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I3HIES COMMUNITY LANDSCAPE

ECOSYSTEM MAPPING ANALYSIS





TABLE OF CONTENTS

I3HIES COMMUNITY LANDSCAPE	1
ECOSYSTEM MAPPING ANALYSIS.....	1
TABLE OF CONTENTS	2
INTRODUCTION.	4
VALUE CREATION FRAMEWORK.	5
AUSTRIA	6
Medical Devices Sector in Austria.	6
Medical Emergency Equipment Sector in Austria.	7
Medical Device Regulation (MDR) Compliance in Austria.	7
Stakeholder Interactions and Strategic Responses to Challenges in Austria.	7
HUNGARY	8
Medical devices in Hungary.....	8
Medical Emergency Equipment in Hungary.....	9
MDR Compliance in Hungary.....	9
Stakeholder Interactions and Strategic Responses to Challenges in Hungary.....	9
LITHUANIA	10
Medical Devices Sector in Lithuania.....	10
Medical Emergency Equipment Sector in Lithuania.....	10
Medical Device Regulation (MDR) Compliance in Lithuania.....	11
Stakeholder Interactions and Strategic Responses to Challenges in Lithuania.....	11
POLAND	11
Medical Devices Sector in Poland.....	12
Medical Emergency Equipment Sector in Poland.....	12
Medical Device Regulation (MDR) Compliance in Poland.....	12
Stakeholder Interactions and Strategic Responses to Challenges in Poland.....	13
ROMANIA	13
Medical Devices Sector in Romania.....	13
Medical Emergency Equipment Sector in Romania.....	14
Medical Device Regulation (MDR) Compliance in Romania.....	14
Stakeholder Interactions and Strategic Responses to Challenges in Romania.....	14
SLOVAKIA	15
Medical Devices Sector in Slovakia.....	15
Medical Emergency Equipment Sector in Slovakia.....	16





Medical Device Regulation (MDR) Compliance in Slovakia 16

Stakeholder Interactions and Strategic Responses to Challenges in Slovakia..... 16

SLOVENIA 17

 Medical Devices Sector in Slovenia..... 17

 Medical Emergency Equipment Sector in Slovenia..... 17

 Medical Device Regulation (MDR) Compliance in Slovenia..... 18

 Stakeholder Interactions and Strategic Responses to Challenges in Slovenia..... 18

BENCHMARK OF THE COMMUNITY ACTORS..... 20

 The methodology 20

 Data results interpretation. 21

 AUSTRIA 21

 HUNGARY 22

 LITHUANIA 23

 POLAND 24

 ROMANIA 25

 SLOVAKIA 25

 SLOVENIA 26

CONCLUSIONS..... 28





INTRODUCTION.

Europe has traditionally excelled in providing high-quality healthcare and still holds the potential to become a global leader in health research and development. To realize this potential, there is a need to establish a long-term, collaborative ecosystem across regions that supports and incentivizes research and development, as well as stable partnerships.

The I3HIES project aims to enhance health innovation ecosystems to optimize the effectiveness of the healthcare sector and facilitate efficient international collaboration among key innovation stakeholders. With 9 partners from Hungary, Austria, Lithuania, Poland, Romania, Slovakia, and Slovenia, the project will focus on three thematic areas: medical devices, emergency equipment, and MDR compliance. Specifically, the partners will expedite the development of validated innovative investments in these areas and promote interregional cooperation within EU value chains. Initially, the partners will support the innovation process by assisting actors in identifying innovation opportunities, enhancing networking, collaboration, and co-creation through ideation support events.

The I3HIES project follows a complex approach to foster interregional innovation investments and collaboration in the health innovation ecosystem. Partners will work thematically in 3 focus areas (medical devices, emergency equipment, MDR compliance) and methodically in 2 implementation pillars (innovation investment and interregional cooperation and participation in EU value chains) on 2 intervention levels (intra-regional and interregional), by providing a comprehensive portfolio of tailored services to 4-helix stakeholder groups (quadruple helix actors representing research, policy, business and society) that will experiment and validate at least 6 innovative methods, tools and techniques (interactive peer reviews, living lab concept, service design, customer friction, intrapreneurship, innovation scouting) in 5 thematic work packages (I3HIES Community Building, Front End Discover, Business Case Design, Preparation for Funding and Strengthening the Ecosystem).

The innovation actors participating in the I3HIES community will be supported i) to prepare innovation investments by facilitating and tutoring the innovation process from ideation through business case design till the preparation for funding, and ii) accelerate the development of validated innovation investments in the thematic priorities, and ii) to enhance interregional cooperation and participation in interregional partnerships and contribute to EU value chains.

The immediate goal is to validate 15 project ideas, establish 3 European partnerships and develop the most promising mini-business cases into concrete investment plans, thereby supporting the ongoing transformation of the healthcare sector.

This benchmark analysis project plays a critical role in defining and refining the scope of the Community's activities. As the project unfolds, it is essential to recognize that actions must be carefully calibrated in geographic, structural, and thematic terms throughout its lifespan.

The aim is to establish the right framework conditions based on identified best practices, fostering an environment conducive to innovation and collaboration. Furthermore, the analysis provides valuable insights about the performance of local innovation actors with those in other regions and EU Member States. This comparative analysis does not only highlight local strengths but also contribute to the development of joint Community actions and value chains, paving the way for impactful and sustainable outcomes.





VALUE CREATION FRAMEWORK.

The innovation assignment and the value proposition of HIES and I3HIES in the context of I3 Programme.

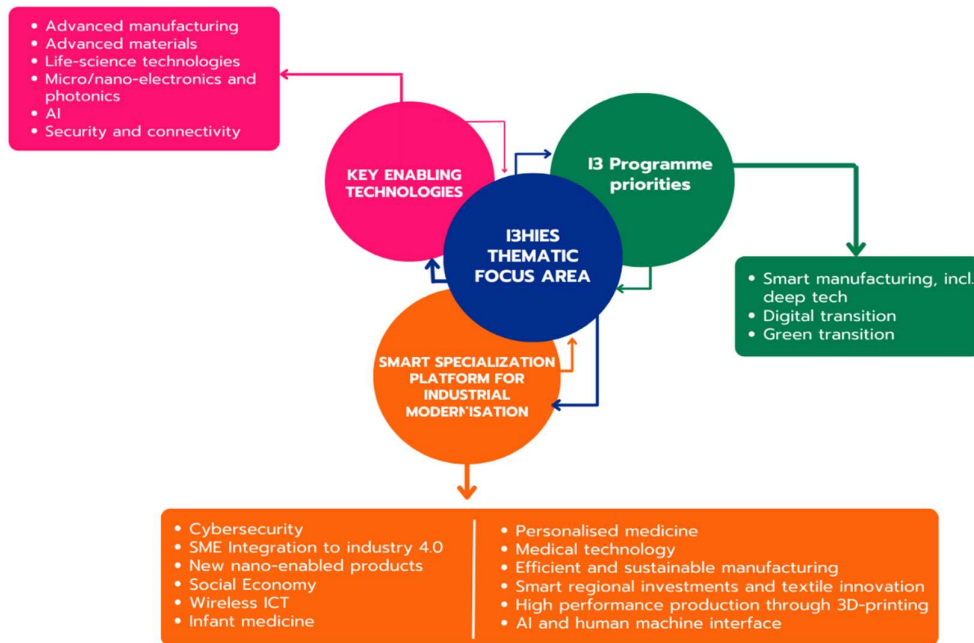


Fig.9 The International HIES and Innovation Assignment

The Central-European Regional Health Innovation Ecosystem (HIES/CERHIES) is a collaborative network comprising national innovation ecosystems focused on the health (MedTech) sector within Central Europe. Its primary aim is to establish and maintain an ecosystem conducive to fostering successful innovation and business collaborations, both internally among its members and externally with partners.

The HIES consists of various stakeholders from academic institutions, business entities, public authorities, and societal actors, all organized and coordinated by a national HIES within each participating country. Each national HIES is structured to include key components such as a Coordinator/Operator responsible for overall management, a Government Coordinator facilitating policy alignment (e.g., S3 contact points), a Health (MedTech) Innovation Hub akin to an EDIH or clusters, an Excellence Hub representing universities and research institutes, and Thematic Centres of Excellence offering consultancy services.

Additionally, governmental partners engaged in policymaking contribute to the ecosystem's strategic direction and regulatory framework. Through this structured organization, the HIES aims to optimize collaboration, innovation, and regulatory alignment across Central Europe's health (MedTech) sector.

