



# Medical device patents—a review of contemporary global trends with an Irish comparison

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## Abstract

**Introduction** Trends in medical technology patents provide an objective comparison of research and development between countries and over time. An analysis of these trends can benchmark innovation within Ireland in a worldwide context. By identifying and examining leading countries, domestic educational, infrastructural, regulatory and fiscal planning may be optimised.

**Materials and methods** Published data filing and granting reports from the two major patent offices (United States Patent and Trademark Office (USPTO) and European Patent Office (EPO)) were analysed.

**Results** USPTO statistics demonstrated an 83.1% decrease in the overall number of medical device patents filed over the 10-year period, from 2005 ( $n = 1092$ ) to 2015 ( $n = 185$ ). Conversely, there was a 166% increase in the number of medical device patents granted over the same period. EPO applications in the field of medical technology represented the single largest industry category. The proportion of patents granted of Irish origin have increased from 0.7 ( $n = 22$ ) to 0.9% ( $n = 73$ ) over 10 years. Switzerland ranks first for medical device patents granted per head of population by the EPO, with Ireland ranking 5th. Ireland’s medical device patents have increased dramatically per head of population, from 4.1 per million in 2012, to 15.3 in 2016. Israel has the highest number of USPTO patents granted per head of population, with Ireland ranking 5th.

**Conclusions** Ireland demonstrates high levels of medical technology patent filing per head of population, reflecting the importance of this industry. However, both Switzerland and Israel demonstrate dominance amongst smaller nations, and serving as benchmarks for national planning.

**Keywords** Medical devices · Medical technology · Patent trends · Patenting

## Introduction

Ireland has the highest proportion of workers engaged in the medical technology sector of any European country, reflecting the national importance of the industry [1]. When comparing medical technology research output, the relative number of employees alone is only part of the picture. The number of employees of the medical technology industry nationally, or other measures such as gross national export values, fail to separate out lower-paid manufacturing and support posts, from the higher-paid research and development posts which may be centred overseas. Similarly, a high proportion of jobs

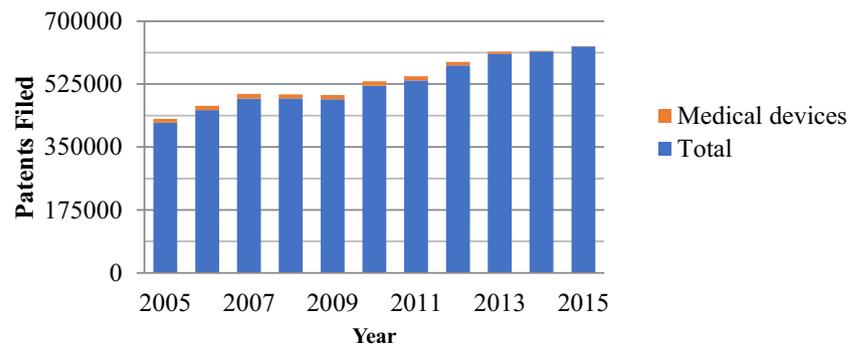
does not necessarily equate to high levels of innovation. Comparing medical technology research output across regions using such measures is therefore limited, failing to measure innovation directly. Furthermore, it does not provide a direct measure of changes in innovation over time. There is a lack of accepted benchmarks reflecting healthcare research productivity, commercialisation and impact on patient care. However, as a common pathway in much research, patent data does offer an insight into innovation and provides objective comparative data both regionally and temporally. As such, an analysis of patent filing and granting trends provides valuable information on research trends and may be valuable for the planning of educational, research and regulatory infrastructure on a national level.

A patent is a legal title granted to a holder which prevents third parties from exploiting their invention without authorisation [2]. A patent applies to a particular country or set of countries for a particular length of time. The term of a new

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**Fig. 1** Number of total patents applications per year to the USPTO and relative proportion of patents relating to medical devices



patent is generally 20 years [2]. There are several possible types of patent—utility, plant and design. Utility patents account for the greatest proportion at 90% of all United States Patent and Trademark Office (USPTO) applications every year, relating to functional aspects of an invention and typically including new devices [3].

