggests that the durability of many relationships rests on external funding. Strengthening instruments that foster long-term partnerships, such as framework agreements or shared research facilities, could increase the stability of these links.

The data presented indicate that the research and implementation cooperation between the surveyed enterprises and universities takes many forms, although it is clearly concentrated on a few of them. The percentages do not add up to 100%, as respondents could select more than one answer; their total (274.3%) means that the average enterprise cooperated in almost three different forms.

The dominant form is joint R&D projects co-financed from public funds, including NCBR, FENG, ABM and Horizon Europe (61.3%). This confirms the key role of public support instruments in initiating science–business cooperation. Service-type forms come next: commissioning specialist expert reports, innovativeness opinions and technical and legal analyses (46.3%), and contracted R&D work fully financed by the company (42.5%). The latter result in particular shows that a considerable proportion of enterprises are willing to finance research on their own.

***Figure 4.*** *Forms of research and implementation cooperation with universities*




*Source: Authors' own study on the basis of primary research.*

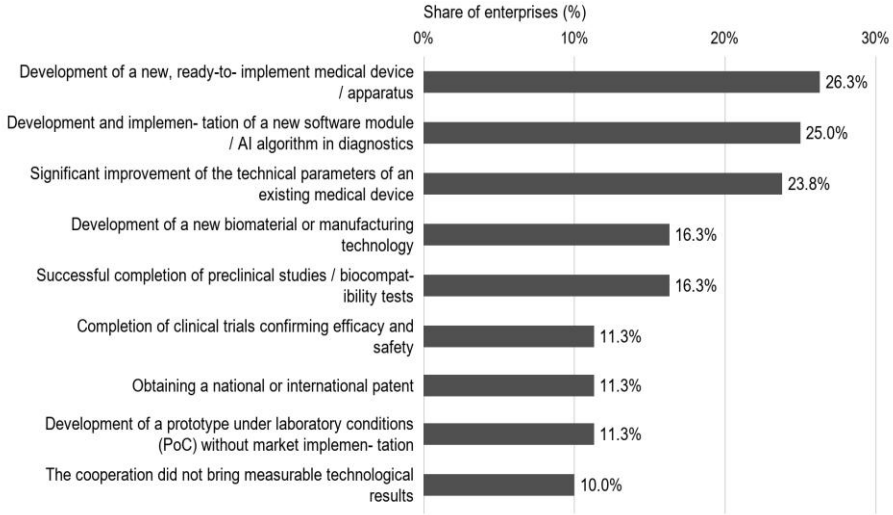
Forms related to human capital development were indicated much less frequently, such as student internships and traineeships (18.8%), joint diploma theses (15.0%) and implementation doctorates (11.3%), as was the provision of research equipment on a commercial basis (16.3%).

The share of clinical trials involving the university's clinical staff (13.8%) and of preclinical, materials and biocompatibility testing (11.3%) is relatively low, despite their importance in the certification of medical devices.

The least common are advanced forms of knowledge transfer: the purchase of rights to patents and licences, joint patent applications and permanent industry–science consortia (11.3% each), and above all the establishment of spin-off companies or joint ventures with the participation of the university's special purpose vehicle (3.8%).

The results therefore indicate that cooperation is primarily project-based and contractual, whereas the commercialisation of university intellectual property and equity links remain marginal.

***Figure 5.*** *Direct technological results achieved by the company through cooperation with universities*




***Source:*** *Authors' own study on the basis of primary research.*

The data presented indicate that cooperation with universities brings measurable technological benefits to the surveyed enterprises. Only 10.0% of firms reported no such results, which means that in the vast majority of cases cooperation translated into concrete outcomes. The percentages do not add up to 100%, as respondents could indicate more than one result; their total (151.6%) means that the average enterprise achieved about one and a half types of results.

The most frequently indicated results are product-related and are distributed almost evenly: the development of a new, ready-to-implement medical device or apparatus (26.3%), the development and implementation of a new software module or AI algorithm in diagnostics (25.0%), and a significant improvement of the technical parameters of an existing device (23.8%).