The joint approach of the I3HIES and HIES initiatives is centred around leveraging smart specialization strategies to drive innovation and foster interregional collaboration within the health sector. Key elements of these strategies include promoting collaboration among actors



across the quadruple helix, creating value chains, and integrating less developed regions into the innovation ecosystem.

To effectively implement these strategies, various organizations and initiatives are involved, each with different focuses and areas of expertise. However, there is a recognized need for reorganization and restructuring of these entities to better align with the overarching goals.

At the European Commission level, coordination is primarily handled by EISMEA, while at the member state level, S3 contact points serve as coordinators. Despite these efforts, there is a lack of proper coordination among the activities of different organizations, particularly at the member state level.

One crucial aspect highlighted by the I3HIES project is the absence of a centralized "umbrella forum/coordinator" for the health sector in Central Europe. Establishing such a coordinator would be instrumental in streamlining efforts, enhancing collaboration, and maximizing the impact of initiatives within the region.

The primary focus of the I3HIES project revolves around medical devices, emergency equipment, and compliance with Medical Device Regulation (MDR). To gain a clearer understanding of the health sector within the scope of the I3HIES focus, this document provides a brief analysis of the ecosystems of the project partners.

AUSTRIA

Austria's health sector showcases the effective implementation of the quadruple helix model, bringing together government, academia, industry, and civil society to foster innovation in healthcare. This model supports a collaborative approach, where government policies and funding pave the way for advanced research and technological development. Academic institutions enhance this environment by pushing forward scientific research and innovation, which are crucial for medical advancements.

Industry and civil society play critical roles in translating these innovations into practical applications and ensuring they meet the real-world needs of the population. Industry stakeholders commercialize scientific breakthroughs, bringing them to the healthcare system, while civil society groups, including patient advocacy organizations, provide feedback and ensure that the outputs are aligned with patient needs and ethical standards. This structured collaboration not only improves healthcare services but also contributes to Austria's standing as a leader in healthcare innovation.

Medical Devices Sector in Austria.

The medical device sector in Austria is distinguished by its dynamic integration of advanced technologies and strong emphasis on research and development. This industry, pivotal in the European medical landscape, benefits from Austria's historical strength in engineering and technology, enabling local companies to innovate and expand their product lines into international markets. The focus on digital health solutions and the development of complex medical devices, such as diagnostic imaging equipment and orthopaedic devices, reflects a deep commitment to enhancing patient care through technology (McKinsey & Company).



LIETUVOS
INOVACIJŲ
CENTRAS



Interizon



SAMORZĄD
WOJEWÓDZTWA POMORSKIEGO



TECHNOLOGY PARK
LJUBLJANA
01



Furthermore, the Austrian MedTech sector is supported by a collaborative environment that includes government backing, academic partnerships, and health institutions. This synergy fosters a fertile ground for technological advancements and ensures that the medical devices produced are not only cutting-edge but also tailored to meet the specific needs of healthcare providers and patients. The sector's growth is also propelled by significant investment in R&D, ensuring that Austrian MedTech companies remain competitive on a global scale (McKinsey & Company).

Medical Emergency Equipment Sector in Austria.

In Austria, the medical emergency equipment sector is a critical component of the healthcare system, ensuring rapid and effective response capabilities in urgent care situations. This sector encompasses a wide range of products, from advanced life-support systems to basic first aid supplies. Austrian manufacturers are known for their high-quality standards and innovative designs that prioritize user-friendliness and reliability in emergency scenarios. The development and enhancement of emergency medical devices are driven by ongoing research and technological innovation, which aim to improve the speed and effectiveness of medical responses in critical situations.

The sector's robustness is further supported by Austria's stringent regulatory standards, which ensure that all emergency medical equipment meets the highest safety and performance criteria. This regulatory environment not only fosters trust in the equipment used by healthcare professionals but also encourages continuous improvement and innovation among manufacturers. The focus on quality assurance and patient safety is paramount, making Austrian emergency medical equipment a trusted choice in both domestic and international markets.

Medical Device Regulation (MDR) Compliance in Austria.

Compliance with the Medical Device Regulation (MDR) in Austria is crucial for ensuring that medical devices meet the EU's stringent safety and efficacy standards. The Austrian Federal Office for Safety in Health Care (BASG) oversees the implementation of these regulations, conducting rigorous assessments and monitoring the market to prevent any non-compliant products from reaching consumers. This regulatory framework is designed to protect patient health and guarantee the quality of medical devices available in the healthcare system ([BASG](#)).

The MDR's impact on Austria includes a more comprehensive approach to product lifecycle management, requiring manufacturers to conduct extensive clinical evaluations and maintain detailed documentation to support the continuous safety monitoring of their products. Austrian companies must adapt to these regulations to maintain market access, necessitating updates to their quality management systems and operational processes. This adaptation not only meets legal requirements but also enhances the overall reliability and trustworthiness of Austrian medical devices in the global market ([BASG](#)).

Stakeholder Interactions and Strategic Responses to Challenges in Austria.

In Austria, the interactions among stakeholders in the medical devices sector are shaped by a proactive regulatory environment and a commitment to high standards of innovation and safety. The sector benefits from strong collaborations between public authorities, private





enterprises, and academic institutions, which help facilitate the development and integration of advanced medical technologies. These collaborations are underpinned by regulatory frameworks that ensure all medical devices meet the EU's stringent safety and efficacy standards before they are marketed ([Public Health](#)) ([MedTech Europe](#)).

Challenges in the sector are met with strategic responses that include fostering an environment conducive to innovation. This is evident in the integration of new technologies such as AI in medical devices, which improves diagnostics and patient care. The Austrian regulatory framework supports these innovations by providing clear guidelines and support for compliance, thereby ensuring that advancements in medical technology can be integrated smoothly into healthcare practices without compromising patient safety ([Fieldfisher](#)).

Additionally, the private sector plays a crucial role by investing in the development of new medical technologies and forming partnerships with public institutions to drive research and development. This collaborative approach not only enhances Austria's capabilities in medical technology but also ensures that the sector remains dynamic and responsive to both domestic and global healthcare needs ([MedTech Europe](#)).

HUNGARY

The health sector in Hungary exemplifies a dynamic quadruple helix model, integrating government, academia, industry, and civil society to enhance healthcare innovation and system reforms. The government not only sets policies but actively invests in health infrastructure, supporting a framework conducive to growth. Academia drives research, translating discoveries into practical healthcare solutions, often backed by public funding. Industry stakeholders, including medical device companies, push these innovations to market, bolstering economic output and competitiveness. Civil society, including patient advocacy groups, ensures the system remains responsive to public needs, influencing policy to foster a more inclusive healthcare environment.

This collaborative approach underpins Hungary's emerging status as a significant hub in the European medical technology landscape, effectively responding to contemporary healthcare challenges.

Medical devices in Hungary.

Hungary's medical device sector is robust, with nearly 180 companies specializing in high-value, export-oriented production that constitutes 5.3% of the nation's exports. The industry, which employs around 53,000 people, thrives on strong traditions in natural and technical sciences, fostering a conducive environment for innovation. Notable production areas include electro-medical equipment, diagnostic devices, and a variety of surgical supplies. Key players with significant investments include multinational giants like GE Healthcare and Medtronic, enhancing the sector's global footprint (Trade.gov) (Blue Europe).

Despite its strengths, the Hungarian medical device industry faces challenges such as a high emigration rate of healthcare professionals and systemic issues related to healthcare infrastructure and funding. To counter these, Hungary is investing in healthcare technology and infrastructure, with a focus on increasing capacities in hospitals and clinics to improve service delivery and reduce waiting times for medical procedures (Trade.gov) (Blue Europe).





Medical Emergency Equipment in Hungary.

Hungary's medical emergency equipment industry is focused on the development and manufacturing of crucial medical devices, with a strong emphasis on meeting both national and international standards. The sector includes significant production of critical care devices like ventilators, which are essential in emergency medical services. This industry benefits from Hungary's established expertise in medical technologies, fostering innovation in products that are vital for acute medical care and emergency responses (trade).

Investments in the medical technologies sector are bolstered by Hungary's commitment to innovation and quality, ensuring the availability and efficiency of emergency medical equipment. The industry's ability to adapt and respond to growing medical needs, particularly in emergency care, underscores its critical role within Hungary's healthcare system. Efforts to enhance production capabilities aim to address both local demands and broader European market needs, reflecting a strategic approach to healthcare readiness and patient care (trade).

