**MICROECONOMICS** of **COMPETITIVENESS** 



AN AFFILIATE NETWORK OF HARVARD BUSINESS SCHOOL

# **MedTech Cluster in Galway Region**

Microeconomics of Competitiveness

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## **1. Introduction**

Since the appearance of the COVID-19 global crisis, MedTech clusters have gained increased consideration. When the pandemic brutally hit unprepared hospitals, the industry rapidly adapted its production lines to support medical staffs with ventilators and other items strictly related to the cures of the coronavirus. Despite this worldwide exceptional situation, the MedTech cluster situated in Galway, has always been a key hub for this industry, which is in a constant growth, particularly enabled by the universities and research centers.

The report contains a profound analysis of the different and various facets of the MedTech cluster of Galway, and it has been structured as it follows. The first chapter describes the country of Ireland with a depth view on Galway region and its economy performance. The second chapter analyses the MedTech cluster, divided into five parts: the overall presentation of the cluster, an analysis of Porter's five forces, the cluster mapping, the MedTech's diamond and the performance and activities of the cluster. The third chapter examines in depth the situation of the COVID-19, having a closer look on the MedTech cluster. The last chapter presents the strategic issues and the recommendations on the region and cluster level.

## 2. Economic Performance of the Country (Region)

## 2.1 Presentation of the Country

Galway is a city located in the West Region of the Republic of Ireland, in the province of Connacht. It is a thriving port city, situated on the Corrib near Galway Bay, and it is surrounded by County Galway. Galway is the 4- largest city in the Republic of Ireland. Concerning the demographics (World population, 2021), Galway has a population composed of 81.4% of Irish, 2% of English, 6.3% of Polish or Lithuanian, 5.2% of other EU nationalities, 5.1% of other nationalities. The ethnic groups are divided into 91.1% White, 3.3% Black, 3.2% Asian, 2.4% other. In the early 2000s, an enormous number of immigrants moved to Galway and the non–Irish population reached an approximately 20% of the region's inhabitants. Slightly more than the half of this group (almost 11%) were White Europeans, coming from Central European and Baltic States, such as Latvia, Poland, and Lithuania. A small number was covered by Asian and African immigrants from each Africa, Nigeria, Sri Lanka, and Zimbabwe. The 2016 latest Census reported a population of 79,934 inhabitants living in Galway.

an expected increase rate of 5,3% per year, the city should have hit the 100,000 inhabitants in 2021, making it the fourth most populous city in the Republic of Ireland (World population 2021).

Talking about the history of Galway, the first record goes back to 1124, when a fort was built there. In 1170 - 71, the English invaded the Eastern Ireland and in 1232, the baron named Richard de Burgh took the area and created a town; after the year 1270, Galway was encircled by walls. For centuries the city had been dominated by 14 families, which were the tribes of Galway; the mayor and the leading citizens came from them (Lambert 2021).

In the Middle Ages, Galway covered an important role for its harbour, especially for the imports of wine and the exports of wool, skins, and leather. At that time, the leading citizens were English; but in the 14<sup>a</sup> and 15<sup>a</sup> centuries, the English kings began to gradually lose control of Ireland (not in Dublin and the surrounding Pale) (Lambert 2021).

In 1473 and in 1500, there were two serious fires, which were dangerous because most of the buildings were made of wood (Lambert 2021).

In the 16- century, Galway was a prosperous city and port. In 1543, the St Bridget's Hospital was built, because the city suffered from an outbreak of sweating disease, which caused many deaths. In 1545, new charters were given, which extended its jurisdiction to the Aran Island. in 1584, the Spanish Arch was built, and nearly the 1600, the Lynch's Castle was constructed. In 1610, James I donated to Galway another charter, making his own right on the city and the land of 2 miles around the county. In 1649, an epidemy hit the city, which caused a heavy number of deaths. Two years later (1651), the English, conducted by the general Edmund Ludlow, laid siege to Galway, which surrendered after one year of long siege. During the 17- and the 18- century, the Irish city continued to be prosperous, thus, in the late 18-century, the suburbs grew outside the walls (Lambert 2021).

Due to the potato famine, occurred from the 1845 to 1849, the population considerably decreased. In fact, at the beginning of the 19<sup>a</sup> century, Galway counted around 5,000 people, but this number fell during the considered period. Galway Courthouse was built, and in 1818, the Salomon Weir Bridge was constructed. In 1849, the Queens College Galway was opened. In this century, an important number of inhabitants of Galway lived in poverty (Lambert 2021).

In the 20<sup>a</sup> century, Galway flourished: by the 1950, the city had a population 21,000 people; the port was busy (exports included farm products, wool, and marble). The industries produced iron, milling, furniture, and hat making. At the end of this century, other modern industries replaced the traditional ones: engineering, IT, and electronics (Lambert 2021).

#### **2.2 Economic situation**

Unemployment rate %

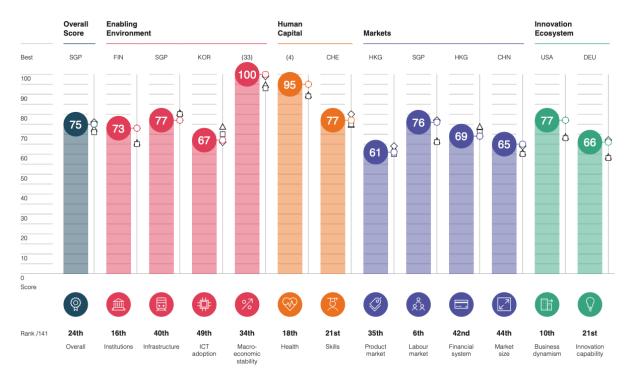
According to Douglas Broom, a senior writer who wrote an article on the world economic forum website (WEF) in 2019, the economic growth rate of Ireland was the second highest in Europe. Although Ireland's economy was one of the hardest hit nations by the economic crisis occurred in 2007/2008, it has bounced back. In 2019, Ireland's economy outperformed most other countries of the Eurozone with almost full employment and rising real wages (Broom 2019).

A particular attention has to be taken for the Brexit situation, and its effects. Recent research conducted in March of 2019, by the Irish Economic and Social Research Institute (ESRI), found that although Irish life satisfaction scores remain above the OECD average, Irish consumers are deeply worried. One of the main concerns of them is Brexit. Austin Hughes, Chief Economist at KBC Bank Ireland, one of the authors of the report, said that a drop of 12.3% in the Consumer Sentiment Index occurred in February 2019. It was among the sharpest in the 23 – year history and the lowest level since November 2014. Economists agreed that the consequences in Ireland of an unmanaged Brexit could be even more severe than the ones in the United Kingdom and the rest of the Europe. Hughes said that the worst was yet to come if the United Kingdom exits the European Union without a deal, especially regarding the exports to the UK and the revenue from the UK tourists (ESRI, 2019).

Figure 1: Ireland Global Competitiveness Index, 2019 Edition

Ireland		24t	
Global Competitiveness Index 4.0 2019 ec	lition	Rank in 2018 edition:	23rd/140
Selected contextual indicators Population millions	4.9	GDP (PPP) % world GDP	0.29
GDP per capita US\$	76,098.6	5-year average FDI inward flow % GDP	17.7
10-year average annual GDP growth %	5.6		
Social and environmental performanc	e		
Environmental footprint gha/capita	5.6	Global Gender Gap Index 0-1 (gender parity)	0.8
Renewable energy consumption share %	9.1	Income Gini 0 (perfect equality) -100 (perfect inequality)	31.8

5.7



**Performance Overview** Key ◇ Previous edition △ High-income group average □ Europe and North America average 2019

According to the Global Competitiveness Index of 2019, Ireland ranked at the 24<sup>s</sup> place out of 141, with an overall score of 75, which is slightly better compared to the average data of Europe and North America. However, it lost one position compared to the previous year (23<sup>s</sup> in 2018).

In 2019, Ireland had a population of 4.9 million people and a GDP per capita of 76,098.6 US\$, with a 10 - year average annual GDP growth of 5.6%. Looking at the social and environmental performance, Ireland had an unemployment rate of 5.7%; an income Gini of 31.8 (0 is perfect equality and 100 is perfect inequality); and a Global Gender Gap Index of 0.8 (0 – 1 gender parity).

