The evolution of Ireland's medical device cluster and its future direction

sustainability

MDPI

Article

The Evolution of Ireland's Medical Device Cluster and Its Future Direction

David McKernan and Olivia McDermott *

College of Science and Engineering, National University of Ireland, H91 TK33 Galway, Ireland
* Correspondence: olivia.mcdermott@nuigalway.ie

Abstract: Ireland has developed a highly successful medical device cluster. Most of the industry started from USA multinationals that moved to Ireland in the 1990s. An ecosystem has now developed with strong linkages between universities, start-ups, multinationals, venture capital, suppliers, and supporting industries. This paper explores the Medical Device cluster in Ireland. It characterizes the industry through the companies, innovation, products, markets, and regulatory framework. It concludes that the Irish MedTech industry is successful but has been highly dependent on USA multinationals that established themselves here in the 1990s. Based on this, we summarize the opportunities and threats the industry now faces. This is one of the first studies that categorized the MedTech industry in Ireland. This study will provide valuable insights to aid government policy to sustain the medical device cluster in Ireland as well as provide insights into other countries.

Keywords: cluster; MedTech industry; Ireland; PEST analysis

Citation: McKernan, D.; McDermott, O. The Evolution of Ireland's Medical Device Cluster and Its Future Direction. *Sustainability* **2022**, *14*, 10166. https://doi.org/10.3390/su141610166

Academic Editor: Mihajlo (Michael) Jakovljevic

Received: 7 July 2022
Accepted: 12 August 2022
Published: 16 August 2022

1. Introduction

The medical device industry has become an important part of the Irish economy and is recognized as a global MedTech cluster [1]. An industrial cluster is defined as a geographic concentration of competitive firms or establishments in the same industry that either have close buy–sell relationships with other industries in the region, use common technologies, or share a specialized labor pool that provides firms with a competitive advantage over the same industry in other places [1].

Ireland MedTech cluster is seen as a significant success triggered initially by foreign direct investment from USA multinationals [2]. The Med Tech sector in Ireland is dominated by several US multinational companies [1]. These companies began investing in the late 1960s with key investments in the 1990s. Multinationals represent 40% of the MedTech companies but represent 90% of the employment [3,4]. Multinational sites that were established in Ireland began with manufacturing with all critical controls in the USA [5]. A generation on from the initial investments the sites have added R&D and significant support roles in Ireland to become a MedTech cluster [5].

Several sectors have been essential as part of Ireland's strong economic growth but in particular, the Irish MedTech cluster has been a success. This paper will investigate the broad characteristics of the sector and contrast it with other European countries of the Irish medical technology sector which is made up of over 450 Med Tech companies [2].

The question of how a small island on the outskirts of Europe has evolved to become a global hub for MedTech as well as how they will continue to compete globally is the research topic for this study. Ireland has previously had a thriving electronics and computer manufacturing industry which unfortunately is no more mainly due to outsourcing of production to cheaper global locations [6]. Similar fates have happened to these industries in other countries [7,8].

Despite the success of Ireland's MedTech industry, other countries such as India have failed with creating a solid MedTech industry base [9]. Rising costs of manufacturing in

Ireland are a concern to the Irish MedTech industry with increasing global competition from countries such as Costa Rica and China [10,11].

This paper addresses the following

1. How has a small island of Ireland positioned itself as a global MedTech cluster?
2. Are there any local competitive strategies, structures, or contexts that explain the success of the Irish MedTech industry?
3. What are the future competencies that can be developed to protect against other lower-cost regions?
4. What are the challenges and critical success factors to becoming a MedTech closer and to maintaining the success of the cluster in the future?

The structure of this paper is as follows. Following the introductory section, Section 2 provides a literature review on the rise of the Irish MedTech industry and its specific attributes. Section 3 discusses the research design and methodology and provides the background of the study. Section 4 presents analyses of the findings. Section 5 concludes the paper by drawing lessons and policy implications regarding the role of the Irish government in promoting high-tech clusters. The practical lessons and experiences from the case of Ireland would be useful for other countries to learn the process of technological and economic catch-ups.

2. Literature Review

A literature review was carried out utilizing academic databases (such as Scopus, Web of Science, and Google Scholar) as well as government regulatory, statistical, and economic databases, in order to review literature related to the Irish MedTech industry. Various search strings were utilized related to MedTech—regulatory, clusters, products, Ireland, and the global economy to develop a picture of the political, economic, social, and technological factors related to the Irish MedTech cluster and its competitiveness.

2.1. The Global Market for Medical Devices

Medical devices are products, services, or solutions that prevent, diagnose, monitor, treat, and care for human beings by physical means [12]. There are more than 2M medical devices on the world market [13]. The global medical device market is valued at USD 425.5 bn in 2018 and is expected to reach USD 612.7 bn by 2025 [14].

Just 15 companies generate 54% of the global sales in medical devices with all 15 of these companies having a significant presence in Ireland. 11 of the top 15 are headquartered in the United States [15]. The industry continues to consolidate through acquisition and partnerships [16]. The USA is the largest producer and also the largest consumer of medical devices [17]. The USA represents 43% of the global medical device market, and Europe is the second-largest market for medical devices with an estimated EUR 120 bn spent in 2018 [18]. Germany is the largest market in Europe at 27% of the total European market, followed by France at 14.6% and the UK at 11% [18].

Health care spending is increasing globally, more than doubling between 2000 and 2019, currently, the spending is USD 8.5 trillion 9.8% of global GDP [19]. China's health care spending has increased by a factor of six from 2000 to 2019 [20]. High-income countries account for approximately 80% of health care spending. Medical devices are a subset of the total health care spending, globally estimated to be USD 540 billion [19].

2.2. Innovation within Medical Devices

Medical devices are characterized by a constant flow of innovation [17]. The average life cycle of a product in this category is 18 months [21]. There were 14,295 medical technology patents in the European patent office in 2020 [22]. Medical devices have been the category with the largest number of patents in the European Patent Office in nine of the last 10 years [22]. It is estimated that 80% of the profits in the industry come from products launched in the last 5 years [23]. It has been shown companies experience significant benefits by having patents for their products. A survey of 127,000 firms showed

those with registered patents had 36% more revenue per employee [24]. For SMEs with patents revenue per employee was 68% greater than non-patent holders [24] According to Schumpeter "carrying out innovation is the only function that is fundamental . . . in history" [25].

As highlighted in Figure 1, the number of European patents granted to Irish companies has grown over the last few years, almost doubling from 2017 to 2020. Per head of population, Ireland is at the 5th highest level in the world on medical patents with Ireland behind Switzerland and Israel both of whom have successful device clusters [26].

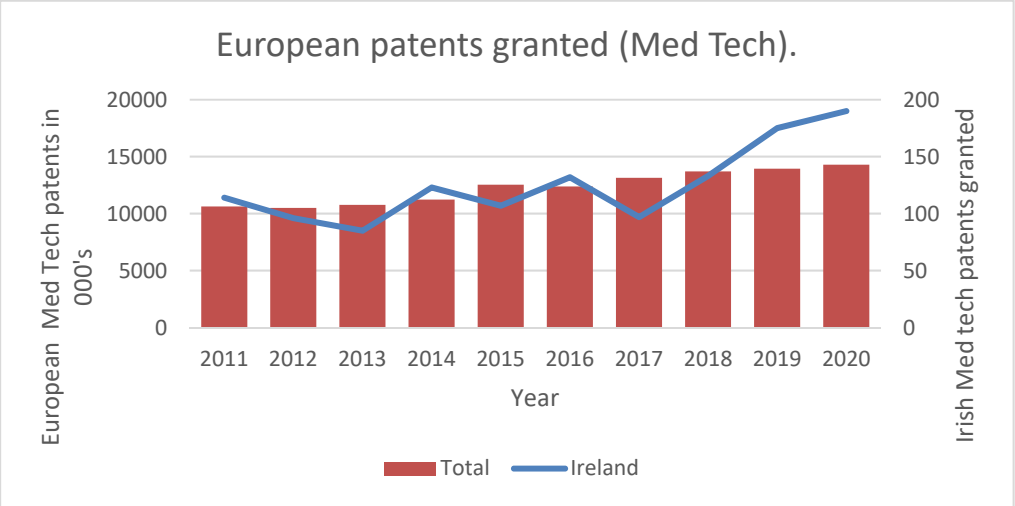

Figure 1. Trend of European patents granted and number from Irish individuals [22].

2.3. Irelands Economy

The graph of Irish exports in Figure 2 shows the economic transformation the country has gone through as highlighted in [27]. There is little growth in Irish exports until the early 1970s but joining the EEC coincides with increasing exports and the beginning of transforming the Irish economy. The impact of economic policies can be seen. Overstimulation of the economy in the 1970s lead to high inflation. This resulted in government cutbacks, increased taxation in the 1980s, and a reduction in export growth. The Irish Taoiseach (Prime Minister) Charles Haughey famously stated "*we (Ireland) are living beyond our means*" in a 1980 state of the nation TV address [28].