MDR Compliance in Hungary.

In Hungary, adherence to the EU's Medical Device Regulation (MDR) is critical for entities involved in the production and distribution of medical devices. The MDR sets stringent standards for device safety and effectiveness, significantly enhancing the regulatory framework to ensure public health protection. Recent legislative adjustments have extended the MDR transition periods for certain medical devices previously certified under older directives, such as MDD and AIMDD. This move aims to prevent shortages and allow manufacturers additional time to meet new compliance standards (SustWorld) (Public Health).

This extension reflects the EU's commitment to a smooth transition to the new regulatory environment without disrupting the medical device supply chain. For Hungarian manufacturers, this means they can continue marketing their currently approved devices while they work towards fulfilling the updated MDR requirements. Compliance with these standards is crucial for maintaining market access throughout the EU and ensuring that medical products are safe and effective for users (SustWorld) (Public Health).

Stakeholder Interactions and Strategic Responses to Challenges in Hungary.

In Hungary, the medical device sector benefits from a robust collaboration framework involving government, academia, and the private sector. While the government provides strategic support and funding to integrate advanced technologies and enhance healthcare infrastructure, bureaucratic challenges and inconsistencies in funding can dampen the effectiveness of these initiatives. Additionally, partnerships between public entities and private companies drive technological advancements, but the application of these technologies in public healthcare can be hampered by systemic issues like funding shortages and workforce deficits, which affect timely access to innovative treatments (Blue Europe) (Trade.gov).

The private sector significantly contributes to the growth of Hungary's medical device sector through investments in research and advanced manufacturing facilities. These enterprises navigate a stringent regulatory environment within the EU, which, while safeguarding market integrity, can delay product launches and complicate market entry. Despite these efforts, the uncertain reimbursement landscape in Hungary poses further challenges, impacting the market dynamics for newer and more advanced medical devices (Blue Europe).





Regulations such as the MDR and IVDR play a crucial role in upholding high safety and efficacy standards within the medical device industry. These regulations ensure that products meet rigorous EU standards, fostering public trust in the healthcare system. While compliance with these regulations demands extensive resources, it is vital for reducing risks associated with medical devices and ensuring that only the most effective and safest products are available. Navigating this regulatory framework is challenging but essential for maintaining the integrity and global competitiveness of Hungary's medical technology sector (Trade.gov).

LITHUANIA

Lithuania's health sector effectively utilizes the quadruple helix model, fostering collaboration between government, academia, industry, and civil society to drive health-related innovation and policy development. The government plays a pivotal role by providing supportive regulations and necessary funding, creating an environment conducive to healthcare advancements. Academic institutions contribute through rigorous research and development, pushing the boundaries of medical technology and healthcare solutions.

In this collaborative framework, industry stakeholders are crucial for transforming academic innovations into commercially viable products that can be integrated into the healthcare system. Meanwhile, civil society organizations ensure that these innovations are aligned with the needs and rights of patients, advocating for accessible and patient-centered healthcare services. This comprehensive approach not only enhances the quality of healthcare in Lithuania but also promotes a sustainable model for ongoing innovation and improvement in the health sector.

Medical Devices Sector in Lithuania.

Lithuania's medical device sector is experiencing significant growth and innovation, particularly in its major cities, Vilnius, and Kaunas. These cities have become central hubs for life sciences, driven by a strong connection between research institutions and the industry. This collaboration has fostered a climate of innovation, particularly in advanced fields like gene-editing technologies and biotech developments. The government's strategic focus aims to boost Lithuania's GDP contribution from the life sciences sector to 5% by 2030, reflecting strong support and potential for future growth ([Medical Device Network](#)).

The sector is also enhancing its capabilities with cutting-edge technologies such as AI, which are becoming integral to the development of medical devices. This integration is evident in efforts to improve medical diagnostics and patient care management, making treatments more personalized and efficient. Companies in Lithuania are not only focusing on developing new medical devices but are also keen on optimizing existing technologies to better meet the healthcare needs of the population ([Wolters Kluwer: Expert Solutions](#)).

Medical Emergency Equipment Sector in Lithuania.

Lithuania's medical emergency equipment sector benefits from the broader advancements within the country's MedTech industry. Innovations in emergency medical technology are crucial for improving the responsiveness and effectiveness of healthcare services in urgent care scenarios. This includes the development of devices that leverage AI to enhance the precision and adaptability of emergency responses.





Medical Device Regulation (MDR) Compliance in Lithuania.

Regulatory compliance remains a critical focus in Lithuania, like other EU countries, under the broader Medical Device Regulation (MDR) framework. This regulation ensures that all medical devices meet stringent safety and performance standards before entering the market, maintaining high standards of patient safety and product efficacy.

Overall, Lithuania's medical device industry shows a promising trajectory of growth and innovation, backed by governmental support and integration of advanced technologies. The focus on research and development, particularly in high-tech sectors, positions Lithuania as an emerging leader in the European MedTech landscape.

Stakeholder Interactions and Strategic Responses to Challenges in Lithuania.

In Lithuania, the medical device sector experiences robust stakeholder interactions, with strong collaborations between the government, private industry, and regulatory bodies. These collaborations are essential for adapting to evolving regulatory landscapes, particularly with the implementation of the EU's Medical Device Regulation (MDR). This framework ensures that all medical devices meet stringent safety and efficacy standards before entering the market, fostering a safe and innovative environment for medical technologies.

However, challenges persist, particularly in aligning national practices with the stringent requirements of the MDR. Smaller manufacturers often face significant hurdles, including the high costs of compliance and the complexities involved in navigating the regulatory process. These challenges are exacerbated by the limited number of Notified Bodies available to process certifications, which can delay market entry for new devices.

Strategically, Lithuania has responded to these challenges by promoting stronger communication and collaboration among stakeholders. This includes regular consultations and the sharing of best practices to ensure a unified approach to compliance. Additionally, efforts are made to support small and medium-sized enterprises (SMEs) through targeted programs that provide guidance and simplify access to necessary resources for navigating EU regulations. This strategic approach aims to maintain Lithuania's competitiveness in the medical device sector, ensuring continuous innovation and adherence to high safety standards.

POLAND

Poland's health sector illustrates a robust application of the quadruple helix model, integrating government, academia, industry, and civil society to enhance healthcare innovation and policy. The government lays the foundational policies and provides crucial funding, setting the stage for advancements in medical research and healthcare technologies. Academic institutions in Poland play a key role, driving forward research and development initiatives that pave the way for cutting-edge medical solutions.

Industry stakeholders are essential in translating these academic innovations into marketable healthcare products, ensuring that new technologies are accessible within the healthcare system. Meanwhile, civil society organizations actively ensure that these innovations align with patient needs, advocating for accessible, efficient, and patient-centered healthcare





services. This synergy among the different stakeholders not only boosts the effectiveness of Poland's healthcare system but also fosters a sustainable environment for ongoing healthcare improvements and innovations.

Medical Devices Sector in Poland.

Poland's medical device sector is marked by strong growth and innovation, particularly in the development and integration of advanced technologies. The market was valued at \$4.8 billion in 2021 and is projected to grow at a CAGR of over 5% from 2022 to 2027. This growth is driven by several factors including increased demand for healthcare services, advancements in medical technology, and rising health awareness among the population. Key segments in the market include cardiovascular devices, hospital supplies, orthopaedic devices, general surgery, and diabetes care devices, with major players like Fresenius, Medtronic, Abbott, and Stryker shaping the industry landscape ([GlobalData](#)).

The sector is also experiencing significant digital transformation, leveraging artificial intelligence (AI) and machine learning to enhance diagnostics and patient management. These technologies are not only improving the functionality of medical devices but are also enabling personalized care, thereby enhancing patient outcomes. The integration of AI in medical devices is part of a broader trend that includes the development of more connected, patient-centric medical devices ([Wolters Kluwer: Expert Solutions](#)).

Medical Emergency Equipment Sector in Poland.

The medical emergency equipment sector in Poland is crucial for providing immediate and effective responses in urgent care situations. This sector benefits from the broader growth and technological advancements within the Polish medical device industry. Innovations in emergency medical technology are focused on enhancing the speed and accuracy of medical responses, which are critical in emergency situations. The adoption of technologies such as smart devices and AI is improving the capabilities of emergency medical equipment, making it more effective during critical care ([Wolters Kluwer: Expert Solutions](#)).

