Medtronic

From Trials to Transformation: Medtronic's Increased Clinical footprint in Denmark

Denmark stands at the forefront of medical technology innovation in Europe, supported by a robust research infrastructure, a digitally advanced healthcare system, and a strong tradition of public-private collaboration. The Danish MedTech sector is known for its agility, high regulatory standards, and emphasis on digital health and patient-centered care. Medical devices can be introduced to the market based on CE marking, which certifies compliance with EU regulations such as the Medical Devices Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR). With over 1,000 MedTech companies from global leaders to innovative startups—Denmark offers a dynamic environment for clinical research and product development[1].

The country's centralized health data registries and close integration between hospitals, universities, and industry create ideal conditions for real-world evidence utilization and clinical trials. Government-backed initiatives further accelerate research in areas such as robotics, diagnostics, and chronic disease management.

This environment makes Denmark a strategic destination for multinational MedTech companies like Medtronic. Over the past decade, Medtronic has expanded its footprint in the country through several clinical trials, investigator-initiated studies, and collaborations with leading hospitals and academic institutions. These efforts not only contribute to scientific advancement and improved patient outcomes but also support Denmark's broader ambitions as a global hub for life science innovation.

This document exemplifies Medtronic's clinical and medical technology initiatives in Denmark, highlighting how the company's involvement supports the collaborative, data-driven approach and the global strengths of Denmark's clinical ecosystem.

Medtronic's Clinical Research Activities in Denmark

Medtronic is one of the world's largest medical technology companies with operations in over 150 countries and a workforce of more than 90,000 employees. Founded in 1949 and headquartered in Dublin, Ireland, Medtronic has a long-standing legacy of pioneering medical breakthroughs, from the first battery-powered pacemaker to today's AI-driven surgical systems and remote monitoring technologies. Throughout its history, the company has heavily invested in research and development, with today's strong focus on evidence-based innovation, AI capabilities and global collaboration.

Medtronic at a Glance

Founded: 1949
Global Headquarters: Dublin, Ireland
Employees: 90,000+ worldwide
Presence: Operations in over 150 countries
Annual R&D Investment: Approx. $2.7 billion

Main Business Segments:
- Cardiovascular
- Diabetes
- Neuroscience
- Medical Surgical

Medtronic's presence in Denmark dates back to 1968[2]. In the past decade alone, Medtronic has built a significant clinical research footprint in Denmark, conducting over 60 clinical trials and investigator-initiated studies across a diverse range of the company's therapeutic portfolio, including cardiology, neurology, diabetes, and surgical innovations.

Since 2015, Danish hospitals have participated in 40 global Medtronic-sponsored clinical studies, consistently ranking among the top-performing countries for patient recruitment, data quality, and protocol adherence. Many of these studies have introduced cutting-edge technologies to Danish clinicians, significantly impacted local patient care and even influenced European treatment guidelines.

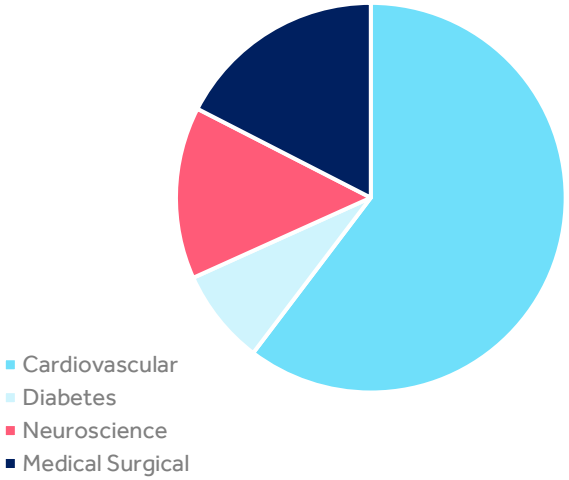
Example: *The Medtronic WRAP-IT trial[3], which included physicians at Rigshospitalet in Copenhagen, demonstrated how antibacterial mesh envelopes could reduce infection rates in patients receiving cardiac implantable electronic devices. Denmark was a high patient enroller, contributing to outcomes that led to European guideline updates recommending these meshes for device implants. A few years later, a study[4] co-authored by clinical stakeholders from several Danish university hospitals and Medtronic health economists showed cost-effectiveness when using the envelope for high risk cardiac patients treated within the national healthcare system. This demonstrated how adoption of an innovative technology can be done with focus on patient selection and data analytics to ensure a cost-effective use of healthcare resources.*

In addition to company-sponsored trials, Medtronic has supported more than 20 investigator-initiated studies, reflecting a strong commitment to academic collaboration and scientific independence. These studies have involved a significant number of Danish investigators and institutions across the country, with a total approved investment of more than 9.5 million USD in direct funding and product support. Collectively, these studies have contributed to international scientific dialogue through a range of joint publications and given investigators opportunities to present their findings to a global audience on conference podiums. During the last 10 years, more than 50 peer-reviewed publications in internationally recognized journals have been produced jointly by Medtronic and Danish investigators as an outcome of these clinical studies. In recent years, the number of Medtronic's clinical initiatives in Denmark has remained steady, reflecting the country's continued strength as a research partner and its stable infrastructure for trial execution.