Attracting foreign direct investment (FDI). was a key part of Irish growth. By 1983, FDI accounted for 70 percent of new employment and 90 percent of increased exports [29]. Ireland attracted 222 FDI projects in 2022, this is 4% of the total number of projects and 6% of the total value of FDI investments in Europe [30]. Ireland was the only European country to experience an increase in FDI in 2020. In 2017, foreign-controlled enterprises accounted for 62.8% of the value-added in the Irish economy [31]. The average for the European Union (EU). is 26%. An example of FDI success is Intel's opening in Ireland in 1989. A corporate tax rate of 12.5% was agreed upon in 1999. The corporate tax rate was a key part of the Irish package for FDI [4].

Ireland agreed to be part of a single European currency in 1999 and joined the Euro in 2002. The country experienced strong export growth until 2008 when an economic collapse was brought about by a banking financial crisis. In 2016, growth was re-established, and exports took off once again.

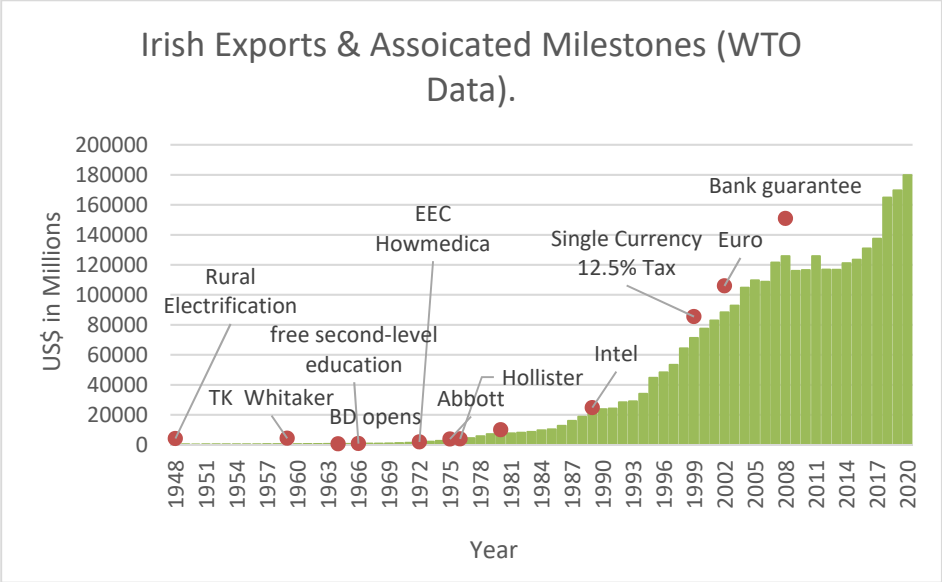

Figure 2. Irish exports, adapted with relevant milestones [27].

2.4. Medical Devices and Ireland

Ireland's initial success in medical device manufacturing was based on its ability to attract Foreign Direct Investment (FDI) from USA companies [21]. The USA is the largest producer of medical devices [17]. Multinationals in the USA wanted access to the European Union market which is the largest medical device market outside the USA. In Ireland, they found an educated English-speaking workforce [32]. Key factor conditions to attract medical device companies were reduced time to market [15], proximity and tariff-free access to the European Union [21], labor availability, and a low tax environment which meant Ireland's economy was like a "clockwork mouse which was fully wound up" [33].

MedTech companies based in Ireland are estimated to have exported €12.2 bn in 2018 [16]. There are 40,000 people directly employed by the MedTech industry in Ireland, which is 1.5% of national employment [16,18]. Ireland has the highest percentage of people employed in MedTech of any European country (three times the rate of Germany and 5.5 times the UK rate) [18]. Ireland is the second-largest European exporter of medical devices and has the largest net surplus of exports in Europe.

Forty-three of the top 1000 companies in Ireland (based on turnover) are medical device manufacturers [3]. In 2021, 90% of medical device employees in Ireland worked in sites that were established prior to 2000. The 43 companies have 71 sites between them in Ireland. Seventy-five percent of the sites are USA multinationals, 10% are Irish, and 4% are German. Medical device exports are dominated by multinationals with over 90% of medical device exports carried out by multinationals [34]. BD in Drogheda is the first Irish Industrial Development Authority (IDA)-backed medical device company in Ireland in 1964 [32].

Ireland had an established pharmaceutical industry when the medical device industry started to look at and set up in Ireland. When drug coatings were developed to be applied to cardiovascular stents, USA multinationals selected the Irish sites to lead these projects because they could source staff with pharmaceutical experience [35].

US-based multinationals that have moved to Ireland first established manufacturing centers. As the sites were established the influence of the Irish sites grew and support functions and Research and development roles were established. The site's growth can be modeled in a 5-step evolution [5]. Starting with the site as an implementer and controlled from headquarters to a site having global influence, setting direction, and leading corporate initiatives. Examples of device manufacturers based in Ireland which have followed this growth model are Medtronic, Boston Scientific, Zimmer, Stryker, and Abbott. As the Irish

site matured, they were involved in proposed acquisitions bringing new business areas to the manufacturing sites. An example of the timelines involved in the different medical device manufacturers coming to Ireland and the jobs they provide is illustrated in Figure 3. The sites have established a reputation for quality and reliability [36].

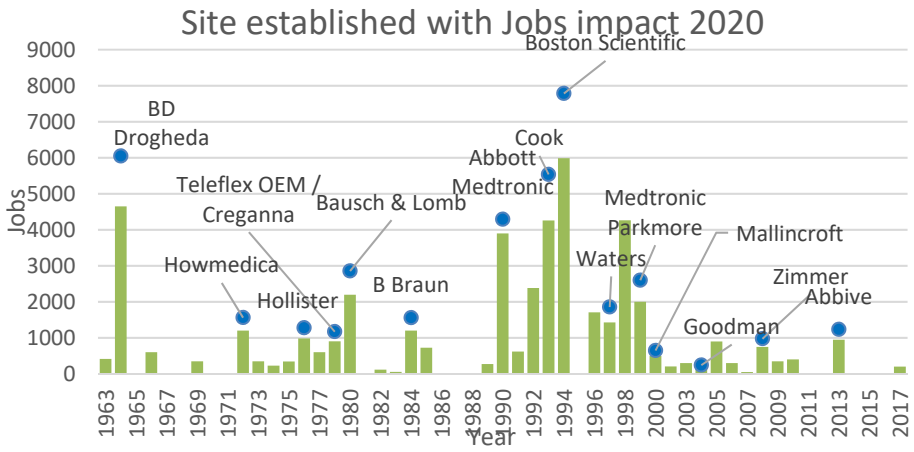

Figure 3. Year site is established with current jobs on site (only key sites labeled).

Key categories of medical devices manufactured in Ireland are shown in Figure 4. Vascular devices are the largest category and represent 28% of total employment. Ireland's mix of products has changed as costs have risen over time. There have been dramatic drop-in low-cost disposable medical devices manufactured from approximately USD 3 billion in 2005 to USD 1 billion in 2006 driven by rising costs and overloaded infrastructure [21]. The industry continued to expand in higher-value therapeutic devices. Therapeutics are characterized by high growth, high margin, greater complexity, and short life cycles [5].

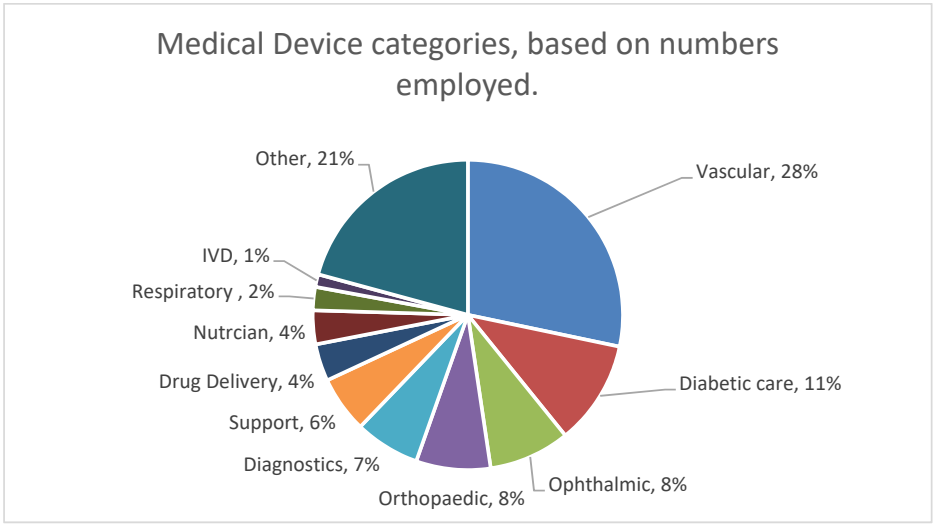

Figure 4. Medical device categories, based on numbers employed in Ireland 2021 [37].