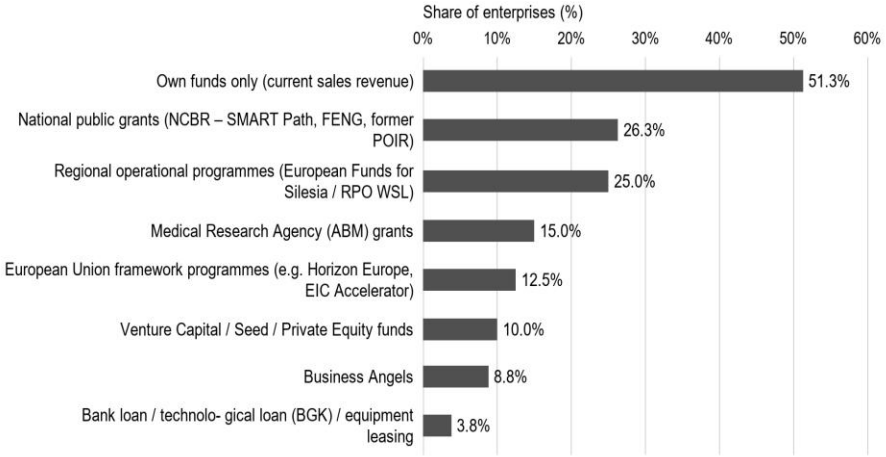
The high share of software solutions should be compared with the low share of medical software (SaMD/AI) implementations (6.3%) reported earlier-this difference may stem from the different scope of the two questions, as the present one also covers modules that are not stand-alone medical devices.

Enterprises less often achieved results related to the early stages of device development, i.e., the development of a new biomaterial or manufacturing technology and the successful completion of preclinical studies and biocompatibility tests (16.3% each). The lowest shares concern results requiring the longest and most costly processes: clinical trials confirming efficacy and safety and obtaining a patent (11.3% each).

The same proportion of firms (11.3%) ended cooperation at the laboratory prototype (PoC) stage without market implementation, which points to a gap between research results and their commercialisation.

The findings show that cooperation with universities serves primarily the development and improvement of products, whereas it less frequently leads to the protection of intellectual property and the clinical validation of solutions.

***Figure 6.*** *Sources of financing for research, development and implementation work to date*




***Source:*** *Authors' own study on the basis of primary research.*

The data presented indicate that own funds are the primary source of financing for the research, development and implementation work carried out to date by the surveyed enterprises. More than half of the firms (51.3%) financed these activities solely from current sales revenue, without using any external sources. The percentages do not add up to 100%, as respondents could indicate more than one source. The remaining 48.7% of enterprises used external financing, often combining several of its forms.

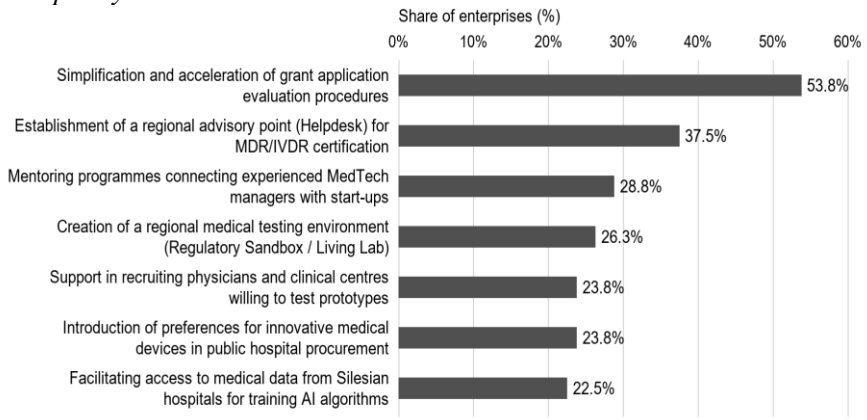
Public funds clearly dominate among external sources. National grants, including NCBR funding under the SMART Path, the FENG programme and the former POIR, were indicated by 26.3% of firms, and regional operational programmes (European Funds for Silesia/RPO WSL) by 25.0%.

The similar share of these two sources confirms the important role of regional innovation policy in financing R&D activity. Grants from the Medical Research Agency (ABM) were obtained by 15.0% of enterprises, and funds from European Union framework programmes, such as Horizon Europe or the EIC Accelerator, by 12.5%. The lower share of the latter may result from the high competitiveness and complexity of application procedures at European level.

Private capital is of much lesser importance. Venture Capital, Seed or Private Equity funds were used by 10.0% of firms, and support from business angels by 8.8%. The least frequently indicated source is debt financing, i.e., a bank loan, a BGK technological loan or equipment leasing (3.8%), which may reflect the high risk of R&D projects and the difficulty of securing them.