Looking in more depth at the performance overview, the overall score is reached by the analysis of four main categories which are enabling environment, human capital, markets, and innovation ecosystem. The first one is divided into institutions, which ranked 16<sup>a</sup>, with a transparent and efficient framework (73 out of 100); the infrastructure, which ranked 40<sup>a</sup> (77 out of 100); the ICT adoption, which ranked 49<sup>a</sup> (67 out of 100). Ireland benefits from a stable macroeconomic environment with a score of 100 out of 100 (34<sup>a</sup>). The second category is split into the health, which ranked 18<sup>a</sup> (95 out of 100); the skills, which ranked 21<sup>a</sup> (77 out of 100). The third category shows that Ireland has a stable and organized markets system, compared to the average of Europe and North America. The product market ranked

 $35^{\circ}$  with a score of 61 out of 100; the labor market ranked  $6^{\circ}$  (76 out of 100); the financial system ranked  $42^{\circ}$  (69 out of 100); the market size ranked  $44^{\circ}$  (65 out of 100). The fourth category illustrates that Ireland is an innovative country and it implements continuous innovation. The business dynamism ranked  $10^{\circ}$  (77 out of 100) and the innovation capability ranked  $21^{\circ}$  (66 out of 100) (WEF, 2019).

According to the IBEC Quarterly Economic Outlook (IBEC, 2019, p. 1), the Irish economy has recorded several years of strong, sustainable growth. This growth has been underpinned by growing business investment, rising employment and wages, moderate inflation, and a rapid improvement in household balance sheets. In the next coming years, a more moderate growth will occur. The company's expansion plans must face significant capacity constraints that materially impact in the labor market. Because of growing congestion in areas like transport, housing, and childcare, attracting and retaining workers is becoming more difficult. These constraints have a binding effect on growth. Business decision makers must globally weigh trade tensions and an uncertain global economic environment.

The sustainable progress performance of a country can also influence its economic perspectives. It enlightens sectors that can be improved to enhance people's life and environment. At the EU15 level, Ireland is ranked 10<sup>th</sup> out of 15 on the Sustainable Development Goals (SDGs) Index. The Sustainable Progress emphasizes that Ireland has significant challenges to overcome in five out of 17 SDGs, namely SDG 7 "Affordable and clean energy", SDG 12 "Responsible consumption and production", SDG 13 "Climate action", SDG 14 "Life below water and finally SDG 9 "Industry, Innovation and Infrastructure" (Clark et al., 2020, p. 63). Improving measures in those domains may also foster innovation and economic as well as social development.

## 3. Analysis of the MedTech Cluster

#### **3.1 Presentation of the MedTech Cluster**

#### 3.1.1 Outline of the MedTech Cluster

Galway is the most important MedTech cluster of the country (Murray, 2018). The region has a solid ecosystem of medical technology start-ups, multinationals and research centers that account for approximately 31% of all medical device employment of the country. The largest employers are Medtronic and Boston Scientific, two US based subsidiaries which employ almost 20% of the workforce. In addition to the international reputation of these two multinational corporations (MNCs), the medical device cluster in Galway occurs through university-industry linkages, highly skilled

workforce, the growth of supplier firms and knowledge transferred with start-ups. Galway has become particularly recognized for its specialization in coronary medical devices, mostly regarding the production of drug-eluting stents.

#### **3.1.2 Attraction of MNCs**

In the book *On Competition* (2008, p. 205), Porter argues that tax incentives can be a very powerful tool for raising the rate of sustained investment in an industry. It is exactly this policy that followed Ireland to attract foreign direct investment, into sectors that were emerging with high-performance potential. The benefits of attracting MNCs are to provide well-paid jobs, superior skills, technology and opportunities for local linkages and exports (Fahy, Giblin & Green, 2008, p. 69). The medical technology sector was strategically targeted by the Industrial Development Agency (IDA), a dedicated state sponsored industrial development agency. Therefore, the MedTech cluster has been a major recipient of inward FDI (Fahy, Giblin & Green, 2008, p. 111).

In Galway, the first investments made in medical technology were recorded in 1973, one year after the Ireland's EU membership. But it is the arrival of the two US subsidiaries CR Bard, in 1982, and Boston Scientific, in 1994, that enabled the Galway-based MedTech cluster to grow and develop organically (Evers & Giblin, 2018, p. 112). Additionally, following a national spatial strategy, IDA Ireland granted aids to promote the establishment of FDI companies outside of the Dublin area (Fahy, Giblin & Green, 2008, p. 67). In particular, the special support for medical technology and ICT companies that was made available from 1994 onwards accelerated the development of Galway's MedTech cluster.

#### 3.1.3 Development of the Cluster

CR Bard, which was later acquired by Medtronic, and Boston Scientific implanted their subsidiaries in the west of Ireland with the primary purpose to solely manufacture facilities (Evers & Giblin, 2018, p. 112). They were attracted by the low corporate tax rate and special grant aid incentives.

As expressed by Michael Porter in *On Competition* (2008, p. 202), governments have the responsibility to produce competitive advantage through advanced and specialized factors. Policy agencies from IDA Ireland and Enterprise Ireland have contributed to "move up the value chain" in order to encompass more knowledge-intensive activities (Fahy, Giblin & Green, 2008, p. 76). In addition to massive investments in the third level education system, various programs have been implemented to encourage the stickiness and sustainability of the sector. The establishments of R&D facilities in local FDI subsidiaries, linked to regional development agencies and universities, aimed to support intellectual property protection, technology transfer and the commercialization of research output. Over time, these

subsidiaries were involved in product designing and developing the next generation devices, boosting R&D activity in the region (Evers & Giblin, 2018, p. 112).

The presence of CR Bard and Boston Scientific has attracted further FDI and MNCs and has strengthened the MedTech cluster ecosystem to stimulate rapid spread of indigenous entrepreneurship. As a result, the product line of the cluster became richer. In addition to the cardiology-related products, in Galway other devices are produced in the areas of muscle and nerve stimulators, soft tissue implants, and pulmonary drug delivery system (p. 113). Porter (2008, p. 200) outlines that the entry from other industries within the cluster enable to further stimulate and diversify R&D approaches and facilitates the introduction of new strategies and skills.

## 3.2 The Five Forces shaping competition in the industry

The five forces model of Porter is a major model drawn from industrial organization, which enables to determine the competitive intensity within a sector and consequently its profitability (Porter, 2008, pp. 3-4). According to the model, industry's structure is shaped by the five following forces: rivalry among competitors, bargaining power of suppliers, the bargaining power of customers, the threat of potential new market entrants and the threat of substitute products.

## 3.2.1 Rivalry among Existing Competitors - Strong

For Porter (2008, p. 18), there are two "degree(s) to which rivalry drives down an industry's profit potential". The first one is the intensity with which companies compete and the second is the basis on which they compete.

In the MedTech industry, there are a lot of firms that compete. Since the end-users of MedTech firms are located globally, Galway cluster's firms also compete with firms located all around the world. Ireland, being part one of the largest exported medical products in Europe (Irish MedTech Association, n.d.), it mainly exports to the EU countries. Therefore, the scope of competition contains principally MedTech firms located in other countries of the European economic area. In 2020, nearly 33'000 MedTech enterprises in Europe employed more than 760'000 people (MedTech Europe, n.d. a).

The growth of the industry also plays a role in the intensity of the rivalry; with a forecast of around 5% of growth for 2020, 2021 and 2022 which can be defined as a relatively normal growth. The companies are more susceptible to compete on price when the growth is slow (Evaluate, 2017).

The basis of the competition is the second degree of rivalry. Hospitals face low switching costs regarding medical devices. In some key markets, there is no large differentiation between the products. This would lead to a considerable competition on price which hinders the industry profitability.

The uncertainty about potential health care reforms can also increase the rivalry between the MedTech enterprises due to the confusion it creates. These reforms could possibly change the dynamics of the industry.

In addition, Deloitte designates that firms do not only compete on their products, but also on attracting investors (Deloitte, n.d.). Early-stage MedTech companies need significant capital to grow, but investors may be more willing to invest in technologies that have proven to be commercially successful and generate enough return.

Taking into consideration those observations, the rivalry of the MedTech industry appears to be especially strong.

#### 3.2.2 Bargaining Power of Suppliers – Moderate

In the book *On Competition* (2008, p.13) it is said that: "Powerful suppliers, [...], can squeeze profitability out of an industry that is unable to pass on cost increases in its own prices".

There are different types of suppliers in the MedTech industry. The raw materials producers are one of them. It includes suppliers of stainless steel, silicon, latex rubber, plastics and all the materials that are necessary to manufacture medical devices. Those suppliers cannot really negotiate their prices because they must follow the market. Thus, the medical devices companies are not facing a lot of switching costs with them (Essay, UK, 2018).

The second type of suppliers are those that provide special materials. Such suppliers are generally large enterprises and have a large market power and, therefore, a strong bargaining power on prices (ibid.). Looking at both types of suppliers, the bargaining power of suppliers can be said moderate in the industry.

#### 3.2.3 Bargaining Power of Buyers – Moderate

Buyers can influence a health industry by "forcing down prices, demanding better quality or more service, [...], all at the expense of industry profitability" (Porter, 2008, p. 14)

The end-users in this industry are hospitals, physicians, and practitioners in the health domain. With orthopedic appliances the buyers are generally wholesalers that work as intermediaries between the medical device producers and the end-users. In this branch of the industry, the wholesalers can obtain a kind of bargaining power (Maresova & Kuca, 2014). However, the Irish MedTech Association (2017,

p. 9) shows that the relationship between MedTech companies and physicians has become more complex and less direct, as hospitals begin to group together. The formation of hospital groups has led to an increase in purchasing power for medical institutions, and the assigned procurement departments approach the buying process with a more commercialized focus compared to previous years.