Ireland exports make an impact globally with key exports: 25% of the world's diabetics are treated with products made in Ireland, one-third of global contact lenses are made in Ireland with exports of EUR 1 bn in 2020. Ireland is also the world's largest exporter of cardiology stents, with exports of EUR 2 bn in 2020, and is the world's fourth largest exporter of artificial joint exports of EUR 1.3 bn in 2020, the 3rd largest exporter of diagnostic reagents for patient administration, and 50% of ventilators worldwide in acute hospitals are Irish made [37].

2.5. The Irish Medtech Cluster

"Clusters are geographic concentrations of industries related by knowledge, skills, inputs, demand, and/or other linkages" [38]. Clusters have a positive impact on regions' industrial performance including job creation [38]. The clusters should be considered a regional ecosystem. The clustering effect matters; 39% of European jobs and 55% of European wages are located in clusters [39].

An example of a medical device cluster is Tuttlingen in Germany. The town has a population of 34,000 people but is recognized as a world leader in surgical instruments. In 1995, 90% of all surgical instruments firms in Germany were based in Tuttlingen [40]. Clustering appears to be a central feature of advanced economies (Porter, 1990 [41]). Nations can become highly competitive in niche areas; for example, Japan has captured 98% of the global market in flexible endoscopes and 31.9% of MRI systems [42]. At the same time, Japan makes only 1.2% of the global market share of vascular stents [42].

According to the EU smart guide clustering policy [39], the key factors that make clusters successful are having a critical mass with more companies in a region leading to higher productivity through specialization and competition as well as linkages with suppliers, partners, government, and educational institutions.

The cluster is focused on higher-value medical devices. Due to high costs, the labor is required to be highly productive. Between 2007 and 2012, a USD 3 billion increase in exports was supported by an increase in 3000 employees. Compared with Baja, California, Mexico, USD 1.5 billion saw an increase in labor of 14,500 employees. Each additional employee in Ireland added 10 times the export value of an additional employee in Baja, California [21].

2.6. Key Elements of the Irish Medical Device Cluster

Hill states that industrial clusters require driver industries at the center [1]. Multinational companies are the drivers of the medical device cluster in Ireland. Some elements of the medical device cluster include: multinationals, start-ups, support companies for example companies that will design and manufacture products to meet the start-up's needs, universities: provide skilled labor, generate ideas, host incubators, funding, e.g., the Irish government's Enterprise Ireland high potentials funds, venture capital, angel investors, and medical practitioners. The stakeholders are based on the "Innovation Ecosystem stakeholder Model" with the addition of clinical stakeholders (Figure 5) [43].

These elements are interrelated and support each other. For example, it is important that medical practitioners can identify unmet clinical needs and provide knowledge to medical companies on how to improve medical devices. Reducing the effectiveness of this link has been shown to directly reduce innovation both the volumes of innovations and the inventiveness of them [44].

Academia has changed to support the medical device industry. The Irish Government had invested heavily in R&D in the higher education institutes (HEIs) with the expressed intent of enhancing the commercialization of HEI research and creating links between HEIs and indigenous enterprises [3,4]. Key academic centers of excellence, including CURAM (Center for Research in Medical Devices), AMBER (Advanced Materials and Bio-Engineering Research), Tyndall National Institute, Insight (research center for data analytics), BDI (Biomedical Diagnostics Institute), SEAM (Southeastern Applied Materials), PEM (Precision Engineering & Manufacturing), and APT (Applied Polymer Technology Center) are closely integrated with the MedTech industry [45]. The BioInnovate program is specifically designed to create medical device start-ups [46]. The BioInnovate program is a medical device innovation training program modeled after Stanford Biodesign. Twenty-two new medical device start-ups have been created through the program [47].

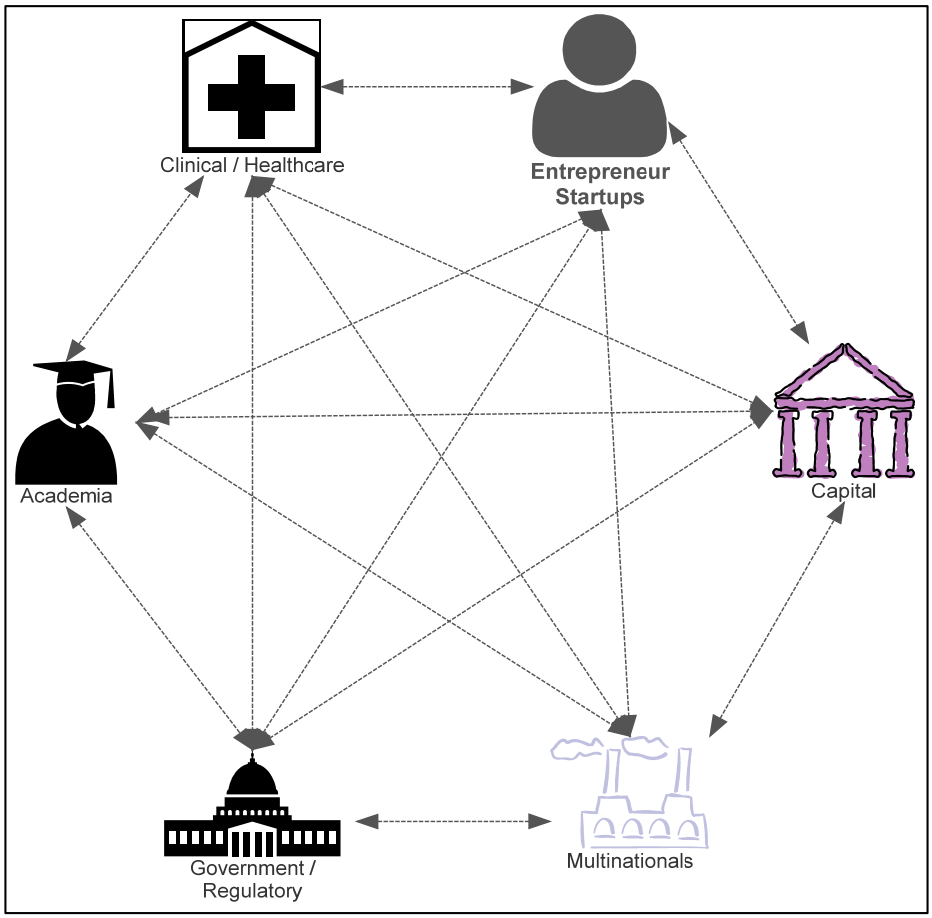

Figure 5. Key elements of medical device cluster in Ireland (Source: Authors own).

A review of 450 medical device companies showed that 43 were large enterprises (multinationals) and 407 were SMEs. Many innovative Irish high-potential indigenous start-up companies have been acquired by global multinationals [35]. Amongst the larger Irish MedTech companies acquired by overseas firms in recent years are: Creagh Medical (2015), Creganna (2016), Neuravi (2017), and Veryan Medical (2018). It is important to note the sequence of events in the Irish MedTech cluster. Multinationals arrived in Ireland and thus engineers and managers from multinationals then established their own companies [35]. In effect, multinationals have "spawned" new entrepreneurial ventures. Typically, there are several large established businesses at the heart of an entrepreneurial ecosystem (Mason and Brown, 2014). Even the failure of a multinational site can lead to the spawning of start-ups or talented employees joining smaller companies or 'whale fall'. Successful start-ups are then bought by a multinational. The owners are now able to fund and advise future start-ups. A characteristic of a successful cluster ecosystem is system growth through 'entrepreneurial recycling' [48].

Studies in the USA have shown that medical device start-ups that have similar regulatory requirements to the multinationals that "spawned" them do better than others, receiving higher valuations in funding rounds, getting funding faster, and receiving faster regulatory approvals [49]. Most firms in Ireland engaged in new product development are small Irish start-ups, not multinationals [21].

US multinationals tend to centralize R&D spending with 85% to 90% of R&D spending in the USA [5]. Approximately 50% of manufacturing and sourcing spend is outside of the USA [5]. The Irish medical device cluster has a challenge and opportunity to increase the proportion of R&D spending based in Ireland. Multinationals may be unable to capitalize on disruptive innovation in part due to a focus on incremental innovations to

existing products [49]. Small and medium firms are twice as likely to launch radical innovations to the market [21]. In effect, multinationals have outsourced much of their R&D to start-ups [50].

Key government agencies are Industrial Development Authority (IDA) and Enterprise Ireland. The support they offer has blurred the lines between government agencies and the venture capital elements of the medical device cluster. Enterprise Ireland is Europe's largest seed investor by the number of investments [51].