Medical Device Regulation (MDR) Compliance in Poland.

Regulatory compliance is a significant focus for the Polish medical device market, especially in light of the European Union's Medical Device Regulation (MDR). This regulation ensures that medical devices meet strict safety and performance standards before they are marketed in Poland and the rest of the EU. Compliance with these regulations is crucial for maintaining market access and ensuring the safety of medical devices used within the healthcare system. The Polish market is characterized by strict adherence to these regulatory standards, which helps maintain high levels of safety and efficacy in medical products available to patients ([Chambers Practice Guides](#)).

Overall, the Polish medical device sector is poised for continued growth and innovation, driven by technological advancements and strong regulatory frameworks that ensure product safety and effectiveness.



Stakeholder Interactions and Strategic Responses to Challenges in Poland.

In Poland, the interactions among stakeholders in the medical devices sector are complex and heavily influenced by regulatory frameworks and the need for innovation. The sector involves a network of manufacturers, regulators, healthcare providers, and legal experts, all working within the constraints and opportunities presented by both national and EU regulations.

The Polish medical device market is guided by EU regulations, notably the Medical Device Regulation (MDR) and the In Vitro Diagnostic Medical Device Regulation (IVDR), which ensure that devices meet high safety and performance standards. National laws, such as the Polish Act on Medical Devices, provide further specific guidelines that align with these EU regulations. These frameworks are essential for maintaining a high standard of medical device safety and efficacy and facilitate the market entry of new and innovative medical technologies ([Chambers Practice Guides](#)).

However, the sector also faces challenges, particularly related to market strategies and digital marketing practices. Regulations around advertising and promotional activities are strictly monitored, with specific guidelines that prohibit certain types of direct-to-consumer advertising and restrict promotional practices to ensure fairness and transparency. The legal landscape necessitates careful navigation by companies to remain compliant while effectively marketing their products. This regulatory environment aims to balance innovation and patient safety, ensuring that new medical technologies are both effective and responsibly marketed ([Chambers Practice Guides](#)).

ROMANIA

Romania's health sector, characterized by the quadruple helix model, engages government, academia, industry, and civil society in collaborative efforts to drive healthcare innovation. Government policies and funding support research and infrastructure improvements, while academic institutions advance medical science, feeding into the commercial pipeline. The industrial sector turns these academic innovations into practical healthcare solutions, introduced to the market with oversight from civil society organizations that ensure alignment with community needs and ethical standards. This approach not only enhances healthcare delivery but also adapts to evolving health challenges.

Significant funding from the National Recovery and Resilience Plan aims to enhance Romania's healthcare system, including primary care and infrastructure, with a goal to increase public health spending by at least 0.5% of GDP annually, improving access to medications and potentially expanding medical coverage. ([Trade.gov](#)).

This strategic approach highlights Romania's efforts to strengthen its healthcare sector and address the ongoing challenges, positioning the country for continued growth in the medical devices market and healthcare services.

Medical Devices Sector in Romania.

Romania's medical devices sector is experiencing growth, with a significant presence of global corporations despite challenges such as harsh claw-back taxes and reimbursement issues. The country's strategic location in Europe, combined with affordable labour costs, has





attracted multinationals to establish manufacturing operations there. Although the generic drug manufacturers have faced challenges due to regulatory and financial pressures, this has led them to focus on using Romania as a manufacturing base for exporting to more profitable markets ([Trade.gov](#)). The market for medical devices in Romania was actively importing with a total of \$427 million in 2021, making it the 47th largest importer of medical instruments globally. Major import partners include Germany, the Netherlands, and China, with a smaller portion coming from the United States. The Romanian market is regulated by the National Agency for Medicines and Medical Devices of Romania (ANMDM), which ensures compliance with EU regulations for medical devices ([Trade.gov](#)).

Medical Emergency Equipment Sector in Romania.

Romania's medical emergency equipment sector is integral to its healthcare system, providing essential tools for urgent care, from basic first aid kits to sophisticated life-support systems. The sector benefits from a mix of local production and imports, adhering to European Union standards to ensure equipment safety and effectiveness. Collaborative efforts between government agencies, private companies, and international entities are essential for enhancing the sector's capabilities, ensuring that Romania's emergency medical services can efficiently handle critical situations across both urban and rural settings. This ongoing development supports Romania's commitment to improving rapid response capabilities throughout the healthcare system.

Medical Device Regulation (MDR) Compliance in Romania.

In Romania, compliance with the Medical Device Regulation (MDR) is crucial for ensuring that medical devices meet the stringent safety and performance standards set by the European Union. The Romanian National Agency for Medicines and Medical Devices (NAMMDR) oversees the implementation of these regulations, rigorously enforcing compliance to protect public health. The MDR framework requires manufacturers to undergo rigorous assessments, including clinical evaluations and quality management system reviews before their products can be marketed. This regulatory rigor helps maintain high standards in the healthcare market, ensuring that medical devices used in Romania are safe, effective, and of high quality. Manufacturers must continuously monitor their products post-market to ensure ongoing compliance and address any safety issues that arise. This comprehensive approach aligns Romania with EU standards and reinforces the country's commitment to healthcare safety and innovation.

Stakeholder Interactions and Strategic Responses to Challenges in Romania.

In Romania, the medical device sector is governed by stringent regulations aligned with the European Union's directives, particularly the Medical Device Regulation (MDR). This regulatory framework ensures that all devices meet high standards of safety and efficacy. The National Agency for Medicines and Medical Devices of Romania (NAMMDR) plays a crucial role in enforcing these regulations, which facilitates a structured and secure market environment for medical devices ([ANMDMR](#)) ([ANMDMR](#)).

Despite the robust regulatory framework, the sector faces challenges, notably in the integration and adaptation to these complex regulations. Stakeholders, including manufacturers and distributors, sometimes struggle with the cost and administrative burden of compliance. This has prompted strategic responses from both the government and industry





associations, aimed at streamlining processes and increasing regulatory transparency to ease the burden on stakeholders. Initiatives such as providing clear guidance on hybrid audits and common specifications for medical devices are examples of efforts to address these challenges and aid stakeholders in meeting regulatory requirements ([Public Health](#)) ([ANMDMR](#)).

Moreover, to enhance collaboration and compliance among stakeholders, Romania has implemented support mechanisms that include workshops, detailed guidance documents, and direct consultations. These measures are designed to foster a better understanding of the MDR and to support stakeholders through the transition phases of regulatory implementation. Such strategic initiatives are vital for maintaining the balance between fostering innovation within the sector and ensuring that the medical devices available in the market are safe and effective for users ([Public Health](#)) ([ANMDMR](#)).

SLOVAKIA

Slovakia's health sector showcases the quadruple helix model, with strong collaborations between government, academia, industry, and civil society driving innovations in healthcare. The government sets the stage with supportive policies and dedicated funding, facilitating a conducive environment for healthcare advancements. Academic institutions play a pivotal role, spearheading research and development that push the boundaries of medical technology and healthcare solutions.

The industrial component in Slovakia transforms these academic insights into tangible products, ensuring that innovative medical technologies reach the market efficiently. Meanwhile, civil society organizations ensure these innovations align with patient needs and societal values, advocating for healthcare solutions that are both accessible and sustainable. This integrated approach not only enhances the efficiency of Slovakia's healthcare services but also nurtures continuous improvement and adaptation to meet future health challenges.

Medical Devices Sector in Slovakia.

The medical device sector in Slovakia is currently navigating through a transformative period marked by technological innovation and regulatory adaptations. The industry is seeing increased integration of digital technologies and software solutions, which are enhancing the functionalities of medical devices and expanding their capabilities in healthcare settings. Companies within the sector are focusing on developing and implementing advanced technologies such as AI and machine learning, which are playing crucial roles in diagnostics and patient management. These advancements are not only improving the efficiency of medical devices but also their ability to deliver personalized patient care ([Fieldfisher](#)) ([McKinsey & Company](#)).

Moreover, Slovakia's medical device market is experiencing growth driven by the global trend towards more minimally invasive devices which reduce patient recovery times and medical costs. This shift is reflective of the broader industry's movement towards devices that are both smarter and smaller, making medical procedures less burdensome for patients and healthcare systems alike. The Slovak medical device sector, in alignment with global trends, is likely to continue its growth trajectory, propelled by ongoing innovations and an increasing demand for high-tech medical solutions ([Fieldfisher](#)) ([MedEng Jobs](#)).