Concerning the switching costs that buyers face, they can be considered relatively low due to the number of firms that operate in the industry. The E-Procurement of products increases knowledge of buyers of the products, allowing them to force down the prices. However, buyers are often looking for quality and reliability which reduce their bargaining power (Essay, UK, 2018). MedTech companies are required to offer more added value beyond pure products and services. With the view to secure customer lock-in through solid long-term partnerships, MedTech firms must gain a strong understanding of customer requirements (Ahmad & Bordon, 2019).

#### 3.2.4 Threat of New Entrants - Strong

There are many factors that can either increase or decrease the barriers of entry in an industry. The government regulation plays an important role. In Europe, it is going to be more difficult because of the revision of the Medical Devices Directive. This law is going to be replaced by the Medical Device Regulation that increases the standards of the medical devices in Europe. This is going to create new barriers at the entrants. In contrast, in the USA the law is trying to reduce the time and costs related to the creation of clinical evidence; typically, the most expensive and lengthy regulatory requirement for marketplace entry. Thus, it is underlined that the regulation of the state can strongly influence the ease of entrance into the industry (VascularNews, 2018).

The importance of the costs of R&D can also become a barrier to entry. Data shows that R&D represents around 7% of the revenue in the MedTech industry (Evaluate, 2018). Therefore, little companies could be suffering from this amount. For example, in Europe 95% of the companies involved in this industry are SMEs (MedTech Europe, 2019).

The requirements of capital are also one of the main criteria that influence the strength of the barriers to entry. The MedTech industry has been on an ascending grade in terms of investments: from 2012 until 2019 the amount of venture capital investments has nearly doubled (EY, 2020).

Taking those facts into consideration, it can be outlined that industry has an important threat of new entrants. Even if the regulation could perhaps hinder the European MedTech industry, the sector will continue to grow.

#### 3.2.5 Threat of Substitutes - Moderate

As defined by Porter (2008, p.17) a substitute "performs the same or a similar function as an industry's product by different means". Medicines and drugs are the substitutes in the MedTech sector, in fact medications have been found to be effective and less invasive in the treatment of certain kind of cardiovascular disease (Lewis, 2019).

As 80% of all the stents produced in the world are manufactured in Ireland, those drugs can be classified as substitute products (IBEC, n.d. a, p.5). Therefore, a depth analysis on them has to be made, yet substitutes are not extremely threatening because of the numbers of patents and licenses deposed. In 2020, more than 14'000 patents were deposed in the European MedTech industry (European Patent Office, 2020). Even though there are many patents, the substitutes continue to appear and develop. Nevertheless, the barriers to entry to the industry, such as the time taken to develop a product and to find the financial resources. It will not hinder the substitutes but slow their emergence (Maresova & Kuca, 2014).

Looking at those considerations, the threat of substitutes is moderate in this industry.

## 3.3 Cluster Mapping

Figure 2 represents the cluster mapping based on Ever & Giblin (2018). It reviews all the actors of the cluster and the links between them. In this section of the paper, all the actors will be presented.

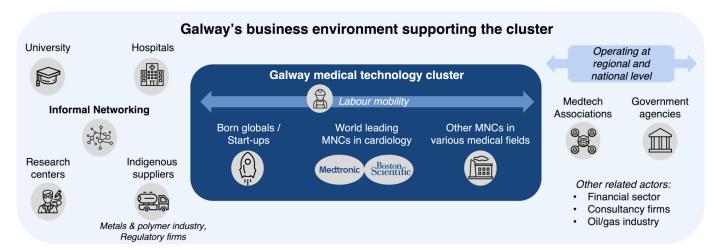


Figure 2: Composition of the Galway's MedTech cluster

Source: own representation based on Evers & Giblin, 2018, p. 113 and further sources

#### World leading MNCs in Cardiology

Porter (2008, p. 263) explains that specialization is an important component for clusters to the initially growth. As showed by Evers & Giblin (2018, p. 119), large MNC subsidiaries in a cluster are mainly driven by scale and hence specialized in a small number of product areas. Regarding the MedTech cluster in Galway, Boston Scientific and Medtronic subsidiaries concentrated their operations around cardiology-related devices (p. 117). Drug-eluting stents and components such as guide wired and hypotubes, are produced by these two MNC subsidiaries. IDA Ireland (n.d.-a) supports this view, stating that the Boston Scientific's subsidiary, based in Galway, was one of the company's hubs for excellence and development regarding Drug Eluting Stent and products that treat endovascular diseases. Regarding Medtronic, the company has a Centre of Excellence for Operations and R&D based in Galway to mainly support Global Cardiac & Vascular Businesses (Medtronic, n.d.).

#### **Other MNCs**

The medical technology industry is worldwide dominated by MNCs (Fahy, Giblin & Green, 2008, p. 76). Alongside with Medtronic and Boston Scientific, other multinational corporations are found, including for example Creganna Medical and Merit Medical. Many of these MNCs are involved in the production of cardiology-related devices; additionally, they produce products in the areas of muscle and nerve stimulators, soft tissue implants and pulmonary drug delivery systems (Evers & Giblin, 2018, p. 113).

#### Born Globals / Start-ups

Despite the strong MNCs presence, 90% of companies in the sector are SMEs (Evers & Giblin, 2018, pp. 108-111). Evers and Giblin underline that the nature of an industry is determined by the internationalization path of firms within the industry cluster. The technological strengths of a high-tech cluster can be easily accepted by global markets through their differentiated offers of products, leading to the Galway MedTech cluster to the creation of so-called born globals. Born globals are companies with a global mindset that seek to derive significant competitive advantage from the use of resources and the sale of outputs in multiple countries. Typically, born globals acquire at least 25% of foreign sales during its first year of trading (Evers and Giblin, 2018, p. 105).

In contrast to the foreign-owned MNC, born globals firms are relatively small in terms of employmentsize. Evers and Giblin (2018, pp. 115-117) assert that labor mobility within the cluster leads exemployees of the large MNCs subsidiaries to act as serial-entrepreneurs and to establish multiple born globals in the region. These entrepreneurs are also often investing and taking a position in the executive management of other born globals. Evers and Giblin (2018, p. 111) assert that in 2015, 10 out of 28 born globals were primarily engaged in developing product within the cardiovascular and endovascular space. In contrast to MNCs, they are focusing on niche areas like biomaterial solutions or materials for catheter-based medical devices. The other 18 companies are involved in activities which differ from the core cluster specialization. They notably produce devices in diagnostics, gastroenterology, urology, pulmonary, and respiratory areas.

The role of born globals is crucial to the sustainability of the cluster. Indeed, the rapid developments in technology and the short product life cycles of the MedTech industry can pose serious threats to the well-functioning of the cluster (Evers and Giblin, 2018, p. 110). The risk of technological lock-in, the lack of entrepreneurial innovation, and the overdependence on product specialization can lead to the exhaustion of the cluster. Born globals, by their size and situation, are more solid and strong than large MNCs to adapt to the cyclical developments in technological innovation, and their collaboration with MNCs enable the whole cluster to develop.

#### **Indigenous Suppliers**

Under indigenous suppliers, a depth analysis on the local focused suppliers that serve the MNCs, startups and spin off companies active in the medical technology sector of Galway, is conducted. Initially, indigenous suppliers mainly supplied the foreign companies, but with the development of the cluster, they also started to supply indigenous MedTech companies. In 2019, the CEO of 4Tech Cardio Tom Fleming stated:

"There are so many supply companies in Galway that understand the needs of the MedTech industry, from manufacturing to milling, extrusion, metals, sterilization and regulatory requirements on the supply chain." (IMA, 2019, p. 27).

The polymer technology is extremely important for the development of medical devices, especially regarding cardiovascular stents (Polymer Technology Ireland, 2018, p.1). Polymer can be seen as a niche area and it is basically the manufacturing and research of synthetic polymers, take plastics for instance. Large MNCs such as Boston Scientific and Medtronic outsource specific polymer parts to specialized companies. Some polymer Irish firms have become specialized for MedTech specialization and are also supplying MedTech firms outside of Ireland. The Galway region hosts 20 sites which are active in different processes involving polymer technology (Polymer Technology Ireland, 2018, p. 30). Regarding regulatory requirements, various consultancy firms provide support to regulatory compliance with other national or regional regulations. The need of professionals specialized in the regulatory affairs environment within the global medical technology industry sector is hugely intense,

that the National University of Ireland Galway decided to open a Master of Science addressing these specific issues (NUI Galway, n.d. c).