3. Materials and Methods

A literature review utilizing a single case study was applied as the main methodology to analyze the Irish MedTech sector [52], utilizing literature reviews and relevant databases. The use of a single case study has a limitation in that it cannot lead to generalization [52]. Despite such limitations, an understanding of the dynamic process underlying the localized context of Irelands MedTech industry can provide important lessons and insights to understand the competencies and strengths behind the growth of the MedTech cluster.

A literature review was completed to assess the current nature of the medical device sector in general and in Ireland given its location within the European regulatory regime. Academic databases, and other relevant sites such as the World Health Organization, World Trade Organization, European Patent Office, and Regulatory Legislation all provided insights into the medical device sector. These sources gave insight into the global scale of the industry, the growth trends, product categories, and key nations and clusters that dominate the industry. A review was carried out on the level of innovation within the Irish MedTech industry and its importance to the Irish medical device cluster. Based on the data, the history and evolution of the medical device industry in Ireland were completed. The current medical device cluster is broken down by device category and company type. With the use of secondary research and obtaining data from various true sources, such as economic data, reports from, various industry organizations, and government sources, this paper has been able to identify the issues discussed in this paper in the path of making Ireland a MedTech manufacturing hub.

An analysis of the cluster has been completed under the headings of political, economic, social, and technology (PEST analysis). Based on the aforementioned analysis the researchers have put forward an analysis summary of the Irish MedTech cluster utilizing PEST analysis. Political, economic, social, and technological (PEST) analysis is also used as a tool to identify these risks related to the Irish MedTech sector [53]. PEST analysis represents a framework of external macro-economic factors that can influence the subject at hand. It can be used to assess the external pressures on a business unit, project, or even an industry [53]. PEST analysis can be used to gain an insight into the external environment in which businesses operate, understand what each PEST factor represents, and how they are interrelated. Once these environmental factors are identified and analyzed, business organizations are in a better position to plan and strategize to meet their goals and minimize any obstacles.

Analysis was performed using PEST analysis (Table 1). Therefore, findings were classified into four aspects: political, economic, social, and technological. PEST analysis is dedicated to evaluating major external factors, which affect directly or indirectly the development, operation processes, and competitiveness level of organizations in the market.

Table 1. PEST analysis results summary.

Political	**Economic**
Medical device regulations De-globalization Brexit and Swiss Exit Made in China Environmental	Ireland competitiveness Tax Declining sales prices
Social	Technology
Ireland education Global demographics	Remote diagnostics Convergent technologies Novel devices and their impact on demand.

3.1. Political Environment Analysis

Within this section, the European and global regulatory environment as well as the growth of markets outside of Europe are discussed. Regulations are an integral part of medical device manufacturing. There are stringent regulations across the globe in different jurisdictions mandating how medical devices are designed, manufactured, and monitored after shipment from factories. Key political factors that are affecting the medical device cluster in Ireland are outlined in Table 2.

Table 2. Political factors affecting the medical device cluster In Ireland.

	1990s	**2020s**	**Change**
Regulatory (Daigle and Torsekar, 2019 [15])	CE mark introduced in Europe. EU faster to market.	MDR was introduced in Europe. USA faster to market	↓
Brexit	UK market could be accessed with CE Mark	UK market requires UK Conformity Assessed mark from 1 July 2023.	↓
Switzerland 3rd country status [54]	Swiss market could be entered with CE mark.	Switzerland is not a third country. Local authorized representative and importer of record to be established in Switzerland. Labelling to be updated.	↓
Deglobalization of USA [55]	Low risk of a trade dispute. USA encouraging globalization.	A concern of risk of a trade dispute.	↓
China [56]	Small market.	Large market. Member of World Trade Organization. Increasing market, reducing selling prices	↑

New medical device regulations (MDR) in Europe have meant that it is now more cumbersome to get a device to market in the EU. The US is now being seen as the first market of choice in terms of launching a new device.

Proficient and compliant regulatory practices in medical device organizations are key to gaining market access. Key changes that the MDR introduces include as outlined in Table 3.

Table 3. Major changes introduced due to MDR.

Major Regulatory Stage	Change from MDD to MDR
Research and clinical trials	Increases existing standards for research and clinical trials. Clinical trials will now be required for lower-risk devices
Conformity assessment procedures	Requires use of Unique Device Identification code. The MDR added new products that did not previously require certification under MDD.
Post-market surveillance	Under MDR Class II and III devices will be required to conduct annual assessments of the product in the EU market, collect more data and be more transparent.

MDR is causing significant issues for manufacturers of medical devices. A key concern is the reduced availability of medical devices due to the need for fresh clinical evidence. Fresh clinical trials will have to be completed for medical devices that are already on the market. It is estimated there are 500,000 medical devices on the European market [57]. COVID-19 has resulted in reduced capacity to complete clinical trials. It has been estimated that 20% of currently registered products may not get released under MDR. This will have a significant effect on the medical devices available to treat patients. The time to approve new medical devices or certify existing medical devices under MDR will increase. Notified bodies assess the conformity of the device before it is placed on the market. Of the fifty-one notified bodies that assess MDD, only twenty-five are designated for MDR [58].

Smaller companies and startups are failing to even get an appointment with the regulatory body. This makes it impossible to predict the time to launch in the European market. There are also increased new requirements for economic operators, including distributors and importers. For the Irish cluster, this will slow the development of products and reduce the likelihood of bringing truly novel devices to market through the EU CE marking pathway [15]. As of January 2022, guidance for approval of medical devices under MDR is a minimum of 18 months with significant risk. The average approval for a medical device in the USA through a 510(k) pathway is less than two hundred days and for other countries can vary [59] as shown in Figure 6.

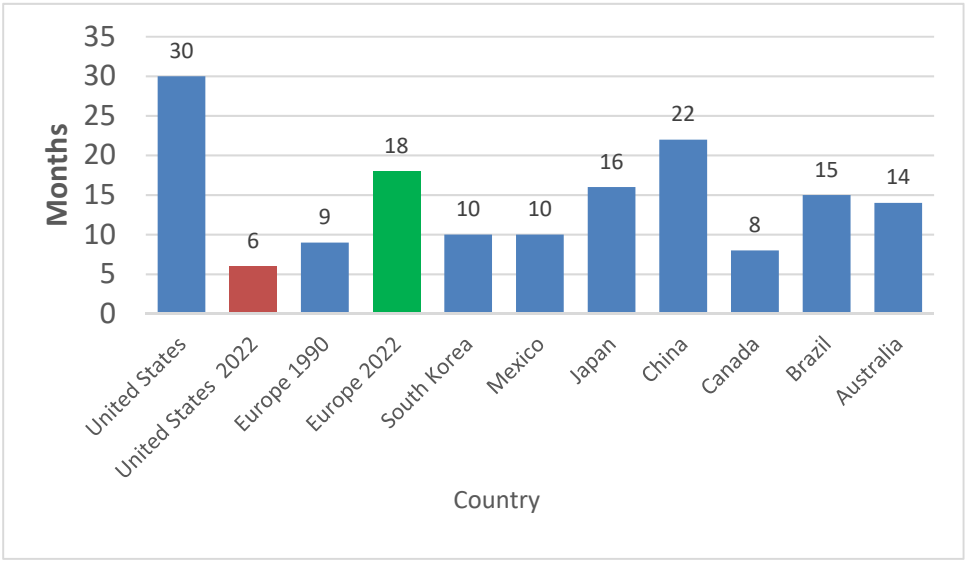

Figure 6. Average time to approve a medical device -graph authors own construction.

Europe is no longer the fastest place to launch medical devices. The USA is now faster than Europe to release new medical devices. Multinationals in Ireland have adopted a launch in the USA first approach [60]. Brexit means the EU will treat Britain as a third country. British medical device manufacturers will be treated as extra EU manufacturers. As of 26 May 2021, Switzerland, through Swiss Exit, is also treated as a third country. This will make accessing those markets more difficult. A local authorized representative is required in the country and their name must appear on the label [54]. This requires the Irish sites to change labeling, creating extra paperwork to sell into those markets.

Posen has argued economic data shows the USA has been reversing its globalization trend and is becoming more inward focused. He states "The United States has, on balance, been withdrawing from the international economy for the past two decades" [55]. The USA has tended to introduce increased protectionism, tariffs, and buy America programs. An example of tariffs is contained in Section 232 of US steel tariffs which was effective on 1 June 2018, applying a 25% tariff on steel imports [61].

As the USA is the largest medical device market in the world [17] and the largest investor in the manufacturing of medical devices in Ireland. The trend of deglobalization could have long-term negative impacts on the medical device cluster in Ireland.