Example: *The LOOP study[5] was a large-scale, multi-center clinical trial in Denmark investigating whether continuous heart rhythm monitoring using implantable loop recorders can help prevent strokes by detecting silent atrial fibrillation. With 6,000 participants and support from four major hospitals and multiple public and private funders— from the Innovation Fund Denmark to the Research Foundation for the Capital Region of Denmark and including Medtronic—the study exemplifies Denmark's collaborative research*

environment. While the study led to a threefold increase in atrial fibrillation detection and anticoagulation use, it found no significant reduction in stroke risk in its general population, but it did show significant reductions in patient subgroups with multiple risk factors. These findings highlight the complexity of stroke prevention and offer valuable insights for future research and clinical decision-making.

During the past decade, Medtronic has supported over 60 clinical studies in Denmark.
Company holds the largest clinical presence in cardiovascular care and is actively engaged in studies across its therapeutic portfolio.



Besides being directly involved in research activities, several Danish physicians also play an active and valued role in Medtronic's global network of clinical advisors and expert forums. Their participation in advisory boards, steering committees, and innovation panels ensures that local clinical insights and patient needs are reflected in the development of new technologies and research strategies across therapy areas. These collaborations not only help shape Medtronic's clinical agenda but also foster knowledge exchange and strengthen Denmark's voice in international MedTech innovation.

From National Strength to European Synergy: Advancing Clinical Trials in Denmark and the EU

Today, Denmark has a highly integrated clinical and life science ecosystem. The Danish Medicines Agency[6] is pivotal in coordinating clinical trial start-up activities. Denmark's centralized ethics review, streamlined regulatory processes, and coordinated healthcare system enable faster clinical trial start-up compared to many EU countries, emphasizing Denmark as an ideal environment for efficient, high-quality clinical research. In addition, Trial Nation[7] offers a single national entry point for life science companies, patient organizations and clinical researchers wishing to sponsor, participate in and conduct clinical trials in Denmark.

Operating under the EU's General Data Protection Regulation (GDPR), Denmark upholds some of the highest standards for data privacy in clinical research. Like all EU member states, Denmark must comply with rigorous requirements for data handling, consent, and documentation. Medtronic has observed that in some cases, GDPR-related processes have contributed to extended initiation timelines, but other operational factors—such as delays due to site staffing constraints, rising institutional costs, and the need for specialized contract reviews —tend to have a greater impact on

study start-up. However, these challenges also present opportunities for improvement. One promising approach to enhance efficiency and reduce contract cycle times is the broader adoption of Master Clinical Trial Agreements across Denmark. This would help standardize processes, foster consistency, and accelerate study start-up—ultimately benefiting both research partners and patients.

While Denmark offers a streamlined and supportive environment for clinical trials, broader harmonization across the EU remains essential. National differences in GDPR interpretation—such as the legal basis for data processing and the role of hospitals as data controllers or processors—can create complexity for sponsors operating across multiple countries. These inconsistencies, along with varying national requirements for trial engagement, may discourage companies from including certain EU countries in global studies. A more unified regulatory approach would strengthen Europe's competitiveness and make it easier for sponsors to plan and execute multi-country trials efficiently.

Leveraging Registries for High-Impact Research

The Nordic countries are globally recognized for their exceptional health registries, and Denmark stands out with some of the most comprehensive and systematically maintained databases in the world. These registries—spanning patient diagnoses, treatments, prescriptions, and long-term outcomes—form a critical foundation for high-quality clinical research. Using personal identification numbers, populations can be followed longitudinally, with both retrospective and prospective data. Additionally, Danish health registries may be connected with other national datasets, such as employment, social benefits, or educational status, enabling comprehensive health economic analysis.

National databases enable researchers and healthcare partners to track patient outcomes over extended periods and evaluate the real-world effectiveness and safety of medical technologies. In addition, databases generate robust evidence to support innovation, regulatory requirements, and health policies. Importantly, these registries are independently managed by national health authorities and academic institutions, ensuring objectivity and scientific integrity in the data they provide. The ability to use clinical trial data beyond the original study purpose—such as for health economics, long-term outcomes research, or innovation development—is increasingly important.