Many of these indigenous suppliers, as well as MedTech companies, also rely on suppliers which come from abroad. The 2020 financial report of Medtronic Ireland (p. 22) states that the company was using resins, other petroleum-based materials, and pulp as raw materials in some products. Therefore, the prices of oil and gas could significantly affect their costs for freight and utilities.

#### University

In order to provide the essential skilled workforce for MedTech companies, the National University of Ireland (NUI) Galway hosts several programs that directly support the cluster (Nathan Trust, 2019). The Bioinnovate program has been recognized as a global center for innovation of medical technologies and allows researchers, industry representatives and clinicians to work together in developing new medical technologies. The Bio-excel program, also based in NUI Galway, is dedicated to assist start-ups to expedite medical technologies into the marketplace. It provides companies with seed funding and the use of an innovative co-working environment.

#### **Hospitals**

Galway hosts two University Hospitals, a public hospital group and two private hospital institutions, which act as end-users and provide feedback on devices in terms of its profitableness and any changes that are needed, as well as the type of instrumentation required for the latest procedures or medical issues (Evers & Giblin, 2018, p. 114). Many physicians working in Galway are well-respected internationally and their network can be also an important asset for MedTech companies. In addition, patient-centric innovation approaches such as Design Thinking, used for example in the Bioinnovate program, require hospitals to closely collaborate with Medtech firms and R&D centers (Bioinnovate, n.d.)

#### **Research Centers**

Research centers enable the cluster to remain updated to the latest technologies and to keep improving in terms of innovation. Cúram is the research center for medical devices led by NUI Galway in collaboration with other national universities and institutes (Cúram, n.d.). It has been established to improve and enhance traditional medical devices and develop the next generation of medical implants, cell and drug device combination products. Cúram supports industry partners from the initial enquiry through to knowledge transfer and the identification of future projects. The Regenerative Medicine Institute (REMEDI) is a research center also established at NUI Galway that focuses on using stem cell and regenerative medicine technologies to treat human disease (NUI Galway, n.d. d). The partnership of REMEDI with companies operating in the medical technology area is central for commercializing the results in novel therapies, clinic trials and research.

The government is aware of the importance of R&D institutions and supports an extensive program of grant aid for RDI projects, including a 25% R&D tax credit designed to encourage companies to undertake additional RDI activity in Ireland. Ireland offers a strong and growing RDI environment, which is also complemented by a robust Intellectual Property regime. The country has been ranked 11<sup>a</sup> in global scientific ranking for overall quality of scientific research (IDA Ireland, n.d.).

#### *Government agencies*

Several state agencies represent the government part and act to enhance directly or indirectly the cluster. Enterprise Ireland is the government organization responsible for the development and growth of Irish enterprises in world markets (Enterprise Ireland, n.d.). Enterprise Ireland is supporting many programs and organization that are directly linked to the MedTech sector. For instance, it has also partnered with many Medtech actors to commercialize their products and reach global markets. Additionally, there is IDA Ireland, who is a state agency that encourages investment into Ireland by foreign-owned companies (IDA Ireland, n.d.-b). As there are many MNCs active in the medical technology sector that are subsidiaries from foreign firms, IDA Ireland has a central role in attracting foreign direct investment (FDI). The Health Innovation Hub Ireland (HIHI) works across the health sector with Irish businesses to develop new healthcare technologies, products and services (HIHI, n.d.).

#### **MedTech** Associations

The Irish MedTech Association (IMA) is the business association representing the medical technology sector (IMA). The association has more than 250 members located throughout Ireland, with the goal to promote and support an environment that encourages the growth of FDI multinationals and SME member companies (IMA, n.d.). The association delivers training and upskilling for MedTech professionals and is working closely with the government to enhance competitiveness within the MedTech sector.

#### Informal Networking

Porter explains in *On Competition* (2008, p. 242) that successful clusters depend on relationship building, which is an important characteristic of cluster development initiatives. Associations play a major role in the formation of networks; it can be highlighted that in Galway several events and congresses where stakeholders meet and tackle various issues regarding the industry. For instance, at the Medical Technology Ireland Expo and Conference that is going to take place in Galway, in September 2020, notably manufacturers, start-ups, academics, providers of subcontract services,

consultants and members of the government, are going to participate (Medical Technology Ireland, 2019).

Furthermore, Porter (2008, p. 395) explains that management skills can be enhanced through networking and partnering with companies that are part of the same cluster or have expertise in needed area. For the Galway MedTech cluster, Evers and Giblin (2018, p. 109) outline that the local network connections lead to labor pooling, access to specialized suppliers and knowledge spill overs. Therefore, MNC behavior in the cluster embraced born global entrepreneurship rather than prohibiting it (p. 118). Indeed, traditional MNC learned from born globals about new technological and market opportunities, while the born globals could access to international markets through MNCs.

In an analysis conducted in 2015 by McCormack, Fallon & Cormican (2015, p. 508), MedTech firms based in Galway were asked to indicate the category of partner within and outside the Galway MedTech cluster.

Figure 3: Internal and External Collaboration of actors	within the cluster
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Parties Internal to MedTech Cluster		Parties External to MedTech Cluster	
Competitors	2	Competitors	4
Knowledge Institutions	20	Knowledge Institutions	18
Consultants or Engineering Firms	14	Consultants or Engineering Firms	16
Suppliers	19	Suppliers	18
Customers	13	Customers	14
Hospitals	13	Hospitals	12
Patient Associations	1	Patient Associations	12
Financiers linked to Cluster	10	Financiers linked to Cluster	12
Other non-competitive Companies	10	Other non-competitive Companies	14

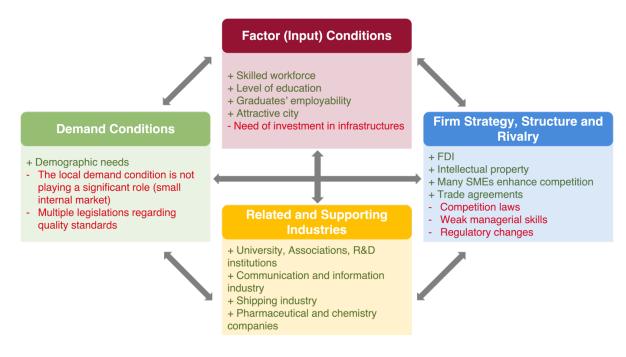
Source: own representation based on McCormack, Fallon & Cormican (2015, p. 508)

The strong networking highlighted by Figure 3 is a key element which explains why Galway's cluster is performing so well. Chapter 3.5 has a further overview of performance and activities of the Galway MedTech cluster.

## **3.4 Cluster's Diamond**

The Porter's diamond model has been used in order to understand the competitive advantage of Galway related to its MedTech cluster. The four dimensions of the diamond explain how firms compete within the region, and which role do the government and the hazard play (Porter, 2008, p. 182). Galway is an important pole for the small open economy that is Ireland. In some parts, the evidence of what happens at the national level is used to the Galway's region.

Figure 4: MedTech Cluster Diamond of Galway



Source: own representation from the authors, based on Porter (2008)

#### 3.4.1. Factor Conditions

From the mid-1990s to the late-2000s, Ireland experienced an economic boom referred as the Celtic Tiger period. This boom, mainly driven by the attraction of foreign direct investment (FDI) enabled the development of modern physical infrastructures, resulting in an increase in productivity. Ireland and Galway succeeded in creating factor conditions enabling the development and production of human-capital intensive goods and services. According to OECD, in 2020 Ireland was the second country with most GDP per hour worked after Costa Rica (OECD, 2021). Nowadays, the quality of Irish infrastructures is qualified low compared to other comparable countries (OECD, 2018, p. 4). The Irish MedTech association identifies that the MedTech sector requires the appropriate resources and a connectivity level. Therefore, the association suggests that the government invests in transport, broadband, water services, health, and education infrastructures throughout the country (IMA, 2017, p. 13).

The Celtic Tiger period also brought to Ireland a well-life quality which was necessary to attract and maintain high-skilled workers. Several newspapers, such as New York Times recently cited Galway as the friendliest and the most charming city in the world. Looking at human capital, Ireland is placed at the 19<sup>a</sup> rank by the World Economic Forum (2017, p. 8). The level of education in Ireland is high. In

Ireland, 47% of people aged 25-64 years old have a tertiary education, which represents one of the largest shares across the OECD (2019, p. 2). The National University of Galway is ranked as the third best University in Ireland and it belongs to the 1% of the top worldwide universities (NUI Galway, 2020). NUI Galway provides also a skilled workforce by virtue of a range of master's degree that are directly connected to the MedTech sector. In addition, IDA Ireland notices that Ireland is globally ranked as the number one in terms of the employability of its graduates (IMA, 2017, p. 27). While the education system related to the MedTech sector is performant, a survey from the Irish MedTech association indicates that the sector is lacking from crucial skills for the upcoming years. According to their report, the business functions where skilled workers are most researched are business excellence, scientists, R&D, regulatory and data analytics (IMA, 2017, p. 42).