China's 'Made in China 2025' initiative, launched in 2015, aims to make Chinese firms world leaders in high-value-added manufacturing. The 'made in China initiative' calls for Chinese hospitals to buy 95 percent more locally produced medical devices by 2030. China's Ministry of Industry and Information Technology (MIIT), as part of China's central government, has for the first time issued strategic ambitions for the medical technology sector. In April 2021, the Chinese government published its new medical technology five-year plan (2021–2025), outlining the goal to make at least six Chinese companies among the leading 50 medical device companies globally (there are none in the top 50 today). MIIT has issued local content requirements for 178 medical devices [56].

A survey by the European Union Chamber of Commerce in China of European companies operating in China showed that 64 percent in the medical devices sector reported that they missed business opportunities due to market access restrictions or regulatory barriers in 2020 [56]. China imported medical devices with a value of EUR 18 billion in 2020. The Chinese market is becoming increasingly important but also increasingly difficult to access.

3.2. Environmental

The Paris Agreement (2016) goal is to limit global warming to less than 2 °C compared to pre-industrial levels. The Paris Agreement is the first universal, legally binding climate change agreement [62]. Ireland's per capita greenhouse gas emissions are the highest in the EU and have increased since 2013 [63].

Investment funds are increasingly concerned about the environmental, social, and governance (ESG) of the companies they invest with. In the USA, ESG investing is now 20% of professionally managed funds [64]. Given the impact of USA companies in the Irish medical device cluster, it will be increasingly important for the Irish cluster to meet the requirements of ESG investment funds.

3.3. Economic

In this section, a number of key economic indicators are discussed in terms of Ireland, including employment levels, labor costs, and corporate tax incentives (Table 4).

At the start of the 1990s, Ireland was a relatively low-cost location for manufacturing. Today's average hourly compensation equals the Euro area average at EUR 32.30 (Figure 7). The compensation is less than Germany but more than double the Czech Republic and almost five times the cost of Bulgaria [65].

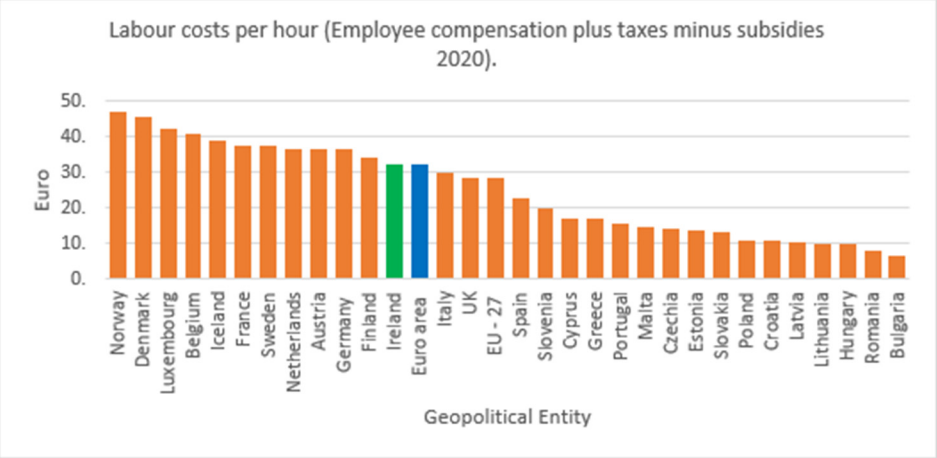

Figure 7. Hourly labor costs (2020 employee compensation plus taxes—subsidies) Authors own construction using data obtained in [65].

Table 4. Economic factors.

	The 1990's	The 2020's	Change
Unemployment rate	12 to 15%	5%	Reduced
Labor costs [31]		€32.3	Increased
Corporate Tax [66]	Ad hoc, special arrangements	12.5% (1999). Increasing to 15% for companies with turnover greater than EUR 750m.	Less flexibility
Global Medical Device market [20]	USD 220 billion (2000)	USD 540 billion (2020).	Growing
Currency	Irish Punt	Euro	Negligible
Nominal weekly earnings	EUR 490.31	EUR 837.42	Growing
The number of medical device companies [4]	50	Greater than 450	Increasing presence
ASPs for commodity Medical Devices [67]	N/A	N/A	Reducing for commodity devices

Ireland's national competitiveness council reported that between 2000 and 2008, Ireland experienced a significant loss in cost competitiveness, and since 2008, Ireland has experienced significant improvements [63].

Major competitiveness rankings show Ireland losing competitiveness between 2005 and 2010. The position is more mixed for the years 2010 to 2020. The Institute for Management Development (IMD) and World Economic Forum (WEF) have shown improvements, while the world bank has shown Ireland's competitiveness continuing to fall [63].

The EU has proposed a directive on a minimum corporate tax rate. This is part of the EU's pledge to implement the OECD/G20 inclusive framework on base erosion and profit shifting (BEPS). It requires large groups to pay a minimum of 15% in every jurisdiction they operate [66].

Declining Sales Price for Medical Devices

Centralized purchasing results in standardization of medical devices and downward price pressure. Increasingly, purchasing decisions and medical device se-lection are being made by purchasing departments with physicians in an advisory role. Commodity products are particularly affected by downward pricing pressure for example the ASP for a carotid balloon catheter is expected to drop in value by 26% from US$ USD 240 to US$ USD 178.90

over the 10 years 2017 to 2027 [67]. This will put pressure on selling prices and drives more competitiveness in the industry. It impacts Ireland as products made in Ireland are sold globally [5].

In the USA groups of hospitals are pooling their purchasing power to reduce costs. Between 72 and 80 percent of non-labor purchases are completed through a group purchasing organization (GPOs) or integrated delivery networks (IDNs) [68]. Office-based labs (OBLs) are increasingly used for outpatient procedures. Almost all endovascular procedures are suitable for an OBL setting. OBL is gaining an increasing share of the USA market. Currently, 25% of peripheral vascular procedures are carried out in OBL settings [67]. OBLs are physician-owned and tend to be more cost-conscious than hospitals. OBLs often receive price discounts of 50% [67]. OBLs are driving down the ASP of medical devices. This impacts the Irish medical device cluster as the products are sold globally [5].

China has introduced a centralized public procurement policy for medical devices in 2019. When the coronary stents were put to tender, 20 companies participated of which 8 were chosen, and of which six of these were Chinese. Only one company, which was Chinese, was given a guaranteed volume based on the price [56]. Reducing selling prices in the Chinese market will make it increasingly difficult for Irish-based MedTech companies to compete in the market.

3.4. Social

Table 5 demonstrates many social and population statistics globally and in Ireland that affect the MedTech market and access to staff.

Table 5. Changes in society (1990 to 2020).

	1990s	2020s	Change
Global population [69]	5.3 billion	7.8 billion	Increasing
Urban population (global) [69]	43%	56%	Increasing
Life Expectancy (both sexes global). Global [69]	64.6	73.2	Increasing
Fertility (births per female global) [69]	3.4	2.5	Decreasing
Supporting institutions	High	High	Increasing
Education (Ireland) % with third-level qualification [70]	13.6%	42%	Increasing
Patients	Recipient of care	Active participant	Increasing

Ireland has the youngest population in Europe; 33.3% of the population is under 25 years old. Ireland is among the most educated population in Europe with 56.3% of 30- to 34-year-olds having a third-level degree; the EU average is 40.7%. In Ireland, 27% of degrees are in STEM subjects; in Germany, that figure is much higher at 34% [63]. Ireland has a high proportion of non-native people employed; in Q2 2019, it was 16.5% of the population increasing the availability of a workforce for the MedTech industry [37]. Ireland ranks first globally for attracting and retaining international talent [71]. Medical device companies can source employees from the EU community and the UK.

Global Demographics—Drivers of Demand for Medical Devices

An aging population is the most significant factor that causes increased spending on healthcare. There is a six-fold increase in health care spending between those aged over 85 and those aged between 55 and 59 years [72]. Fertility rates are expected to decrease from 2.5 births per woman in 2020 to 2.2 births in 2050. Life expectancy is forecast to increase

from 72.3 years to 76.8 years in 2050 [73]. Globally, in 2020, there were 728 million people aged 65 or over, and this is projected to double to 1.5 billion in 2050 [73].

Economic development and increasing urbanization are leading to more sedentary lifestyles and greater consumption of unhealthy foods linked with obesity. This is driving a rise in chronic conditions such as type II diabetes [14]. Early detection and improved treatments mean people are living longer with chronic conditions.

Medical devices in Ireland are typically designed and manufactured for a global market. Healthcare spending is increasing globally, more than doubling between 2000 and 2019 (Figure 8); currently, the spending is USD 8.5 trillion 9.8% of global GDP [19]. China's healthcare spending has increased by a factor of six from 2000 to 2019. High-income countries account for approximately 80% of healthcare spending [19].