Patent protection varies from country to country and therefore inventors must seek patent protection in all countries desired. The patenting process commences with a patent application to an authorised body or patent office. Following the payment of an administrative fee, a patent is examined and a decision is made to grant or reject a patent. This process typically takes 3 years for the USPTO and 5 years for the European Patent Office (EPO) [4]. The European Patent Convention allows a single patent application to apply to a number of contracting countries. However, each country still retains its own patent office governed by its own national laws [5]. Therefore, in order to annul a patent, separate proceedings are required for each country. An international patent system also exists whereby filing one international patent application can protect intellectual property in a large number of abiding countries [2]. Two of the largest patenting bodies, the USPTO and the EPO form the basis of this study.

In addition to differences in patent-seeking processes between jurisdictions, what can actually be patented also varies; surgical techniques, along with methods of medical treatment or diagnosis, are patentable in the USA and in Australia. This

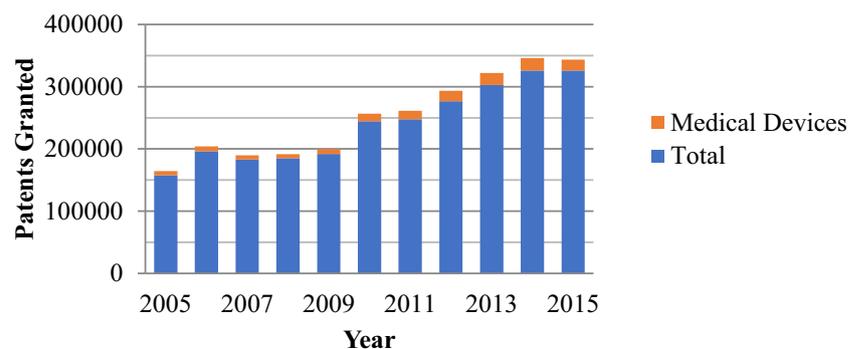
contrasts to Europe and other countries such as Canada, South Korea or Japan where medical methods are not patentable [6]. Products that can be used in undertaking a particular method, however, are patentable [7]. Diagnostic methods carried out on fluids or tissue once removed from the body typically remain patentable also [7].

A study of the main worldwide patent office data was performed, and regional and temporal trends were analysed. The performance of the Republic of Ireland, a medical technology hub, relative to its global competitors, and trends over time were assessed. Factors which may influence trends in patent filing nationally are discussed. Trends were also used to identify countries with disproportionately high patent filings as a surrogate for successful research and development cultures, which may offer lessons on how to increase productivity nationally.

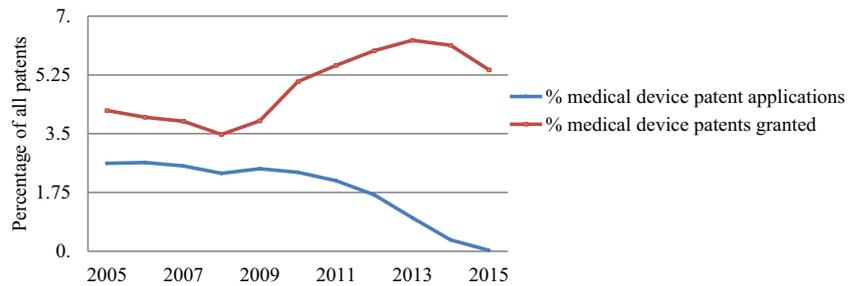
## Materials and methods

Publicly available published databases by the two largest patent-granting bodies (USPTO and EPO) were examined for the period of 2005 to 2016 (the most recent year for which fully published reports are available). Data analysed included patent applications and granted patents, medical device patents and the international breakdown of patents.