Looking at the mobility, the relatively small distances between Irish cities allows mobility of goods and people, in addition to the strong connections and spread of information within different cities across countries. By its proximity to Dublin and Shannon, Galway is also internationally connected through their airports, which act as international gateways to Ireland. Nonetheless, Keogh (2017) notices that traffic congestion imposes costs on businesses by increasing journey times and hampers the attraction of skilled workers. Moreover, she notices that there are disproportions in the quality between the West and the East of the country regarding the infrastructures. Galway is located in the Western part and it is suffering from poor developed infrastructures.

#### 3.4.2. Firm, Strategy, Structure and Rivalry

Ireland has been ranked 10- by the World Bank in terms of net inflows of FDI in percentage of GDP (World Bank, 2020a). The low corporate taxes of 12,5%, the tax credit for R&D and the flexible regulations are consequences of the policy followed by the government since 1990s and it makes the country and Galway very attractive places for FDI. In particular, Ireland has a strong dependence to the US. According to an analysis conducted in 2019, Ireland is the first destination for FDI by US tech companies (Goodbody, 2019). As explained in chapter 3.1, the attraction of FDI is the trigger event that enabled Galway's cluster to initially grow. Moreover, although the recent global tax reform developed by the OECD could threaten Irish tax advantage and investments in MedTech, Ireland would still be a place that can attract FDI. As said former Central Bank commissioner and economic Professor John FitzGerald: "No firm could do better by leaving Ireland, so if 15% is everywhere you might as well be in Ireland and pay If the US implements the rules, Ireland could end up with more revenue." (RTÉ News, 2021).

In terms of innovation, the openness of Ireland facilitates the transfer of knowledge from abroad. Ireland has also been ranked 1<sup>st</sup> by the World Bank in terms of charges for the use of intellectual property (World Bank, 2018b). Innovation is a central aspect that drives the MedTech sector. This requires the appropriate level of focusing. In Galway, if the MNCs have large market shares, it still be denoted that more than 90% of the active companies in the MedTech sector are SMEs (Evers & Giblin, 2018, p. 111). Looking at mergers and acquisitions, Ireland follows the EU Merger Regulation. The Competition and Consumer Protection Commission is responsible for the enforce competition and consumer protection law in Ireland. In contrast to some other European countries, it does not exist a mergers control rule in Ireland that consider the value of the merger's transaction or the national security concerns (McCarthy, 2019).

The capacity of local firms to absorb and implement new technologies is hindered by relatively weak managerial skills (OECD, 2018, p. 4). Regarding the Galway's MedTech cluster, Evers and Giblin (2018, p. 122) notice that this especially occurs in born globals. Once the technology of born globals has been fully commercialized, they tend to opt for foreign MNCs acquisition rather than growing them independently as born global firms. The authors notice the lack of national policy that should develop and incentivize born globals to grow the venture internationally or employ a manager who can be in charge for it. The Irish MedTech Association mentions that mergers and acquisitions, in the MedTech sector, have recently decreased due to new business models and financing (IMA, 2019).

The Irish MedTech Association reveals that the MedTech sector is experiencing current regulatory changes at an unprecedented and relentless pace (p. 25). These changes may include quality management system, health IT, and cybersecurity or technical considerations related to the manufacture of 3D printed devices. Since changes are coming from different jurisdictions, regulators do not necessarily consider the cumulative impact on MedTech manufacturers that have products in multiple global markets. To be able to bring new and innovative medical products to global markets, firms are seeking for regulatory talent which better understand the implications of the rapid changing regulatory landscape. As mentioned in chapter 3.3, NUI Galway opened a specific program to create workforce in that specific area.

#### 3.4.3. Related and Supporting Industries

Besides universities, R&D institutions and MedTech associations, that we presented for the cluster mapping in chapter 3.3, we denote also three other industries, which are related and supporting the

MedTech cluster: communication and information industry, the shipping industry and pharmaceutical and chemistry companies.

#### **Communication and Information Industry**

With the top 10 global Information and Communication Technology (ICT) companies located in Ireland, the country has a strong reputation in that area (IMA, 2017, p. 9). In the country of Galway, 196 enterprises are active in that sector. This concentration of firms generates strong incentive to support high-tech industries globally. As explained in 3.4.2, the demand for connected medical devices is going to increase in the coming years. Data management is an important trend since the MedTech actors expect that in the future patients will be more involved in their healthcare. Therefore, cooperation between MedTech actors and ICT companies become crucial for the cluster to be competitive. The Galway City Innovation District (GCID) is an innovation park that has been created to support the global and interdisciplinary high-tech orientation of the city.

#### **Shipping Industry**

As an island-based economy, maritime transport represents the lifeblood of Irish industry with 99% of all Irish imports and exports travelling by sea (SEMRU, 2019, p. 70). The Irish shipping market connects Irish industry and its economy with the world. Maritime commerce is the main element of the ocean economy that, in 2018, represented about 2% of national GDP. In order to ensure and enhance patient and clinician access to reliable and effective medical technologies, MedTech companies often engage third parties to assist with sales and distribution (MedTech Europe, n.d. b). Traceability is an important component and it is tightly regulated. The new Medical Devices Regulation of the EU requires that distributors and other authorized representatives should cooperate with manufacturers to achieve an appropriate level of traceability of devices (HPRA, 2018, p. 17)

#### Pharmaceutical and Chemistry Companies

Ireland's drugs and medicine exports have been ranked the 6<sup>a</sup> of the overall worldwide exports, with a total of 5.8% market share (World's top export, 2020b). As it is for the MedTech sector, pharmaceutical companies are implemented in the major cities of the country where they gain access to the well-educated workforce. The industry is mainly dominated by foreign companies and 24 of the world's top pharmaceutical and biopharmaceutical companies are located in Ireland (IMA, 2017, p. 27). In the past years, the collaboration between the MedTech sector and pharmaceutical companies resulted in several investments around drug delivery and drug device combination.

#### 3.4.4. Demand Conditions

Like the most advanced economies, Ireland is experiencing a major shift in demography with the aging population and the rise in obesity levels. In Ireland, about 40% of its population is expected to have a chronic disease (IMA, 2017, p. 19).

Since the internal market of Ireland is limited by its population of 5 million citizens, the external market is more important. Ireland is the second country of the OECD after Luxembourg, where demand relies most on the other countries. Indeed, its overall exports, in 2019, accounted for 127% of Ireland's gross domestic product (OECD, 2020). In terms of export sales, the United States is the biggest trading partner of Ireland, representing approximately 30% of all Irish exports in 2019 (World's Top Exports, 2020a). Regarding the MedTech, in 2019, Ireland enterprises signed a strategic partnership with the leading US healthcare provider AdventHealth, allowing Irish MedTech companies to access to the key market leaders in the US (McCall, 2019). The MedTech cluster of Galway has also an access to the American market, since the two largest firms are subsidiaries from US companies.

Moreover, Ireland trades with the United Kingdom and with the European Union. In order to be able to place a product on the European market, manufacturers of the MedTech sector must observe the requirements of all EU legislation. This is mainly related to clinical trial data, safety and performance of devices through their lifetime (MedTech Europe, 2019, p. 8).

#### 3.4.5 Diamond as a System

Porter said (2008, p. 325): "Together the four types of location-based advantages in the diamond constitute a dynamic system more important than its parts". In Galway, all facets of the diamond are interrelated. The innovation is a key element in the MedTech industry. A survey recently conducted shows that 73% of the Irish MedTech respondent enterprises increased their R&D expenditures during the last five years. (Irish MedTech Skillnet, 2019, p. 2). In order to follow the R&D, skilled people must be trained. The NUI Galway provides many skilled individuals for the MedTech industry. The graduates have one of the largest employability rates in the world (IMA, 2017, p. 27). The interconnectivity of the facets comes also with the demand condition. As the 40% of the population is expected to have a chronic disease (IMA, 2017, p. 19), the MedTech cluster has a great potential demand. Moreover, the Internet of Things is expected to grow more and more in the medical device sector. The related and supporting industries are extremely relevant, especially the Communication and Information industry.

ones because they are interrelated, thus they allow the region to compete in the global MedTech industry.

## 3.5 Performance and Activities of the Cluster

The MedTech sector in Galway suffers from a lack of data which evaluates the performance. Some insights can be found and by using the national performance of the MedTech industry, the presentation of the Galway MedTech cluster performance can be obtained. In terms of employment, Ireland MedTech sector was the first employer per capita in Europe with 79 employees per 10'000 inhabitants, in 2017 (MedTech Europe, 2019, p. 19).