The results point to a high degree of self-financing of innovation activity and to the limited use of market sources of capital. This creates a risk that the scale and pace of development work in the sector will depend on the current financial condition of enterprises and on the availability of public funds.

***Figure 7.*** *Non-financial instruments most helpful in strengthening the company's innovation capacity*




***Source:*** *Authors' own study on the basis of primary research.*

The data presented indicate that the surveyed enterprises primarily expect instruments that reduce administrative and regulatory barriers. The percentages do not add up to 100%, as respondents could indicate more than one instrument; their total (216.5%) means that the average enterprise indicated more than two types of desired support.

The simplification and acceleration of grant application evaluation procedures was considered the most helpful (53.8%). This result is consistent with the major role of public funds in financing R&D activity and shows that the time-consuming and complex nature of the application process is a significant burden for firms.

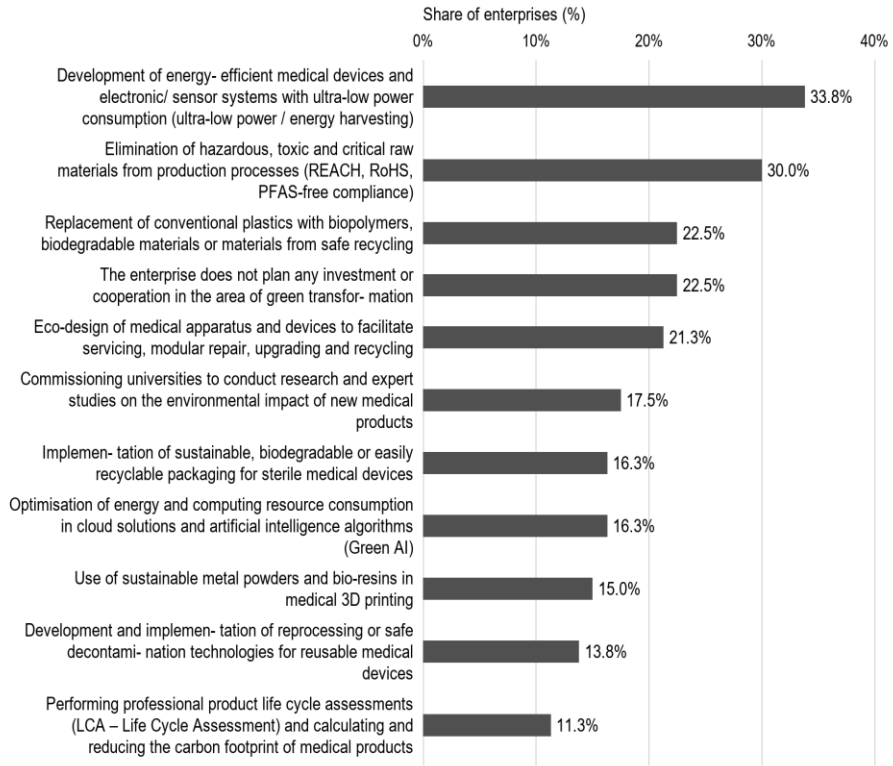
Second place went to the establishment of a regional advisory point (Helpdesk) for MDR/IVDR certification (37.5%), which confirms that the requirements of the new EU regulations on medical devices and in vitro diagnostic medical devices are perceived as one of the main challenges facing the sector. Mentoring programmes connecting experienced MedTech managers with start-ups were indicated by 28.8%

of firms, which points to a need for the transfer of business and market knowledge, not only technological expertise.

The remaining instruments received similar numbers of indications, ranging from 22.5% to 26.3%. They concern the creation of a regional medical testing environment such as a Regulatory Sandbox or Living Lab (26.3%), support in recruiting physicians and clinical centres to test prototypes (23.8%), the introduction of preferences for innovative devices in public hospital procurement (23.8%), and facilitating access to medical data from Silesian hospitals for training AI algorithms (22.5%). All of them relate to enterprises' relationships with the healthcare system, both at the stage of validating solutions and at the stage of bringing them to market.

The results indicate that strengthening firms' innovation capacity depends not so much on creating new forms of support as on streamlining existing procedures and better linking enterprises with the regional healthcare ecosystem.