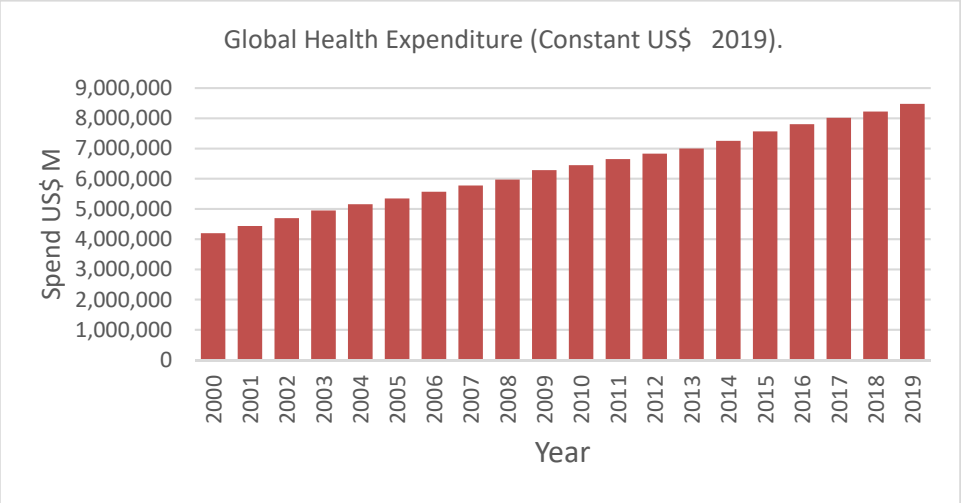

Figure 8. Global health expenditure, Based on World Health Organization database 2021.

In Europe, 7.4% of healthcare spending is on medical technology, 6.7% on devices, and 0.7% on IVDs [18].

3.5. Technology

Technology innovation has driven changes in medical device use and design in recent years. A sum of the key technology trends in the industry is highlighted in Table 6. COVID-19 stopped elective procedures. It also caused a rapid increase in remote diagnostics and the need for telemedicine. PatientMPower is an example of an Irish start-up providing remote monitoring solutions to patients living with chronic diseases. It enables the patient to measure and track lung health, oxygen saturation, and blood pressure enabling it to be shared with clinical teams.

Healthcare facilities have very different expectations for technology. Sites described as innovators saw robotic surgery as having the highest impact on the quality and outcome of care [74]. The innovative sites also used and saw the following related technologies as having a positive impact: artificial intelligence, telemedicine, wearables, data-supported decision making, and embedded biometric monitoring. These areas may offer new growth opportunities to the Irish medical device cluster.

Convergent technologies are based on one or more technology platforms [36]. An example is a drug-coated stent. Implementing convergent technologies give medical device companies the opportunity to differentiate themselves and introduce disruptive technologies. An example is intelligent implants. The company's smart fuse product combines its electrotherapeutic technology with an orthopedic implant for the spin. It uses electrical signals to promote and measure bone growth and has the ability for remote data collection [75].

Table 6. Technology trends in medical devices.

	1990s	2020s	Change
Telehealth	Not used	95% of physicians use virtual technology (USA) [76].	COVID-19 triggered the use of technology to enable Telehealth
Patient/consumer (lifestyle health)	Basic measurements in the home, i.e., temperature.	Consumer electronics are adding medical features such as ECG monitors in watches.	A completely new market was created.
Records	Paper	Increasingly electronic, with Manufacturing Execution Systems capturing data live from equipment	
Orthopedics	Joints cast	3D printing of joints	3D printing enables the possibility of creating bespoke medical devices, i.e., hip replacement is specifically designed for the patient.
Digital health care	Minimal	Remote monitoring linked to data and artificial intelligence.	
Cardiovascular		A growing trend for minimally invasive interventions. Increasingly complex procedures.	

The availability of novel medical devices to treat unmet clinical needs has created new demand for medical devices. An example of new demand is endovascular stroke therapy (EST). There has been a continuous increase in EST over the 10-year period from 2006 to 2016. The number of ESTs went from less than 50 in 2006 to 1000 in 2016 [77]. A significant jump in demand occurred when multiple clinical trials confirmed positive outcomes.

There is a growing trend towards minimally invasive interventional surgery. For example, a USA study on peripheral arterial disease showed the use of endovascular interventions grew by a factor of three between 1996 and 2006. Simultaneously, traditional bypass surgery was reduced by 43%. Overall, the number of procedures completed almost doubled in the decade. Patients benefited as the rate of amputation reduced by 29% [78].

4. Discussion

In terms of the results of the PEST analysis on the Irish MedTech cluster, political and economic factors are deemed to be most critical to the future success and survival of the Irish MedTech Industry. While technological and social factors are also key drivers in the Irish MedTech cluster they are not as prominent as political and economic factors. The political and economic involvement of the Irish government supports the mercantilist hypothesis that the state still remains the primary actor in the international economy by supporting multinational investment and proliferation [79]. Barry and van Egeraatt [80], in their study of "The decline of the computer sector, how Ireland adjusted", concluded that the flexibility of the Irish labor market will be enhanced by the increasing educational attainment of the workforce and that the skills structure in these sectors being less closely related to cognate services activities than in the case of computer hardware. Ireland as a MedTech cluster presents an ideal cluster with the right elements: an excellent manufacturer and supplier backbone, access to first-rate clinics, universities, and research facilities, a high number of technology start-ups, and easy access to funding.

4.1. Concerns for the Irish Med Tech Sector

Ireland has succeeded in attracting mainly US-based multinationals. There is relatively little FDI from other countries around the world into Ireland. Most of the MedTech companies came to Ireland when you could launch new products in Europe typically

12 months faster than in the USA. This is now reversed, and companies have a US launch first strategy for new products [15].

Ireland was a low-cost location and has now become expensive in comparison to low-cost parts of the EU and alternative clusters such as Costa Rica [81]. For example, Dublin is the sixth most expensive city in the world to rent. Government corporate tax is at least part of the reason for Ireland's MedTech cluster's success. Global policies have reduced Ireland's ability to set its own corporate tax rate [66].

Alternative medical device hubs are being created globally. Costa Rica is a growing center of success in Central America [21]. Penang, in Malaysia, has attracted significant investments and some Irish-based multinationals have invested there. This is where the Irish government's policies will aid research, innovation, investment, skills availability, and attract new investment. Despite the level of Irish government support, a study by [82] suggested support was mainly offered at the seed and high-performance stages, which left a gap in the middle and pre-launch phases. She also cited the highly regulated nature of the MedTech sector as a barrier to Irish indigenous start-ups in the sector.

4.2. Opportunities for the Irish Med Tech Cluster

If the Irish MedTech cluster can keep competitive, there are many opportunities for growth and innovation. Rising and aging global populations mean the demand for MedTech products is growing.

Fostering innovations means future markets and expansion of the current number of manufacturers is an opportunity. Ireland needs to continue to capitalize on medical device development and manufacturing opportunities by building an ecosystem where companies collaborate with government organizations and academic research centers to drive innovation [83]. The Irish MedTech Association (IMA) is advocating that with the right policies, the industry can take a greater share of the global MedTech market which is forecast to grow to EUR 530 billion by 2024 [1]. The IMA has put forward 3 pillars to the Irish government to drive future Irish MedTech growth which are health and patient access, enterprise and innovation, education, and skills. It is also important that Irish MedTech organizations expand on the traditional manufacturing activities towards more value-adding competencies such as research and development (R&D), new product development, and activities closer to the customer such as logistics, sales, and marketing [84].

5. Conclusions

The Irish medical device cluster has been a success with a global impact. It has reinvented itself over time, transitioning away from disposable items to higher-value therapeutics.

The cluster was initiated through investment from USA multinationals. The key advantages that Ireland offered were faster access to the EU market with a well-educated, English-speaking workforce. As the multinational sites matured, they expanded their capabilities and responsibilities, and many Irish sites are leading global programs and have R&D and support functions on site.

The global market for medical devices is growing. An aging global population and chronic diseases are the primary cause of the growth. New medical devices that provide solutions for unmet clinical needs have created completely new markets and initial additional growth. Time to market is critical, the selling price for commodity items reduces year on year due to the purchasing power of customers, and the bulk of profits in the industry are made with devices that have been developed within the last 5 years.

The most recent threat to the cluster is proposed changes to medical device regulations (MDR). This will remove the advantage of faster new product launches in Europe compared to the USA. It may require the cluster to reinvent how it adds value once again.

New opportunities may come from within the cluster itself. Disruptive technologies are more likely to be created in startups. The cluster has the required elements to enable start-ups to thrive. Improving the ecosystem is a way for the Irish medical device cluster to create a competitive advantage that is difficult to copy. The Irish MedTech industry

can provide important lessons as it responds to changing regulatory requirements and low-cost competition.