With 39% of the entire MedTech workforce Galway is viewed as the most important MedTech cluster in Ireland. (Innopharma Education, n.d.). As said before a large proportion of companies are SME (Evers & Giblin, 2018, p. 111). The rest of employers are MNCs with 8'333 people employed by three large companies that operate in Galway: Medtronic, Boston Scientific and Creganna (Armstrong, 2018). Nevertheless, the growth of the workforce between 2006 and 2015 occurred in little Irish-owned companies (261%) rather than in MNCs (16.9%) (Evers & Giblin, 2018, p.112). Galway MedTech cluster has also known an increase in job searchers mainly coming from Dublin (increase of 70% since 2015) (*ibid*.).

In terms of results, it is noted that the Irish MedTech industry performs as the second-best exporter of medical technologies in Europe with an annual number of 12.6 billion of euros, which represents 8% of the total Irish exports (IDA Ireland, n.d. c). The global MedTech market is expected to annually grow by 4.1% and Ireland will also benefit of this growth on account of its extremely innovative sector (Irish MedTech Skillnet, 2019, p. 2).

In such an innovative sector, numbers of patents delivered can be a great performance information. A study conducted by O'Cearbhaill et al. (2019) shows that Ireland was ranked 5<sup>th</sup> in the patents granted per head which increased from 0.7% to 0.9% in ten years. Last year, Ireland expanded its patent application by 6.3%. in 2019, medical devices patents application represented 19% of all Irish applications. From this 19%, the NUI Galway ranked 2<sup>nd</sup>, right behind Accenture PLC a multinational professional services company (Gorey, 2020).

## 4. COVID-19

In March 2020, Ireland, similarly to many other European countries, had announced a general confinement for their inhabitants to stop the propagation of the COVID-19. Since this announcement, Ireland has faced three additional waves of the pandemic, taking drastic measures and restrictions to contain the spread of the virus and its impact on the population. These measures have hit the Irish economy and the MedTech sector has not been spared. The four facets of the diamond have been affected and in contrast to some other industries, the virus can be perceived as a chance for the Galway MedTech cluster in various ways.

#### 4.1 Factors Conditions

The general confinement, social distancing as well as illness cases have decreased the availability and the productivity of the workforce. Firms have responded by a reduction of working hours, following the switch of the demand factor. Indeed, measures taken by the government require that products, which are not considered to be essential, are not produced anymore. One of the main issues of the medical device sector is the lack of employees who can construct the devices demanded, in order to avoid the disrupt of the production (Carswell, 2020a). Following the demand of ventilators, Medtronic has increased its workforce in the manufacture of this device by updating the working hours to a 24/7 plan (Carswell & Hamilton, 2020).

The European Commission warned that the actual crisis can lead to "attempts to acquire healthcare capacities (for example for the productions of medical or protective equipment) or related industries such as research establishments (for instance developing vaccines) via foreign direct investment" (McCannFitzgerald, 2020). Therefore, FDI becomes a central issue from a political point of view. Politicians and governments are judged by their capacity to handle this crisis and by protecting its population, thus FDI can be seen as a loss of power that could potentially harm citizens. In April 2019, the Irish Government decided not to follow the EU Regulation on screening of foreign direct investment for possible security and public order risks, but now it considers to apply some intern guidelines to ensure the sustainability of its healthcare capacities. and screen FDI (Fieldfisher, 2021).

FDIs have also been affected by the virus. As many enterprises implemented travel restrictions for their executives, visits of Irish firms have been slowed down. However, after a substantial decline of investment in 2020, investments recovered substantially (IDA Ireland, 2021). Indeed, 142 investments

have been undertaken during the first semester of the year 2021, and 62 of them were financing new projects, creating about 12'530 new job positions.

#### 4.2 Context for Firm's Strategy and Rivalry

The heart of the cluster has also been impacted by this crisis. While Galway was firstly famous for its production of coronary medical devices, at the beginning of the crisis the production of respiratory devices was in full swing. Half of all ventilators present in the world were manufactured in Ireland. The CEO of Aerogen, which is a firm that produces non-invasive ventilation systems, expects to double its shipments compared to 2019 due to the global shortage of ventilators (The Irish Advantage, n.d.a). "Innovation often requires pressure to succeed" (Porter, 2008, p. 180). The COVID-19 has spurred the innovation and forced leading companies of the cluster to tackle these issues. At a national level, Ireland was ranked 6th in a global study, looking at the innovation responses to COVID-19. Just after the COVID crisis began, in April 2020, more than 100 projects were concerning innovation to fight against the virus and its implications, especially in Personal Protective Equipment (PPE) and diagnosis (Kennedy, 2020). Innovation also occurs in the utilization of medical devices. To face the shortage of ventilators in intensive medical units, NUI Galway has developed adjustable ventilators that treat two patients at the same time (NUI Galway, n.d.a). The Galway-Mayo Technology Institute works on the production of face visors using 3D printers and it is now able to provide Galway hospitals with 20'000 units per week (GBFM News, 2020). In addition, the virus has opened new opportunities for actors of this cluster. In 2016, NUI Galway became the host of a long-term collaboration between Aquila Bioscience, an Irish start-up active notably in immunology and the Irish Defense Forces to develop a novel decontamination wipe. While the product was originally developed for defense purposes, researchers found that it has a specific chemistry which also captures the virus. Therefore, the wipe can be used by first-responders, healthcare workers, and civilians to significantly reduce and prevent pathogen transmission (NUI Galway, n.d. b). Since the beginning of the crisis the NUI Galway collaborates on 45 COVID-19 related research projects, enlightening thus the important role of university and researchers in a cluster (NUI Galway, n.d. e).

The Irish MedTech industry was also able to find new kind of developments in the healthcare sector. Even though the production of medical device like ventilators had been fostered, the MedTech industry also adapted and innovated in new technologies combining medical devices and digital techniques. Because the pandemic reinforced the telemedicine, remote monitoring became a huge opportunity for the sector. Therefore, the Irish MedTech sector has successfully shown flexibility and resilience (Skillnet Ireland, 2020).

#### 4.3 Related and Supporting Industries

Business associations play an important role in this crisis by supporting the MedTech sector. MedTech Europe assures that the "National associations are constantly in contact with health authorities to make sure that these devices reach hospitals and dedicated structures and that technologies can keep flowing inside and outside national borders." (MedTech Europe, 2020).

The shipping industry has also been affected by the COVID-19. A study conducted at the University of St. Gallen discovered that the growing conflict of national interests raised trade barriers of 122 export curbs on medical goods from January to April 2020 (Evenett, 2020). 73 export cubs have been introduced in March 2020, when western countries were trying to deal with the first wave. However, although the sector have been challenged, shipping services have still developed during the pandemic. The fact that the sector is closely associated with pharmaceuticals, agri-food and medical device and that those exportations did not suffer from the crisis allowed the sector to compensate in the ferry business and continue the development of the shipping industry (Irish Exporter Association, n.d.).

Since ventilators are considered as gold in those challenging times, governments were focusing their efforts on importing them as much as possible. The former president of the United States, Donald Trump, considered to apply the Defense Protection Act (D.P.A), a wartime production law which forces companies to produce ventilators only for the United States (Spencer & Belz, 2020). The Galway-based cluster had been under the spotlights and became highly strategic because of Medtronic which has its operational headquarters in Minnesota, United States and several other US-subsidiaries of Medtronic assembles its main ventilator, the PB980, in Galway. Nonetheless, despite the position of the former U.S. administration, Geoff Martha, who took over the post of chief executive of Medtronic during the pandemic has challenged and criticized this position, which she believes could lead to retaliatory measures and create many issues in today's globalized economy (The Irish Times, 2020). Finally, the 2 September 2020, Trump administration cancelled all ventilators contracts, as the ventilator industry managed to provide enough machines, without applying the D.P.A. (AP NEWS, 2020).

In addition, shipping covers a key role in the assemblage of MedTech products. Considering once again the PG980, the device is composed of 1'700 parts, coming from 100 different suppliers, located in 14 countries (Carswell, 2020). Coronavirus-related lockdowns in Asian countries, where many key

materials come from were creating challenges to the increased production of ventilators. To ensure the supply of materials, MedTech actors must work closely to their suppliers. Due to the emergency, the shipment could not had been done by sea; airplanes had to be used instead. Nonetheless, the reduction in air freight made shipping harder more expensive.

## **4.4 Demand Conditions**

All over the world the healthcare systems have been put under high pressure by the virus. The lack of healthcare professionals and infrastructures have led to a reduction of operative surgeries and a special and close attention to the treatment of patients suffering from the COVID-19 (Pedersen, 2020). Therefore, the demand for ventilators has exploded and it has exceeded the supply so far. In Italy and many more countries after it, doctors had to choose between life and death. Hence, ventilators have become extremely valuable as expressed by the Dr. Daniele Macchini who consider that "every ventilator becomes like gold" (O'Brien, 2020). While Irish public hospitals owned nearly 500 ventilators before the crisis, in March 2020, they ordered 900 pieces in order to prevent to be overwhelmed by events.