***Figure 8.*** *Areas related to the green transformation and sustainable development in which the company plans investment or cooperation with universities over the next 3–5 years*




***Source:*** *Authors' own study on the basis of primary research.*

The data presented indicate that the green transformation is an area of interest for the majority of the surveyed enterprises. 22.5% of firms reported no plans for investment or cooperation in this field, which means that 77.5% of entities intend to take action in at least one area over the next 3–5 years. The percentages do not add up to 100%, as respondents could select more than one answer; enterprises planning such activities indicated more than two areas on average.

The most frequently indicated area was the development of energy-efficient medical devices and electronic and sensor systems with ultra-low power consumption (33.8%). In this area, environmental benefits are combined with a product advantage, e.g., longer operation of devices without an external power supply. Second place went to the elimination of hazardous, toxic and critical raw materials from production processes (30.0%), which should be linked primarily to the need to meet the requirements of the REACH and RoHS regulations and the tightening restrictions on PFAS.

Activities in line with the circular economy are also important: the replacement of conventional plastics with biopolymers and recycled materials (22.5%) and the eco-design of apparatus to facilitate its repair, upgrading and recycling (21.3%).

Less frequently planned were commissioning universities to study the environmental impact of new products (17.5%), the implementation of sustainable packaging for sterile medical devices and the optimisation of energy consumption in cloud solutions and AI algorithms (16.3% each), the use of sustainable materials in 3D printing (15.0%) and reprocessing technologies for reusable devices (13.8%). The fewest firms (11.3%) intend to conduct product life cycle assessments (LCA) and calculate their carbon footprint, despite growing ESG reporting requirements.

The results indicate that the green transformation in the sector under study is pursued primarily where it coincides with regulatory requirements or product benefits, whereas systematic environmental impact assessment tools remain less widespread.

## 5. Conclusions

This study examines innovation activity and research cooperation among the surveyed biomedical engineering enterprises. The findings indicate that innovation is predominantly incremental and oriented towards improvements at the enterprise level. Product innovations new to the firm were reported by 76.3% of respondents, whereas innovations new to the international market were reported by only 3.8%. This pattern suggests scope for strengthening firms' capacity to develop solutions with broader market novelty.

Universities constitute an important part of the surveyed enterprises' research networks, particularly medical and technical universities in the Silesian

Voivodeship. Cooperation is primarily organised through recurring grant projects, publicly co-financed joint R&D and contracted research. Strategic partnerships are less widespread, while equity-based relationships and the commercialisation of university intellectual property remain relatively uncommon. These findings suggest opportunities to complement project-based cooperation with more durable institutional arrangements.

Reported technological outcomes include the development of ready-to-implement medical devices, software modules and AI algorithms, as well as improvements to existing products. However, the descriptive evidence does not establish that cooperation caused these outcomes or explain which partnership characteristics are most effective. The findings are consistent with the relevance of open innovation and university–industry relationships, while the specific role of absorptive capacity requires further empirical investigation.

The financing and support patterns suggest practical priorities for enterprises, universities and public institutions. These include strengthening long-term research partnerships, simplifying grant procedures and improving access to regulatory advice and clinical testing environments.

Planned investment in green transformation provides a further opportunity for cooperation, particularly in energy-efficient devices, safer materials and circular product design. Greater attention to life cycle assessment could help firms evaluate the environmental implications of these activities more systematically.

## 6. Limitations and Directions for Future Research

The survey of 80 biomedical engineering enterprises in the Silesian Voivodeship provides a regional basis for further research on university–industry cooperation. Future studies could extend this approach to additional Polish regions and other countries, using harmonised questionnaires to compare institutional environments, funding opportunities and healthcare innovation ecosystems.

The enterprise perspective captured through telephone-supported CAWI could be complemented by interviews with university researchers, technology transfer centres, clinicians and regulatory specialists. Combining these perspectives could deepen understanding of partnership governance and knowledge-sharing practices. Comparative analyses across enterprise size groups, R&D arrangements and prior collaboration experience could further clarify how organisational resources shape cooperation outcomes.

Longitudinal follow-up could build on the questionnaire's retrospective accounts of the previous three years and investment plans for the next three to five years. Tracking partnerships and projects over time, alongside indicators of patents, clinical validation and market introduction, would help explain how project-based

cooperation develops into lasting relationships and how research results progress towards commercialisation.

Further studies could use enterprise-level data and validated measures of absorptive capacity to examine the mechanisms linking external knowledge, internal capabilities and innovation outcomes. Following the implementation of planned green investments would also enable assessment of their environmental and business outcomes, particularly in energy efficiency, circular product design and life cycle assessment.

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