The implications for this study both to academics, government, and manufacturers are many. The key implication and finding is the vulnerabilities of the cluster and the need for this vulnerability to inform government policy. The findings can inform government support and policy in relation to MedTech industry support, funding and sponsoring of future innovation, fostering entrepreneurship, start-ups, spin-offs, and promoting convergent technologies. Moreover, the government and universities have a role in aiding in reducing skills gaps through increased educational funding and collaboration with manufacturers. From an academic and industry point of view, this is one of the first in-depth and exhaustive studies into the Irish MedTech industry, specifically in light of the new European MedTech regulations. From a manufacturer's viewpoint, this paper provides important feedback on the current state of the cluster and future challenges and opportunities. The effect of the new European device regulations on the cluster and wider European manufacturing network is also an important vulnerability to be recognized by the cluster stakeholders.

Author Contributions: Conceptualization, D.M. and O.M.; methodology, D.M.; formal analysis, D.M. and O.M. data curation, D.M.; writing—original draft preparation, D.M. and O.M.; writing—review and editing, O.M. and D.M.; supervision, O.M. All authors have read and agreed to the published version of the manuscript.

Funding: This research received no external funding.

Institutional Review Board Statement: Not applicable.

Informed Consent Statement: Not applicable.

Data Availability Statement: All data are available upon request.

Conflicts of Interest: The authors declare no conflict of interest.

References

1. Hill, E.W.; Brennan, J.F. A Methodology for Identifying the Drivers of Industrial Clusters: The Foundation of Regional Competitive Advantage. *Econ. Dev. Q.* **2000**, *14*, 65–96. [CrossRef]
2. Brazys, S.; Regan, A. Small States in Global Markets. In *The Oxford Handbook of Irish Politics*; Oxford University Press: Oxford, UK, 2021.
3. Irish Times. The Irish Times Top 1000 Companies. Available online: https://www.top1000.ie/ (accessed on 5 December 2021).
4. Irish MedTech Association. *Strategy 2022–2025*; Irish MedTech Association: Dublin, Ireland, 2022.
5. Walsh, P. *Achieving Your R&D Ambition*; Irish MedTech Association: Galway, Ireland, 2021.
6. van Egeraat, C.; Jacobson, D. The Rise and Demise of the Irish and Scottish Computer Hardware Industry. *Eur. Plan. Stud.* **2004**, *12*, 809–834. [CrossRef]
7. Cattaneo, O.; Gereffi, G.; Staritz, C. Global Value Chains in a Postcrisis World: Resilience, Consolidation, and Shifting End Markets. In *Global Value Chains in a Postcrisis World: A Development Perspective*; Cattaneo, O., Gereffi, G., Staritz, C., Eds.; The World Bank: Washington, DC, USA, 2010; pp. 3–20.
8. Baldwin, R.; Lopez-Gonzalez, J. Supply-Chain Trade: A Portrait of Global Patterns and Several Testable Hypotheses. *World Econ.* **2015**, *38*, 1682–1721. [CrossRef]
9. Siddiqui, A.A.; Singh, P. Identifying Export Markets for Indian Medical Devices. *Int. J. Pharm. Healthc. Mark.* **2020**, *14*, 587–605. [CrossRef]
10. Vlckova, J.; Thakur-Weigold, B.S. Global Value Chains in the MedTech Industry. *Int. J. Emerg. Mark.* **2020**, *15*, 70–92. [CrossRef]
11. Yingming, Z. *Analysis of Industrial Clusters in China*; CRC Press: Boca Raton, FL, USA, 2009.
12. Trubetskaya, A.; Manto, D.; McDermott, O. A Review of Lean Adoption in the Irish MedTech Industry. *Processes* **2022**, *10*, 391. [CrossRef]
13. World Health Organisation. Medical Devices. Available online: https://www.who.int/health-topics/medical-devices#tab=tab_1 (accessed on 23 December 2021).
14. Fortune Business Insights. Medical Devices Market Size, Share, Trends_Analysis, 2028. Fortune Business. 2020. Available online: https://www.fortunebusinessinsights.com/aboutus (accessed on 10 August 2022).
15. Daigle, B.; Torsekar, M. *The EU Medical Device Regulation and the U.S. Medical Device Industry*; United States International Trade Commission: Washington, DC, USA, 2019.
16. Department for Business, Energy and Industrial Strategy. *Focus on Medical Technologies*; Government of Ireland: Dublin, Ireland, 2020.
17. Maresova, P.; Penhaker, M.; Selamat, A.; Kuca, K. The Potential of Medical Device Industry in Technological and Economical Context. *Ther. Clin. Risk Manag.* **2015**, *11*, 1505–1514.

18. MedTech Europe. *The European Medical Technology Industry in Figures 2020*; MedTech Europe: Brussels, Belgium, 2020.
19. World Health Organisation. *Global Expenditure on Health: Public Spending on the Rise?* World Health Organisation: Geneva, Switzerland, 2021.
20. World Health Organisation. Global Health Expenditure Database. Available online: https://apps.who.int/nha/database/ViewData/Indicators/en (accessed on 26 December 2021).
21. Bamber, P.; Gereffi, G. *Costa Rica in the Medical Devices Global Value Chain: Opportunities for Upgrading*; Duke University Global Value Chains Center: Durham, NC, USA, 2013.
22. European Patent Office. Total European Patent Applications in Medical Technologies. Available online: https://www.epo.org/about-us/annual-reports-statistics/statistics/2020/healthcare-and-life-sciences/Graph2.jpg (accessed on 24 December 2021).
23. Simoens, S. Which Barriers Prevent the Efficient Use of Resources in Medical Device Sectors? *Appl. Health Econ. Health Policy* **2009**, *7*, 209–217. [CrossRef]
24. Epo; Euipo. *Intellectual Property Rights and Firm Performance in the European Union—Firm-Level Analysis Report, February 2021—Executive Summary*; Epo and Euipo: Munich, Germany, 2021.
25. Śledzik, K. *Schumpeter's View on Innovation and Entrepreneurship*; Faculty of Management Science and Informatics, University of Zilina & Institute of Management by University of Zilina: Zilinia, Slovakia, 2013; pp. 89–96.
26. O'Cearbhaill, R.M.; Murray, T.E.; Lee, M.J. Medical Device Patents—A Review of Contemporary Global Trends with an Irish Comparison. *Ir. J. Med. Sci.* **2019**, *188*, 653–659. [CrossRef]
27. World Trade Organisation. WTO Stats. Available online: https://stats.wto.org/ (accessed on 5 December 2021).
28. O'Connell, J. A Brief History of Ireland in 33 Great Delusions. Available online: https://www.irishtimes.com/life-and-style/people/a-brief-history-of-ireland-in-33-great-delusions-1.3580854?mode=sample&auth-failed=1&pw-origin=https%3A%2F%2Fwww.irishtimes.com%2Flife-and-style%2Fpeople%2Fa-brief-history-of-ireland-in-33-great-delusions-1.3580854 (accessed on 29 March 2022).
29. O'Boyle, B.; Allen, K. *Tax Haven Ireland*, 1st ed.; Pluto Press: London, UK, 2021.
30. Dettoni, J. *The FDi Report 2021, Global Greenfield Investment Trends*; FDI: London, UK, 2021.
31. Eurostat. Foreign-Controlled Enterprises in EU: Value Added. Available online: https://ec.europa.eu/eurostat/web/products-eurostat-news/-/ddn-20200414-1 (accessed on 20 January 2022).
32. Molloy, G. The Role of Customer Centricity in Medical Device Innovation—An Irish Perspective. Master's Thesis, Institute of Technology, Sligo, Ireland, 5 September 2011.
33. Gerald, J.F. *Understanding Ireland's Economic Success*; ESRI: Dublin, Ireland, 1999.
34. Department for Business, Energy and Industrial Strategy. *Focus on Medical Technologies*; Government of Ireland: Dublin, Ireland, 2018.
35. Walsh, P. *Interview, Conducted by David McKernan*; MedTech Cluster: Dublin, Ireland, 2022.
36. Forfas. *Health Life Sciences in Ireland—An Enterprise Outlook*; Forfas: Dublin, Ireland, 2009.
37. Industrial Development Authority (IDA). *Facts about Ireland*; IDA: Dublin, Ireland, 2019.
38. Delgado, M.; Porter, M.E.; Stern, S.; Bathelt, H.; Feser, E.; Neffke, F.; Alcacer, J.; Kerr, B.; Murray, F.; Ketels, C.; et al. *Defining Clusters of Related Industries*; NBER: Cambridge, UK, 2014.
39. European Union. *Smart Guide to Cluster Policy*; European Union: Brussels, Belgium, 2016.
40. Halder, G. *The Surgical Instrument Cluster of Tuttlingen, Germany*; Institute of Development & Peace, Gerhard Merkatour Universitat: Duisburg, Germany, 2002.
41. Porter, M.E. *The Competitive Advantage of Nations Porter*; Springer: Berlin/Heidelberg, Germany, 1990.
42. EU-Japan Centre for Industrial Cooperation. *MAGIA Study on the Japanese MedTech Industry*; EU-Japan Centre for Industrial Cooperation: Brussels, Belgium, 2021.
43. Budden, P.; Murray, F. *An MIT Approach to Innovation: Eco/Systems, Capacities & Stakeholders*; MIT's Laboratory for Innovation Science & Policy: Cambridge, UK, 2019.
44. Chatterji, A.K.; Fabrizio, K.R. Does the Market for Ideas Influence the Rate and Direction of Innovative Activity? Evidence from the Medical Device Industry. *Strateg. Manag. J.* **2016**, *37*, 447–465. [CrossRef]
45. Industrial Development Authority (IDA). Medical Technology in Ireland IDA Ireland. Available online: https://www.idaireland.com/doing-business-here/industry-sectors/medical-technology (accessed on 11 February 2022).
46. Bruzzi, M.S.; Linehan, J.H. BioInnovate Ireland—Fostering Entrepreneurial Activity through Medical Device Innovation Training. *Ann. Biomed. Eng.* **2013**, *41*, 1834–1840. [CrossRef]
47. History—BioInnovate Ireland—Innovative Medical Device Training. Available online: https://www.bioinnovate.ie/what-we-do/history.html (accessed on 12 February 2022).
48. Mason, C.; Brown, R. *Entrepreneurial Ecosystems and Growth Oriented Entrepreneurship*; OECD: Paris, France, 2014.
49. Chatterji, A.K. Spawned with a Silver Spoon? Entrepreneurial Performance and Innovation in the Medical Device Industry. *Strateg. Manag. J.* **2009**, *30*, 185–206. [CrossRef]
50. Lynn, S.; O'Malley, P.; Tanner, D.; Moore, S. Refining Early Stage Interventional Composite Catheter Design. *Procedia Manuf.* **2019**, *38*, 282–290. [CrossRef]
51. Enterprise Ireland. Start a Business in Ireland. Available online: https://www.enterprise-ireland.com/en/start-a-business-in-ireland/startups-from-outside-ireland/why-locate-in-ireland-/ireland-is-a-dynamic-source-of-start-up-funding.html (accessed on 26 May 2022).