Medical Emergency Equipment Sector in Slovakia.

Slovakia's sector for medical emergency equipment is crucial for its emergency medical services, focusing on high standards of safety and innovation. The sector is supported by advancements in medical technology that enhance the effectiveness and reliability of emergency responses. Slovak companies are at the forefront, developing emergency medical equipment that incorporates smart technologies to improve care delivery in critical situations. These technologies not only enhance the functionality of emergency equipment but also ensure quicker and more effective responses, which can be vital during medical emergencies.

The regulatory framework in Slovakia ensures that all medical emergency equipment adheres to stringent safety and performance standards. This compliance is vital for maintaining the trust and safety of healthcare professionals and patients alike. Innovations in the sector continue to focus on enhancing the capabilities of emergency equipment through integrated technologies, ensuring that the equipment is not only effective but also user-friendly and highly responsive in emergency scenarios.

Medical Device Regulation (MDR) Compliance in Slovakia.

Compliance with the Medical Device Regulation (MDR) is integral to the operation of Slovakia's medical device industry. The MDR provides a stringent regulatory framework designed to ensure the safety and efficacy of medical devices across the EU, including Slovakia. Slovak medical device manufacturers must adhere to these regulations, which involve comprehensive clinical evaluations and extensive documentation to ensure ongoing compliance. This regulatory oversight is crucial for safeguarding public health and maintaining the high standards of medical devices available on the market ([Fieldfisher](#)).

The Slovak authorities, in enforcing these regulations, ensure that all medical devices meet the necessary safety standards before they reach the market. Continuous monitoring and compliance checks are part of the regulatory framework, aimed at preventing any non-compliant devices from being sold. This rigorous approach helps in maintaining the trust in Slovak medical devices and supports the industry's growth by ensuring that the products are not only effective but also safe for public use ([Fieldfisher](#)).

Stakeholder Interactions and Strategic Responses to Challenges in Slovakia.

In Slovakia, the medical devices sector benefits from a collaborative framework involving regulatory bodies, industry participants, and healthcare providers. This cooperative environment is essential in adapting to the evolving regulatory landscape, particularly with the implementation of the EU's Medical Device Regulation (MDR), which aims to enhance market surveillance and increase the overall safety and performance of medical devices across Europe.

However, challenges to effective collaboration among stakeholders persist. One significant hurdle is the alignment and synchronization of national regulations with EU directives, which can sometimes lag or be inconsistently applied. This misalignment can lead to uncertainties that complicate compliance for medical device companies, especially smaller firms that might lack the resources to navigate complex regulatory environments.

To address these challenges, strategic responses have been developed, including the enhancement of communication and cooperation channels between the national regulatory





authorities and industry representatives. This includes regular consultation sessions and workshops to ensure that all stakeholders have a clear understanding of regulatory changes and compliance requirements. Additionally, there is an increased focus on supporting smaller enterprises through targeted programs that provide guidance and assistance in meeting EU standards, thereby fostering a more inclusive and competitive industry landscape.

SLOVENIA

Slovenia's health sector effectively utilizes the quadruple helix model, integrating efforts from government, academia, industry, and civil society to foster innovation in healthcare. The government underpins this structure with robust policies and funding, creating a supportive environment for advancements in medical research and healthcare technologies. Academic institutions contribute by driving forward scientific research and innovation, crucial for developing new healthcare solutions.

Industry stakeholders play a vital role by bringing these innovations to market, ensuring that breakthroughs in healthcare are accessible to the public. Meanwhile, civil society organizations ensure that these innovations meet the real-world needs of patients, advocating for healthcare services that are both effective and equitable. This collaborative approach enhances Slovenia's healthcare system, promoting a sustainable and patient-centered healthcare model that is responsive to the evolving health challenges of the population.

Medical Devices Sector in Slovenia.

The medical device sector in Slovenia is integrating advanced technologies and focuses significantly on research and development, enhancing its growth within the European medical landscape. Like global trends, Slovenian MedTech companies are investing in digital health technologies and sophisticated medical devices such as diagnostic imaging equipment and orthopaedic devices. These efforts are underpinned by Slovenia's strong technological infrastructure and the collaboration between government, academia, and the healthcare industry, fostering an environment conducive to innovation and high-quality production ([Wolters Kluwer: Expert Solutions](#)) ([McKinsey & Company](#)).

Moreover, the industry is characterized by its adaptability to evolving market demands and technological advancements. This includes the shift towards in-home healthcare delivery and the use of artificial intelligence and machine learning to improve medical diagnostics and patient care. Slovenian MedTech firms are actively engaged in developing and marketing connected, patient-centric medical devices that enhance healthcare delivery and patient outcomes, ensuring the sector's growth and sustainability ([Wolters Kluwer: Expert Solutions](#)).

Medical Emergency Equipment Sector in Slovenia.

Slovenia's medical emergency equipment sector is critical for its healthcare system, providing essential products that are integral to emergency medical services. This sector covers a wide range of products, from high-tech devices used in ambulances and emergency rooms to simpler, yet vital, supplies found in first aid kits. Slovenian companies focus on manufacturing high-quality, reliable medical emergency equipment, adhering to both national and international safety standards to ensure efficacy in critical care situations.

The development of emergency medical devices in Slovenia is enhanced by ongoing research and technological innovations aimed at increasing the efficiency of medical responses during





emergencies. This includes the integration of smart technologies that improve the functionalities of emergency equipment, making them more effective and easier to use in urgent care scenarios. The robust regulatory framework in Slovenia ensures that all emergency medical equipment meets stringent safety standards, fostering trust and reliability in the products developed within the country.

Medical Device Regulation (MDR) Compliance in Slovenia.

Compliance with the Medical Device Regulation (MDR) is a cornerstone of Slovenia's medical device sector, ensuring that all medical devices meet the EU's stringent safety and performance requirements. The Slovenian regulatory body oversees the implementation of these regulations, conducting thorough assessments and monitoring to ensure that non-compliant products do not reach the market. This rigorous regulatory environment helps protect public health and maintains the high quality of medical devices available in Slovenia ([Wolters Kluwer: Expert Solutions](#)).

The MDR framework in Slovenia mandates extensive documentation and regular compliance checks, requiring manufacturers to conduct comprehensive clinical evaluations and maintain detailed records throughout the product's lifecycle. This ensures continuous oversight and safety monitoring of medical devices, from development to post-market. By adhering to these stringent regulations, Slovenian medical device companies not only comply with legal requirements but also enhance the reliability and safety of their products, fostering trust and ensuring their integration into the European market ([Wolters Kluwer: Expert Solutions](#)).

Stakeholder Interactions and Strategic Responses to Challenges in Slovenia.

In Slovenia, stakeholder interactions within the medical devices sector are robustly structured around the collaborative efforts between regulatory bodies, industry participants, and healthcare providers. The regulatory framework, guided by the EU's Medical Device Regulation (MDR), ensures that stakeholders maintain high standards of safety and efficacy in medical devices. This environment fosters a culture of compliance and innovation, with a significant focus on incorporating advanced technologies such as AI and machine learning into medical devices to enhance patient care and diagnostic accuracy.

The Slovenian Agency for Medicinal Products and Medical Devices (JAZMP) plays a central role in this ecosystem, emphasizing the protection of public health through rigorous regulation and supervision of medical devices. The agency's focus on maintaining high standards contributes to the development of the sector by ensuring that all medical devices introduced in the market are safe and effective. This approach helps in addressing challenges like the rapid integration of new technologies and navigating complex regulatory landscapes.

Moreover, Slovenia's medical device sector benefits from collaborative projects and EU-funded programs that support the integration of innovative technologies into healthcare systems. These collaborations are crucial for advancing the medical device industry in Slovenia, allowing for a dynamic response to the evolving needs of healthcare systems both domestically and across Europe. These efforts are underpinned by a commitment to continuous improvement and adaptation to new regulatory requirements and healthcare challenges.

The development of the innovation assignment in the context of I3HIES.





The development of the innovation assignment in the I3HIES project serves as a strategic blueprint for fostering collaboration and enhancing innovation investments within the community. To define this assignment comprehensively, it's necessary to address key questions: *WHY, WHO, WHERE, WHAT, WHEN, and WHICH.*

The **WHY** aspect underscores the necessity of making the healthcare system more efficient, accessible, sustainable, competitive, simplified, and of improved quality, while also fostering knowledge-sharing and collaboration, and promoting personal satisfaction and development.