Like many other companies in the industry, Medtronic has enhanced its scientific scope and rigor by integrating national registry data with trial data, allowing the incorporation of a more diverse patient population. One local registry extensively used for research purposes is the Danish Pacemaker and ICD Register (DPIR). Established in 1982, it is one of the oldest and most comprehensive device registries in the world. By tracking all cardiac device implants nationwide, DPIR has provided comprehensive real-world data to supplement some of Medtronic's key clinical trials, ensuring trial conclusions reflect real-world conditions. As the demand for real-world evidence continues to grow globally, Medtronic is increasingly leveraging registry-based data to complement traditional clinical trials and support more personalized, data-driven healthcare decisions and technologies.

Example: *Medtronic has provided a general research grant to clinical investigators at a leading Danish university hospital specializing in ablation therapy. The grant supports the integration and analysis of data from the Danish Ablation Registry, combined with national economic and societal databases. This approach enables comprehensive insights into both clinical outcomes and healthcare resource utilization. To date, four conference abstracts have been presented, and two peer-reviewed publications have been produced from this study. Beyond this research grant, Medtronic and clinicians from university hospital co-authored a cost-effectiveness analysis[8] of first-line cryoablation using clinical trial data combined with Danish registry data.*

Outcome-Centered Procurement: The Way Forward

Value-based procurement enables healthcare systems to maximize the return on investment in medical technologies by rewarding solutions that measurably improve patient outcomes and care pathways. Rather than focusing solely on upfront costs, this approach considers the full patient journey —including procedural efficiency, recovery time, and long-term health impact.

As part of Denmark's commitment to healthcare innovation, the Danish Life Science Strategy[9] (first published in 2021 and updated in 2024) allocates funding for the development of a national value-based procurement model. Medtronic contributed clinical and economic evidence to a prototype developed by a national consortium, comparing surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR). In this case, the prototype demonstrated that while TAVR carries a higher purchase cost, it delivers greater overall value when accounting for total procedural costs, hospital stay duration, adverse events, and other downstream factors – an example of how data-driven procurement can support both clinical and economic goals.

Innovation Partnerships: A Win-Win

In recent years, Medtronic's clinical presence in Denmark is strengthened by a network of public-private partnerships that foster innovation, accelerate research, and enhance patient care. Collaborations with leading Danish hospitals, universities, and national research institutions have enabled the co-development of technology pilots and data-driven healthcare solutions. These partnerships are often supported by national innovation programs, creating shared value across sectors. For example, Medtronic has participated in co-funded initiatives focused on the application of advanced data modeling to elucidate patient outcomes, enhance capacity and resource allocation, and implement multi-objective optimization programs — areas aligned with Denmark's strategic priorities in healthcare innovation.

Example: *Rigshospitalet collaborated with Medtronic Integrated Health Solutions to transform operations in its Heart Center's cath labs. Over five years, this partnership achieved over 2 million euros in savings through optimized staffing, reduced waste, and streamlined processes. It introduced innovations like the CardioLounge for same-day patient discharge and implemented data-driven systems for better care delivery. The collaboration now focuses on leveraging digital innovation and advanced analytics to enhance patient outcomes.*

These partnerships demonstrate how collaborative innovation fosters operational efficiency, improves patient care, and achieves substantial cost savings, thereby establishing a standard for transformative healthcare solutions. Moreover, such collaborations benefit not only the industry but also contribute to strengthening the national ecosystem by enhancing long-term capacity within the Danish healthcare system through knowledge transfer, professional training, and infrastructure development.

"In Denmark, we see how health data, public-private partnerships, and leading clinical research accelerate progress from trials to transformation in the healthcare system — ensuring better outcomes for patients. Together with clinicians and policymakers, we co-create the future of healthcare, today and for generations to come."

— Jeppe Højholt, Regional Senior Director, Medtronic

Invest in Denmark has collaborated with Medtronic for many years, facilitating public-private partnerships, clinical studies and R&D activities.

« Medtronic's strong commitment to doing clinical research and developing public-private partnerships with the Danish healthcare system is a testament to Denmark's life science sector, and to the Danish government's continuous commitment to making Denmark one of the leading healthcare nations in the world. »

— Vanessa Vega Saenz, Director, Invest in Denmark

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References

1. The Ministry of Industry, Business and Financial Affairs, 2023: Economic Footprint of the Life Science Industry in Denmark
2. Medtronic Denmark website
3. Tarakji KG et al. NEJM (2019); 380:1895-1905
4. Frausing MHJP et al. EP Europace (2023); 25(6):euad159
5. Svendsen JH et al. Lancet (2021); 398(10310):P1507-1516
6. Danish Medicines Agency
7. Trial Nation
8. Hein R et al. J Cardiovasc Electrophysiol (2024); 35(7): 1429-1439
9. The Ministry of Industry, Business and Financial Affairs, 2024. Strategy for Life Science Towards 2030