52. Yin, R. *Case Study Research Design and Methods*, 5th ed.; Sage: Thousand Oaks, CA, USA, 2016.
53. Achinas, S.; Horjus, J.; Achinas, V.; Euverink, G.J.W. A Pestle Analysis of Biofuels Energy Industry in Europe. *Sustainability* **2019**, *11*, 5981. [CrossRef]
54. Thema Swiss Exit: What Requirements Should EU Manufacturers MD Satisfy Now? Available online: https://www.thema-med.com/en/swiss-exit-what-requirements-should-eu-manufacturers-of-medical-devices-satisfy-now/ (accessed on 29 May 2022).
55. Posen, A.S. Trade Protectionism. Available online: https://www.cfr.org/podcasts/trade-protectionism-adam-s-posen (accessed on 10 August 2022).
56. Erixon, F.; Guildea, A.; Guinea, O.; Lamprecht, P. *China's Public Procurement Protectionism and Europe's Response: The Case of Medical Technology*; ECIPE: Brussels, Belgium, 2021.
57. Melvin, T.; Torre, M. New Medical Device Regulations: The Regulator's View. *EFORT Open Rev.* **2019**, *4*, 351–356. [CrossRef]
58. The European Association Medical Devices—Notified Bodies. *Notified Body Position Paper*; TEAM-NB: Sprimont, Belgium, 2021.
59. Darrow, J.J.; Avorn, J.; Kesselheim, A.S. FDA Regulation and Approval of Medical Devices: 1976–2020. *JAMA* **2021**, *326*, 420–432. [CrossRef]
60. Johnson, C.; Mccaney, J.; Ulmer, K.; Eichelberger, M.; Lawyer, P.; Trommer, G.; Rosenberg, B. *Interstates and Autobahns Global Medtech Innovation and Regulation in the Digital Age*; BCG: Boston, MA, USA, 2022.
61. Smith, K. Section 232 Tariffs on Steel & Aluminum. Available online: https://www.strtrade.com/trade-news-resources/tariff-actions-resources/section-232-tariffs-on-steel-aluminum (accessed on 21 May 2022).
62. European Commission. Paris Agreement. Available online: https://ec.europa.eu/clima/eu-action/international-action-climate-change/climate-negotiations/paris-agreement_en (accessed on 29 May 2022).
63. National Competitiveness Council. *Ireland's Competitiveness 2020*; National Competitiveness Council: Dublin, Ireland, 2020.
64. Boffo, R.; Patalano, R. *ESG Investing: Practices, Progress and Challenges*; OECD: Paris, France, 2020.
65. Eurostat Statistics Eurostat. Available online: https://ec.europa.eu/eurostat/databrowser/view/LC_LCI_LEV__custom_1956891/default/table?lang=en (accessed on 23 January 2022).
66. European Commission. Questions and Answers on Minimum Corporate Taxation. Available online: https://ec.europa.eu/commission/presscorner/detail/en/qanda_21_6967 (accessed on 24 January 2022).
67. Amador, F. *Peripheral Vascular Devices Market Analysis, USA*; IMD: Toronto, ON, Canada, 2018.
68. Wilson, B. GPO & IDN Sales Process: Unraveling Affiliations and Identifying Decision Makers—Carevoyance. Available online: https://www.carevoyance.com/blog/gpo-and-idn-sales-process (accessed on 20 January 2022).
69. Worldometer. World Demographics 2020 (Population, Age, Sex, Trends). Available online: https://www.worldometers.info/demographics/world-demographics/ (accessed on 22 January 2022).
70. Central Statistics Office. Level of Education—CSO. Available online: https://www.cso.ie/en/releasesandpublications/ep/p-cp10esil/p10esil/le/ (accessed on 22 January 2022).
71. Institute for Management Development. *IMD World Competitiveness Yearbook 2019*; IMD: Lausanne, Switzerland, 2019. ISBN 9782970108542.
72. Murakami, Y.; Morgan, D. *Focus on Health Spending*; OECD: Paris, France, 2016.
73. Krys, C.; Born, D. *Megatrend 1 People & Society*; Roland Berger: Munich, Germany, 2021.
74. van Poucke, A.; Baran-Chong, R. *2021 Healthcare CEO Future Pulse*; KPMG: Newark, DE, USA, 2021.
75. Intelligent Implants. Available online: https://intelligentimplants.ie/ (accessed on 25 May 2022).
76. Ernst & Young. *Pulse of the Industry: Medical Technology Report*; Ernst & Young: New York, NY, USA, 2020.
77. Saber, H.; Navi, B.B.; Grotta, J.C.; Kamel, H.; Bambhroliya, A.; Vahidy, F.S.; Chen, P.R.; Blackburn, S.; Savitz, S.I.; McCullough, L.; et al. Real-World Treatment Trends in Endovascular Stroke Therapy. *Stroke* **2019**, *50*, 683–689. [CrossRef]
78. Goodney, P.P.; Beck, A.W.; Nagle, J.; Welch, H.G.; Zwolak, R.M. National Trends in Lower Extremity Bypass Surgery, Endovascular Interventions, and Major Amputations. *J. Vasc. Surg.* **2009**, *50*, 54–60. [CrossRef] [PubMed]
79. Casey, B. *Ireland's Industrial Policy in an Integrated Global Economy: The Case of the Celtic Tiger in the 1990s*; University of Cape Town: Cape Town, South Africa, 2004.
80. Barry, F.; Van Egeraat, C. The decline of the computer hardware sector: How Ireland adjusted. *Q. Econ. Comment.* **2008**, 38–57.
81. Lo, C. Inside Costa Rica's Super-Sized Medical Device Sector. Available online: https://www.medicaldevice-network.com/features/inside-costa-ricas-super-sized-medical-device-sector/ (accessed on 18 March 2022).
82. Moran, T. *Challenges Developing a Digital Marketing Roadmap for a MedTech Startup in Ireland*; National College of Ireland: Dublin, Ireland, 2020.
83. Kuuskvere, L.; DelConte, A. The Medical Device Industry in Ireland: Creating an Environment for Innovation (When Academia, Government, and Industry Collaborate). *J. Med. Mark.* **2018**, *16*, 74–78.
84. Fennelly, D.; Cormican, K. Value Chain Migration from Production to Product Centered Operations: An Analysis of the Irish Medical Device Industry. *Technovation* **2006**, *26*, 86–94. [CrossRef]