The **WHO** dimension encompasses all relevant entities enthusiastic about innovation, with a focus on SMEs, startups, healthcare providers, policymakers, research institutions, and patients.

The **WHERE** dimension directs us to involve actors from the EU community and seek partnerships for international collaboration.

The **WHAT** aspect revolves around digital innovation in healthcare, services supporting decision-making and trust-building, matchmaking, and connecting people, as well as advocating for an innovation-oriented environment across three key topics. This is conducted transparently, aiming for value creation for customers and supporting transformation through innovations.

The **WHEN** indicates immediate action after thorough mapping and understanding the state-of-the-art.

Finally, the **WHICH** aspect identifies the main results, including validating 15 concepts, establishing 3 partnerships through submitted projects, and selecting the most promising mini-business cases within the I3HIES project.



BENCHMARK OF THE COMMUNITY ACTORS.

The benchmark analysis within our project serves as a foundational pillar for the creation of value and the facilitation of tailored servicing. Through a comprehensive framework, we aim to enable the benchmarking of innovation actors across our consortium members' countries, each uniquely contributing to the health focus areas of the project. By analysing the specificity of each project country within the consortium, we can discern valuable insights into the landscape of medical devices, emergency equipment, and MDR compliance.

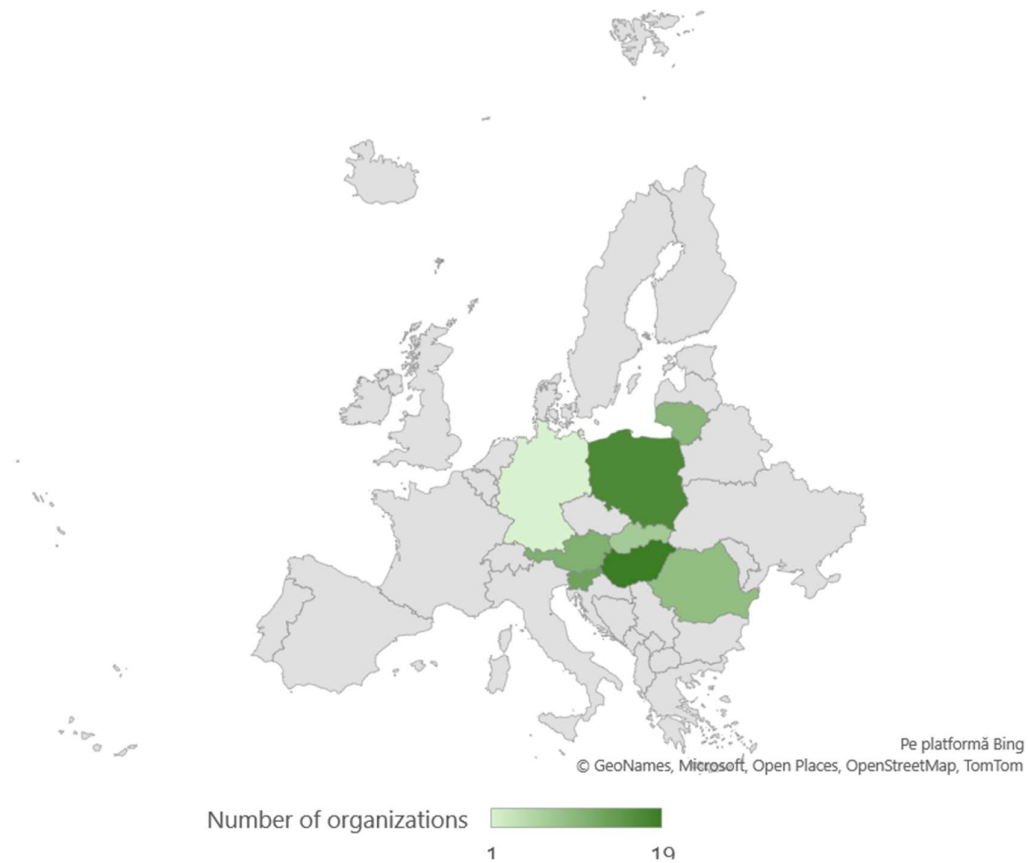


Fig.10 The geographical distribution of the survey respondents.

The methodology

The methodology for collecting the data followed a structured approach aimed at gathering comprehensive insights from the consortium partners, with a particular focus on the quadruple helix actors within each country. The process began with the creation of a questionnaire, meticulously crafted based on the definition of the Health Innovation Ecosystem (HIES) and the innovation assignment component of the project. This questionnaire was designed to capture relevant information pertaining to the ecosystem's actors, activities, and challenges, aligning closely with the project's objectives.



Once the questionnaire was developed, it was disseminated among the consortium partners, with a specific emphasis on reaching out to quadruple helix actors. The distribution strategy aimed to ensure a balanced representativeness of all ecosystem actors, including those from academic institutions, businesses, public authorities, and societal organizations. By engaging stakeholders across the quadruple helix, we sought to gather diverse perspectives and insights into the health innovation ecosystem within each country.

Following the dissemination phase, the collected data were analysed for each consortium country individually. By conducting country-specific analyses, we were able to gain a nuanced understanding of the unique characteristics and dynamics shaping health innovation in each context. This tailored approach enabled us to develop targeted strategies and interventions to support the growth and development of the health innovation ecosystem across the consortium countries.

Data results interpretation.

AUSTRIA

The analysis of Austria's innovation performance and collaboration within the health focus areas of the project reveals several key insights. With 11 respondents representing a diverse range of stakeholders, including large companies, public institutions, research and technology centres, SMEs, and startups/incubators/accelerators, Austria demonstrates a robust ecosystem conducive to innovation.

In terms of positioning within the value chain, respondents predominantly serve as technology providers, research and development providers, or healthcare providers, highlighting Austria's multifaceted approach to innovation in the health sector. A significant proportion of respondents (6 out of 11) focus on areas such as medical devices and Medical Device Regulation (MDR) compliance, underscoring Austria's commitment to advancing healthcare technologies and regulatory standards.

Furthermore, Austria's orientation towards Key Enabling Technologies (KET) such as advanced manufacturing, advanced materials, life science technologies, and artificial intelligence underscores its strategic alignment with cutting-edge innovations in the health sector. Austria's innovation landscape is characterized by a strong emphasis on product development, with 8 out of 11 respondents actively developing their own products. These products span a wide range of Technology Readiness Levels (TRL), indicating the breadth and depth of innovation activities in the country, from telehealth platforms to data management and communication platforms.

Collaboration is a key aspect of Austria's innovation strategy, with 9 out of 11 respondents having partners regionally or internationally, with Germany being the most preferable country for collaboration. This highlights Austria's commitment to fostering international partnerships to drive innovation and enhance the efficiency, accessibility, sustainability, competitiveness, simplicity, and quality of healthcare systems. In terms of funding, Austria's innovation ecosystem benefits from access to regional/national and EU funds, with 7 out of 11 respondents leveraging these resources to support their projects and initiatives.





Austria's medium and long-term strategies for partnership development within the quadruple helix framework prioritize sustaining long-term innovation and market adaptability, with a focus on societal impact, particularly in the field of hearing solutions. Despite Austria's strengths in innovation, there are also areas for improvement, including addressing organizational weaknesses such as inertia, lack of funding, and retention issues. However, Austria's commitment to supporting upskilling and reskilling processes within organizations through activities such as workshops, trainings, individual mentoring, and career development paths demonstrates a proactive approach to addressing these challenges.

Overall, Austria's innovation ecosystem exhibits resilience, diversity, and scientific excellence, positioning the country as a key player in driving innovation in the health sector.

HUNGARY

Hungary analysis on innovation performance within the quadruple helix ecosystem reveals a diverse and dynamic landscape with 19 respondents representing various stakeholders. These include public institutions, research and technology centres, SMEs, universities, NGOs, state-owned agencies, and civil advocacy groups, highlighting Hungary's robust and inclusive innovation ecosystem.

In terms of positioning within the value chain, respondents play various roles such as policy makers, technology providers, research and development providers, standards and professional adviser organizations, education and research institutions, technology consultants, and innovation agencies. This diverse representation underscores Hungary's collaborative approach to innovation across multiple sectors.