Therefore, manufacturers of Galway have responded by increasing the production of some key devices. Since nearly half of all the ventilators produced in the world are from Ireland, the cluster has experienced an increase of demand conditions for respiratory devices while it has decreased the demand for other devices such as those used in orthopedics or cardiology. The world's leader in ventilator technology Medtronic was for instance on track to double its production of ventilators, in order to follow the increased demand during the crisis (Farragher, 2020).

In addition, administrative and legal systems have also been slowed down by the crisis. In order to overcome the shortage of ventilators, the government has temporary, and until 2021, suspended the new regulations regarding the medical devices that would have led manufacturers to cancel orders of older models (Carswell, 2020b).

Overall Ireland was ranked 5th in the world for global export of Covid 19-related goods behind Germany, the USA, Switzerland, and China. This shows that the Irish MedTech sector has been able to respond to the demand in a flexible way during the beginning of the pandemic. Moreover, it has performed good innovation in medical devices as well as in technologies like software in order to face the new demand that appears during the crisis (The Irish Advantage, n.d.b).

# 5. Strategic Issues and Recommendations at the Region and Cluster Levels

Smart devices are drastically transforming the way used to produce and the interactions between different factories (Porter & Heppelmann, 2014). At both levels, the region one and the cluster one, the focus is on digitalization and new technologies. Irish MedTech Association Senior Executive Adrienne McDonnell said, "All around the world smart technologies are changing the way people live and work. Similarly, the rapid evolution of production, information and operating technology is slowly transforming manufacturing. Making strategic choices about the digitalization of manufacturing will differentiate Irish operations and overall global competitiveness." (Irish Tech, 2020).

In order to better understand the feasibility and to facilitate the implementation of recommendations, a depth analysis about the Galway region and the MedTech cluster has been conducted, taking into consideration the issues which were divided into the four facets of Porter's diamond. This approach led to some gains as it can be seen in the following table.

	Issues	Recommendations	Benefits
Region	Poor performance of the infrastructures	Draw an investment plan for the long run to enhance specific infrastructures and to support the upskilling of advanced manufacturing skills.	High rate of productivity made by smart and motivated people
Cluster	Suppliers of special materials have large market power	Increase competition by helping new firms to enter the market	Suppliers provide materials at lower prices and MedTech firms are less dependent on their suppliers.
	The ongoing need for skilled workers (for business excellence, scientists, R&D, regulatory and data analytics)	Implement ongoing formation in firms Collaboration with third-level institutions and input in the course content. Collaboration with other industries.	High quality and specialized products. Remain competitive and innovative for the future trends coming.

## Factor Conditions

As explained by Porter (2008, pp. 225-227), the competitiveness of a location depends on the ability of firms to compete successfully in the global economy, while supporting high living standards and

sustained wages for the average citizen. Therefore, the competitiveness is the long–run productivity of a location as a place to do business; it is calculated by the productivity of existing employee and the ability to achieve high participation of working age citizens in the workforce (Porter, Lecture Chapter 6). The ongoing need for skilled workers in order to gain more business excellence, scientists, R&D, regulatory, and data analytics, is an essential presence that has to be respected to have high quality and specialized input. Indeed, the MedTech cluster has been growing and knowledge required are strictly related to the education and skills. As IBEC MedTech explained, a crucial role is covered by the continuous support of learning new knowledge of world's needs, and the sustainability of the new programs of apprenticeships must be preserved (IBEC, 2020).

As shown by Michael Porter on the lecture related to the Diamond Model, and explained more in details on the case study of "The Californian Wine Cluster", the endowments (including natural resources, geographical location, population, and country size) create a foundation for prosperity, but true prosperity arises from productivity in the use of endowments. Indeed, the inherited prosperity (for example the inherited natural resources) is limited and Porter explained that this is dividing the pie, and the government is the central actor in the economy, which leads to the allowance of unproductive policies and practices to persist. On the other hand, the created prosperity, which is the case of MedTech cluster in Galway, results from productivity in producing goods and services, thus it is unlimited. In fact, in the MedTech cluster, compared to the discussion of Porter, the created prosperity expands the pie, instead of diving it; thus, the companies are the central actors in the economy, and the government has the role to create the enabling conditions for productivity and foster private sector development. Various regulations and small changes must be considered in order to permit the lifelong growth of the MedTech cluster. Looking more in depth, the new EU Medical Device Regulations must be implemented; as well as a regulatory convergence after Brexit and the recognition of CE marks has to be promoted; also other Health Technology Assessment regulations have to be applied on purpose (MedTech Intelligence, 2019).

Ireland has created an efficient ecosystem for MedTech that is profitable for the development of business innovations. Thus, it is extremely important for Irish manufacturers to embrace new technologies in order to be highly competitive, take AI, data analytics, 3D printing or augmented reality for instance. This latter is another interesting aspect of this technological evolution. As mentioned by Porter and Heppelmann (2017), it allows to bridge the gap between the world of data and the real world and takes advantage of quantity of new information and reproduce them in 3 dimensions. This opens

up promising applications in MedTech sector such as facilitating vein localization for clinicians by converting the heat signature of a patient's veins into an image overlaid on the skin. The trend characterized by the digitalization is spread worldwide and it is unstoppable; partnerships between MedTech industry and large tech companies is essential to gain adequate infrastructures and developments. However, a need for greater security services is required, avoiding cyber-attacks which are a threat, introducing new areas such as blockchain that is a protection for particularly sensitive information. The breakthrough in technology has an important impact on patient care, which is going to be more and more personalized, occurring some changes in supply chains and in manufacturing operations, that must evolve to provide innovative solutions. In fact, the MedTech industry is going to be more efficient and effective in the involvement of patient lifecycle offering new postoperative treatments (MedTech Intelligence, 2019).

	Issues	Recommendations	Benefits
Region	Merger control rule in Ireland are less restrictive than some other European countries	Establish merger control rule considering the value of transaction merger and national security concerns	Reduce the risk of formation of monopolies and enhance competition within the MedTech sector
Cluster	Born globals tend to sell their technology to MNCs once it has been commercialized	Adopt policies that incentivize born globals entrepreneurs to grow the venture internationally	Reduce dependency upon the MNCs. Diversify the cluster and ensure it remains competitive on the long run.
	Weak managerial skills for small businesses	Support new ventures and start-ups with leadership programs	Enhance the growth of new ventures and start-ups. Generate employment and diversification within the cluster
	Low differentiation of products in some key markets.	Invest in successful technologies, and foster cooperation.	The markup can be higher since firms do not compete on prices
	High barriers to enter the market	Enhance the financing of small and new companies (example: in R&D)	More competition and product diversification within the cluster

The context for firm strategy and rivalry is determined by local rules and incentives that encourage investment and productivity (Porter, 2008, p. 261). Take salaries, incentives for capital investment,

intellectual property protection, corporate governance standards, for instance. Furthermore, also vigorous local competition in terms of openness to foreign competition and competition laws play an important role. Looking in more details the context for the firm strategy and the rivalry as explained by Michael Porter, the strong competition among locally based competitors leads to strong antitrust law; the openness to trade and investments has to be considered; free trade agreements lead to some regional unions; the local context and rules that encourage investment and sustained upgrading (for example: intellectual property protection and anticorruption law). In fact, in the MedTech cluster it is seen that the so called born globals tend to sell their technology to MNCs once it has been commercialized, thus it has to be implemented an adoption of policies that produce incentives to born globals entrepreneurs to grow the venture internationally. Furthermore, the issue on MedTech cluster related to the weak managerial skills for small businesses could be improved by supporting new ventures and start – ups with leadership programs. Looking more in depth the related and supporting industries, as explained by Porter in his lecture of the diamond model, the access to capable, locally based suppliers, firms, institutions in related fields, boost an improvement for the cluster. In the MedTech cluster the most important are the efficient suppliers, universities, R&D institution, and specialized institutions, associations, and councils.

The issue related to the high competition on prices due to not having any differentiation on products in some key markets, in the MedTech, could be solved by investing in successful technologies, and increasing cooperation between firms and institutions. Porter (2008, p. 77) notices that a company can achieve differentiation through the contribution of each value activity toward fulfillment of buyer needs. As such, MedTech firms can achieve higher willingness to pay by being leaders in solving emerging customer needs. In order to understand those emerging needs, MedTech firms should rely on local partnerships and exchange of information and technology within the cluster. Institutions fostering collaboration could be set to improve the business environment by creating strong relationships and supporting firms by increasing the level of trust; encouraging the definition of common standards; making easier the management of joint actions; supporting the definition and communication of shared beliefs and attitudes. As Porter valued in 2008 (p. 89) the development of information technology to enhance differentiation, it is nowadays mainly digitalization that has been growing and which is the main character of the daily life of everybody and every industry. Thus, MedTech firms should particularly consider developing partnerships with digital companies that offer them solutions to satisfy the identified customers' needs.