A significant proportion of respondents (10 out of 19) focus on critical health areas such as medical devices, emergency equipment, and Medical Device Regulation (MDR) compliance, reflecting Hungary's commitment to advancing healthcare technologies and regulatory standards. Hungary's orientation towards Key Enabling Technologies (KET) spans a wide spectrum, including advanced manufacturing, advanced materials, life science technologies, micro/nano-electronics and photonics, artificial intelligence, and security and connectivity. This broad orientation highlights Hungary's strategic alignment with cutting-edge innovations across various domains.

Product development is a key focus area for Hungary, with 11 out of 19 respondents actively developing their own products across different Technology Readiness Levels (TRL), ranging from TRL 5 to TRL 9. These products address diverse needs ranging from visual infant monitoring to hospital information systems, underscoring Hungary's innovative prowess in healthcare solutions.

Collaboration is a cornerstone of Hungary's innovation strategy, with 16 out of 19 respondents having partners regionally or internationally. These partnerships span prominent regions including the EU, Asia, the USA, and Canada, reflecting Hungary's global outlook and commitment to fostering international collaborations.

Access to funding is essential for innovation, and Hungary benefits from access to regional/national and EU funds, with 12 out of 19 respondents leveraging these resources to support their projects and initiatives.





In terms of project ideas, 12 out of 19 respondents have initiatives focused on various aspects of healthcare innovation, including the development of interoperable patient lifecycle identifiers and patient-specific implants, highlighting Hungary's focus on addressing pressing healthcare challenges.

Hungary's medium and long-term strategies for partnership development within the quadruple helix framework prioritize R&D cooperation, knowledge transfer, industry-education collaboration, international networking, and excellence in research and education. The protection of intellectual property (IP) is crucial in collaborative initiatives, and Hungary employs various strategies including patenting, foundation protection, and non-disclosure agreements (NDAs) to safeguard IP rights.

To support upskilling and reskilling, Hungary focuses on vocational training, continuous education, and participation in cooperative doctoral training programs, demonstrating a commitment to nurturing talent and expertise within its workforce.

While Hungary boasts strengths such as high organizational levels, creativity, and international networking, it also faces challenges such as funding constraints, project management issues, and scarcity of resources. However, Hungary's proactive approach to addressing these weaknesses underscores its resilience and determination to drive innovation forward.

LITHUANIA

Lithuania's innovation ecosystem highlights a dynamic landscape characterized by collaboration, expertise, and a strong focus on healthcare technologies. With 10 respondents representing various stakeholders including research and development centers, SMEs, universities, clusters, NGOs, and digital innovation hubs, Lithuania demonstrates a diverse and inclusive approach to innovation.

Positioned across the value chain as research and development providers, technology providers, and beneficiary stakeholders such as patient associations, Lithuania's stakeholders play critical roles in driving innovation forward. A significant proportion of respondents (3 out of 10) focus on medical devices and Medical Device Regulation (MDR) compliance, aligning closely with the objectives of the I3HIES Project. Additionally, expertise in key enabling technologies such as life science technologies, artificial intelligence, and advanced manufacturing underscores Lithuania's commitment to advancing cutting-edge healthcare solutions.

Several respondents (3 out of 10) have developed their own projects, ranging from TRL 5 to TRL 8/9, showcasing Lithuania's capabilities in developing innovative healthcare solutions. Moreover, partnerships are a cornerstone of Lithuania's innovation strategy, with 8 out of 10 respondents having partners regionally or internationally. These partnerships span a wide range of organizations, including industry partners, universities, governmental institutions, and NGOs, demonstrating Lithuania's extensive network and collaboration efforts.

Interest in extending networks to the EU, Asia, and the USA reflects Lithuania's global outlook and ambition to foster international collaborations. Access to regional/national/EU funds is also a priority for Lithuania, with 7 out of 10 respondents having accessed funds and all intending to access new opportunities. Perspectives on medium and long-term strategies for





partnership development emphasize collaborative efforts between academia, industry, government, and society. Initiatives such as data sharing, spin-off support, and collaborations with clinics underscore Lithuania's commitment to driving meaningful progress in healthcare innovation.

Internal protocols for IP protection demonstrate Lithuania's proactive approach to safeguarding intellectual property rights. Upskilling and reskilling initiatives focus on technological training, mentoring, and consultancy, with opportunities for project rotations and long-term trainings.

Organizational strengths for innovation include collaboration, flexibility, and expertise, while weaknesses include a lack of resources, administrative support, and specialized personnel. Overall, Lithuania's innovation ecosystem demonstrates resilience, collaboration, and a strong commitment to driving innovation in healthcare.

POLAND

With 17 respondents representing a diverse range of stakeholders including large companies, SMEs, startups, universities, NGOs, and projects, Poland demonstrates a multifaceted approach to innovation.

Positioned across the value chain as technology providers, research and development centres, training and consulting companies, and medical equipment suppliers, Poland's stakeholders play integral roles in driving innovation forward. A significant proportion of respondents (4 out of 17) focus on medical devices and Medical Device Regulation (MDR) compliance, aligning closely with the objectives of the I3HIES Project. Additionally, expertise in key enabling technologies such as life science technologies, artificial intelligence, and advanced materials underscores Poland's commitment to advancing cutting-edge healthcare solutions. Several respondents (11 out of 17) have developed their own products, ranging from medical platforms to liquid biopsy analysis tools, with Technology Readiness Levels (TRL) between 7 and 9, showcasing Poland's capabilities in developing innovative healthcare solutions.

Partnerships are a key driver of innovation in Poland, with 11 out of 17 respondents having partners regionally or internationally. There is a particular interest in developing new partnerships, especially with countries located in the EU and the USA, reflecting Poland's global outlook and ambition to foster international collaborations.

While only a subset of respondents has accessed regional/national or EU funds, there is a considerable interest in accessing new funding opportunities, particularly focused on supporting R&D activities. Strategic investment and resource allocation opportunities focus on enhancing technological infrastructure, expanding collaborative networks, and advancing digital health and AI capabilities. This reflects Poland's strategic priorities in driving innovation and collaboration within its ecosystem.

The average score of the innovation potential of organizations, based on the scores they provided, is 7.76 out of 10, indicating a strong overall perception of innovation capabilities within the ecosystem.





Top organizational strengths for innovation include people and knowledge, technology, and cooperation, while weaknesses include funding, technology, lack of organizational culture, and limited market appetite. Support and opportunities for reskilling and upskilling personnel include training opportunities, mentoring, forum discussions, career paths, and flexibility, demonstrating Poland's commitment to nurturing talent and expertise within its workforce.

ROMANIA

Positioned across the value chain as research and development providers, technology providers, and ecosystem support and enablers, Romania's stakeholders play pivotal roles in driving innovation forward.

A significant proportion of respondents (4 out of 9) focus on medical devices, emergency equipment, and Medical Device Regulation (MDR) compliance, aligning closely with the objectives of the I3HIES Project. Additionally, expertise in key enabling technologies such as artificial intelligence, security and connectivity, and life science technologies underscores Romania's commitment to advancing cutting-edge healthcare solutions. Several respondents (4 out of 9) have developed their own products, ranging from medical diagnostic devices to educational products for medical training, showcasing Romania's capabilities in developing innovative healthcare solutions.

Partnerships are a cornerstone of innovation in Romania, with 8 out of 9 respondents having strategic partners within the quadruple helix. There is a clear need for expanding the network globally, with interests in regions including the EU, Asia, Africa, the USA, Latin America, Canada, and Australia. Access to regional, national, and EU funds is widespread among respondents, reflecting Romania's proactive approach to securing funding for innovation initiatives. Moreover, opportunities for strategic investment or resource allocation focus on interdisciplinary collaboration, talent development, digitalization grants, and EU funding for regional ecosystem development.

Intellectual property (IP) protection varies among respondents, with some organizations having strict regulations while others lack formal IP policies, particularly in the university and R&D sectors.

The average score of the innovation potential of organizations, based on their self-assessment, is 8.66 out of 10, indicating a high level of confidence in Romania's innovation capabilities. Top organizational strengths for innovation include openness to collaboration, strategic positioning as a nexus for public-private partnerships, and comprehensive life science research. However, challenges such as limited resources, bureaucratic inertia, and lack of experience in the health ecosystem pose significant barriers to innovation.

Opportunities for employee upskilling and reskilling include mentorship programs, internal and external training, defined career paths, and involvement in diverse projects, reflecting Romania's commitment to nurturing talent and fostering a culture of innovation within its workforce.

SLOVAKIA

The innovation landscape in Slovakia, within the framework of the quadruple helix, reflects a dynamic and evolving ecosystem driven by collaboration, expertise, and a focus on emerging





technologies. With 7 organizations responding to the questionnaire, including research and development centres, SMEs, local authorities, startups, and limited liability companies, Slovakia demonstrates a diverse and inclusive approach to innovation. Positioned across the value chain as technological providers, research and development bodies, healthcare providers, and regional development organizations, Slovakia's stakeholders play integral roles in advancing innovation across various sectors. While only one organization shares a common focus with the I3HIES project on medical devices, the top KET technologies applicable for 4 of them include AI and life science technologies, highlighting Slovakia's strengths in cutting-edge technology adoption.

Two organizations have developed their own products, ranging from AI-based forecasting and content generation to mobile applications, demonstrating Slovakia's capabilities in driving innovation and product development. Strategic partnerships have been developed with organizations from Western Europe, the USA, and North Macedonia, indicating Slovakia's global outlook and ambition to expand its networks. There is a clear interest among all organizations to extend their networks further, particularly in regions within the EU and the USA.

While only one organization has accessed regional/national/EU funds, there is a collective intention among all organizations to access funding in the future, reflecting Slovakia's proactive approach to securing resources for innovation initiatives. Significant opportunities for strategic investment or resource allocation include the development and integration of artificial intelligence technologies, securing financial resources, and leveraging Slovakia's education system and expertise in AI and machine learning.

Organizational strengths for innovation include education, deep expertise in AI and machine learning technologies, and a motivation to approach tasks innovatively. However, challenges such as data acquisition, partnership development, and resource constraints pose barriers to innovation.

Support for upskilling and reskilling of employees includes opportunities to share knowledge, participate in education sessions, and access support programs, reflecting Slovakia's commitment to nurturing talent and fostering a culture of continuous learning within its workforce.

SLOVENIA

The innovation ecosystem in Slovenia, within the framework of the quadruple helix, showcases a vibrant landscape characterized by collaboration, technological prowess, and a commitment to addressing societal needs. With 13 organizations responding to the questionnaire, including large companies, research and development centres, SMEs, startups, universities, clusters, and patient interest representative bodies, Slovenia demonstrates a diverse and inclusive approach to innovation.

Positioned across the value chain as research and development providers, technology providers, business support organizations, and patient advocates, stakeholders in Slovenia play integral roles in advancing innovation across various sectors. A significant portion of organizations, seven in total, express interest in the focus areas targeted by the I3HIES project, particularly medical devices and Medical Device Regulation (MDR) compliance.





Additionally, the top KET technologies applicable include life science technologies, advanced materials, and AI, highlighting Slovenia's strengths in cutting-edge technology adoption.

Eight organizations have developed their own products, ranging from smart home solutions for elderly care to AI-driven dental practice management software and innovative diagnostic and therapeutic technologies. These products reflect Slovenia's innovative spirit and focus on addressing healthcare challenges. Strategic partnerships have been developed with organizations from Germany, the UK, Spain, and other regions, with an interest in expanding networks further into the EU, USA, Canada, Australia, and beyond.

While nine organizations have accessed national/regional or EU funds, all organizations envision accessing new ones in the future to further fuel their innovation initiatives. Opportunities for strategic investment and resource allocation include the development and penetration of health wearable devices, collaboration with venture capital funds, and upskilling the workforce in digital health technology. Strengthening collaboration with public healthcare organizations and fostering collaborative research and development initiatives are also identified as significant opportunities for advancing innovation.

Organizational strengths for innovation include expertise in data analytics, digital transformation skills, collaboration between academia, industry, and healthcare organizations, and a focus on knowledge transfer. However, challenges such as lack of entrepreneurial knowledge, research funding, and technical teams pose barriers to innovation.

To address these challenges, organizations prioritize and support the upskilling and reskilling of their personnel through continuous education, training opportunities, and collaboration with external experts. This focus on talent development underscores Slovenia's commitment to staying at the forefront of innovation and driving positive change in the healthcare sector and beyond.

SERVICE SELLING POINT.

Through the ecosystem mapping process, a range of needs was discerned among the community actors, spanning from technical expertise to network expansion, among others. In response, the I3HIES project has formulated a comprehensive services portfolio encompassing offerings from consortium partners. These services are designed to facilitate the development and expansion of the healthcare ecosystem, with a specific focus on the project's targeted areas. Accessible to all interested parties within the community, these services aim to foster growth and innovation within the healthcare sector.





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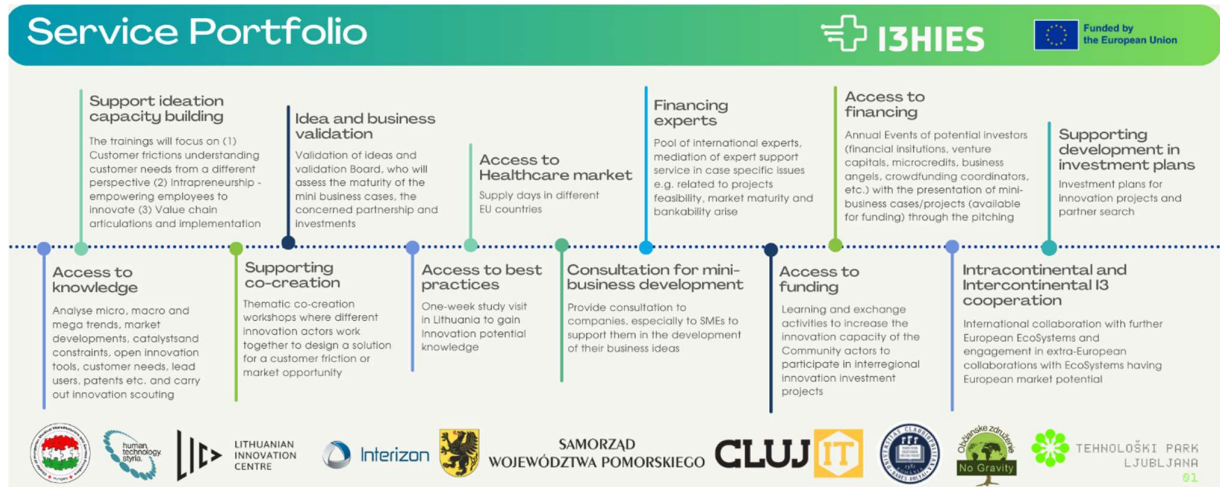


Fig3. Service portfolio of the I3HIES consortium members

CONCLUSIONS.

The analysis of the innovation ecosystems within the quadruple helix communities of the I3HIES project consortium members reveals a rich tapestry of collaboration, technological innovation, and commitment to addressing healthcare challenges. Across Austria, Hungary, Lithuania, Poland, Romania, Slovakia, Slovenia, and other regions, organizations spanning research and development centres, SMEs, universities, startups, and public institutions converge to drive innovation forward.

The project's focus on medical devices, emergency equipment, and Medical Device Regulation (MDR) compliance aligns closely with the expertise and interests of many consortium members. From developing AI-driven diagnostic tools to innovative medical platforms and wearable devices, organizations demonstrate a keen understanding of the evolving needs of the healthcare sector. Strategic partnerships, both within and beyond regional borders, underscore the collaborative spirit of the consortium, with a shared vision of leveraging collective expertise to drive meaningful progress. Access to national, regional, and EU funds further empowers organizations to accelerate their innovation initiatives and scale their impact.

While strengths such as deep expertise in key enabling technologies, collaboration between academia, industry, and healthcare organizations, and a focus on talent development propel innovation forward, challenges such as funding constraints and lack of entrepreneurial knowledge require concerted efforts to overcome. In addressing these challenges, organizations prioritize upskilling and reskilling initiatives, ensuring their workforce remains agile and equipped to navigate the evolving technological landscape. By fostering a culture of continuous learning and collaboration, the consortium members are poised to unlock new opportunities, drive innovation, and create lasting impact in the healthcare sector and beyond.

As the I3HIES project progresses, the diverse expertise and collaborative spirit within the quadruple helix communities will continue to fuel groundbreaking innovation, paving the way for a more efficient, accessible, and sustainable healthcare ecosystem. Through shared





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resources, knowledge exchange, and strategic partnerships, the consortium members are poised to make significant strides in advancing healthcare innovation and improving patient outcomes.