In the context of firm strategy and rivalry, the government has a crucial role in terms of eliminating barriers to local competition; the organization of relevant government departments around the cluster; the efforts have to be focused on attracting foreign investment around the cluster. In the MedTech cluster in Galway, the issue related to the high barriers to enter the market could be solved by the government which could help by financing new and small companies (for example R&D), leading to an increase in cooperation between companies and gaining a major offer in terms of products.

	Issues	Recommendations	Benefits
Region	No global vision regarding the collaboration with other industries (biopharmaceutical, ICT, high tech).	Establish an international research and development center in biomedical (like the Biopolis center of Singapore).	The presence of the global biopharma in Ireland can be used to promote Ireland as a unique Healthtech hub.
Cluster	Relationship between MedTech companies and physicians has become more complex and less direct	Cooperating closer with physician associations and asking for more feedbacks.	More feedbacks on the products, increased quality and reliability of the devices.
	Need for more expertise in high tech to follow the next trends. Need of more data-security (avoid cyber-attacks)	Create partnerships with tech companies, like artificial intelligence, machine learning Hire skilled workers, adapt firms' strategy and organization model.	Huge gains to device makers especially for connected devices and patient-focused solutions

**Related and Supporting Industries** 

With the development of smart connected products in the MedTech industry, firms will experience a major shift in the strategies used to compete. Connected products are expanding the mechanisms which create value, and consequently, the value chain in its whole (Porter & Heppelmann, 2014). Products become more complex systems that involve sensors, software, connectivity, and operating cloud. Deloitte (2018, p. 14) notices that, by the year 2023, MedTech firms will allocate an increase of 8% of their R&D budget to the development of connected medical devices. Manufacturers of the MedTech sector will become hybrids of a software company and a traditional product company. In order to support that transition, they will need multifaced new skills, such as software development, user interface design, and data scientists which are in scarce supply. As explained in chapter 3.4.1, in 2017, the Irish MedTech Association published a report, declaring that data scientists are one of the most researched skills for the MedTech industry. MedTech firms may consider concluding strategic

alliances, which could overcome the shortage of skilled workers. Nonetheless, if strategic alliances can achieve selective benefits, Porter (2008, p. 210) notices that they always exact significant costs. Indeed, no company can rely on another outside and alliances are best used as a selective tool, employed on a temporary basis or by involving noncore activities. Looking at the long term, MedTech companies could alternatively consider acquiring firms which are active in the high-tech sector. A suitable example may be Tesla, which acquired SolarCity to gain competitive advantage and explored new markets as explained in class during the discussion of the related case study. Indeed, Porter (p. 145) shows that acquisitions or start-ups facilitate the entrance in new industries and if the acquirer pays a price which does not fully reflect the predictions of the new unit, it could beat the market.

Additionally, with the development of alternative health care financing models, for example the valuebased model, MedTech actors will play an increased role in providing robust and reliable data (Deloitte, 2018, p. 16). Connected medical devices can help healthcare providers to improve costs, quality, and productivity of care delivery and it will also support better patient engagement and outcomes. In order to achieve this, MedTech firms must have a closer relationship with the health care system and with health care providers such as doctors and nurses. In chapter 3.2.3, it was highlighted that since hospitals have begun to group together, the relationship between MedTech companies and physicians has become more complex and less direct. Porter (2008, p. 191) claims that sophisticated demanding buyers will pressure companies to meet high standards. Therefore, it is recommended that MedTech firms of the cluster strengthen their relationship and cooperate closer to end-users, leading to an increase in the value of the offered products.

	Issues	Recommendations	Benefits
Region	Small local demand	Sign strategic alliances with foreign firms. Acquisition of foreign firms.	Reach new markets and customers Find end-users for
			specialized products
	Tax implementation due to the Brexit	Medtech-realted agreements between the UK and Ireland	Offer more competitive products in the United Kingdom and improve competition within Ireland
Cluster	Complexity to comply with all requirements of the multiple legislations	Create a regulatory guideline for small businesses. Promote the establishment and competition of	Expand the accessibility of foreign markets.

## **Demand Conditions**

	specialized legal consultancy firms.	
Patients' needs become more complex and sophisticated.	Develop data analytics programs that improve patient engagement	Patients' needs are fulfilled; data can be managed in order to keep improving and specializing

In chapter 3.4.2, it was showed the strategic partnership between the Entreprise Ireland and AdventHealth which allowed the Irish MedTech companies to access to key market leaders in the US. As already discussed for the related and supporting industries, Porter (2008, p. 241) considers that alliances with foreign companies bear significant costs linked to the coordination which separates operations and reconciliates the goals with an independent entity. Nonetheless, he admits that employment on a temporary basis, could lead to benefits for strategic alliances. While Entreprise Ireland is not a firm but a government agency, MedTech firms of the Galway cluster could pick several alternatives. Indeed, firms often decide to acquire foreign companies in order to penetrate foreign markets and reach new customers. This will be beneficial only if the price paid for the acquisition reflects the expected value of future earnings.

Due to Brexit, taxes on trade of goods between Ireland and the United Kingdom have been implemented. This results in a form of protectionism, where customers face lower prices from the goods produced by firms located in the home country. Porter (2008, p. 400) views protectionism as dulling motivation and retarding costs and quality improvement. Indeed, firms are facing a lower grade of competitiveness; consequently, they are less pressed to perform better and to deliver a higher value to the customer. At a national level, MedTech actors would take advantages if the Irish government is able to implement new agreements with the UK.

MedTech firms have difficulties to respect all legislations of markets regarding the decisions on exports. This is mostly related to small businesses which cannot afford an implementation of a legal department. Their products might be extremely specific, thus to grow and develop, they need to reach specialized healthcare institutions located in foreign countries. Porter (2008, p. 424) mentions that the associated defensive medical practices are immensely expensive for everyone. Lawsuits should be appropriate only in cases of verifiable bad medical practice such as the use of obsolete treatment. This could be avoided by following what Porter proposes, which is to invest in better information, that can remove administrative and legal costs from the system. Therefore, it could be argued that a guideline which

leads smaller businesses into the legalities of the exportations of medical devices would help them to reach new markets.

To conclude, the opportunities given by smart connected products and data analytics, enable firms to better meet patients' needs. Nowadays healthcare institutions compete tremendously fiercely to attract patients within their institutions. Due to the COVID-19 crisis, many elective surgeries have not taken place, leading these institutions to an even more complicated financial situation. Therefore, it has become salient for them to perform better and to enlarge the experience of their patients. MedTech devices have a crucial role to play in the patient experience and it is recommended that the firms located within the Galway MedTech cluster, invest a larger part of their expenditures in R&D, particularly in smart connected devices.

## 6. Conclusion

This paper provides an analysis of the MedTech cluster located in the region of Galway, Ireland. Through deep research the main characteristics related to the development and the establishment of such cluster have been presented. Firstly, the presentation of Ireland had been made in order to understand the framework in which the cluster had been built. Thanks to the WEF Global Competitiveness Report (2019) the main competitive performances had been understood and described. Then the development and the birth of the Galway's MedTech cluster had been shown. This cluster had been built upon the attraction of MNC's thanks to preferential tax imposition and the stimulation of FDI. Regarding the MedTech industry the five forces had helped to understand why this sector is competitive. A strong rivalry among competitors and a strong threat of new entrants had been pointed out showing that innovation is a key factor for this industry. The moderate bargaining power of buyers and suppliers compiled with the threat of new entrants reinforce this fact. Concentrating on the Galway's MedTech cluster the study of the mapping allows to present the main actor of the cluster especially the role of born globals. After having presented the main actors, the cluster's diamond according to Porter's theories had been exposed. Looking at the four facets of the diamond and explaining the diamond as a system showed that the real competitiveness of a cluster comes with the interrelationship between all the components of its. This analysis had been completed with the performances of the cluster pointing on the fact that this MedTech cluster counts for a large part of the exportation of the Ireland and that the MedTech sector is very innovative sector.

The main presentation of the cluster had been followed by a more personal analysis of the main issues and challenges faced by the cluster. The influence of the COVID-19 crisis had been analyzed showing that it will probably hinder the cluster especially regarding the related and supporting industries and the attraction of FDI. However, as the COVID-19 crisis is a sanitary crisis, the Galway MedTech cluster would play an important role thanks to the great amount of innovation it provides. Looking more globally the establishment of the main recommendations concerning the future issues the cluster would encounter had been presented. For each of the four facets of the diamond a table summarizes the main issues and recommendations had been compiled. To put it in a nutshell, each facet is facing challenges at a regional and cluster level, highlighting the complex interrelation between actor that embrace the cluster theory.

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