**Fig. 2** Number of total patents granted by the USPTO and proportion of medical device patents granted over a 10-year period from 2005 to 2015



**Fig. 3** USPTO medical device patent applications and patents granted relating to as a percentage of all patents

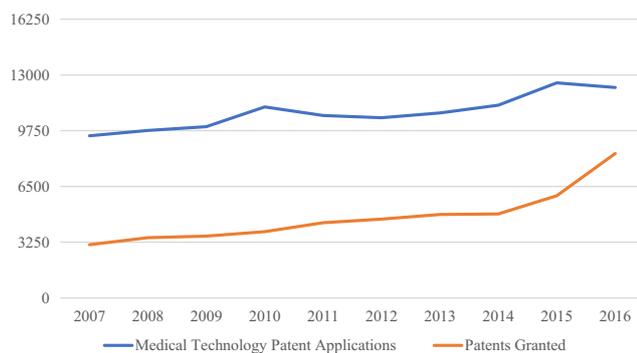


## Results

### Overall patent filing and granting trends

Data from publicly available USPTO statistics revealed that there was an 83.1% decrease in the overall number of medical device patents filed over the 10-year period, from 2005 ( $n = 1092$ ) to 2015 ( $n = 185$ ). The greatest decrease was a 91.3% decrease between 2014 and 2015. This decline is out of proportion with the number of total patents filed in the USA, which increased by 50.8% (417,508 to 629,647) over the same 10-year duration. Despite the fall in the number of medical device patents filed, there was a 166% increase in the number of medical device patents granted over the same 10-year period from 2005 ( $n = 6603$ ) to 2015 ( $n = 17,596$ ). During this period, medical device patents granted represented an increasing percentage of all patents granted, increasing from 4.2% in 2005 to 5.4% in 2015 (Fig. 1).

In analysing reports by the European Patent Office, patent applications in the field of medical technology accounted for 7.7% of all industries in 2016. This represents the single largest industry category, which has been the case for each of the past 10 years. The number of medical technology patent applications has increased by 29.8% over a 10-year duration from 2007 to 2016, from 6.7% ( $n = 9451$ ) in 2007 to 7.7% ( $n = 12,263$ ) in 2016, except for a small dip in growth of 2.1% from 2015 to 2016. The proportion of total patents applications that related to medical technology has remained consistent, accounting for 6–8% of all patent filings annually (Figs. 2, 3, 4 and 5).



**Fig. 4** Total number of EPO patent applications and patents granted in the field of medical technology

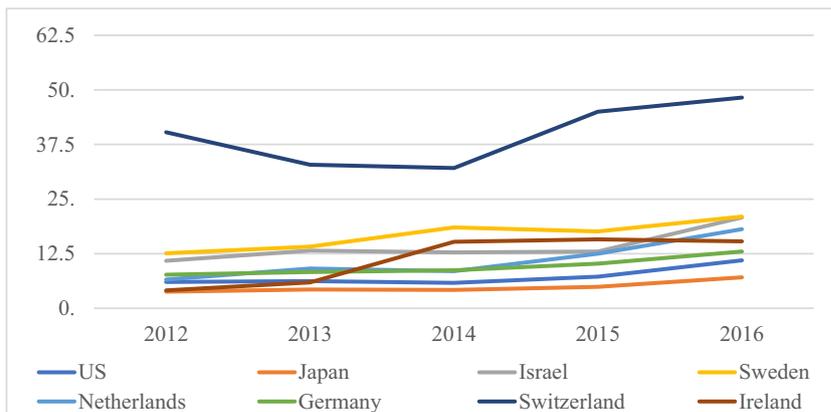
### Irish and international comparisons

The proportion of foreign origin patent applications to the USPTO decreased markedly over the 10-year period from 31.9% in 2005 to 20.5% in 2015. Japan was the greatest contributor to the foreign origin patent applications in 2005 with 7.7%; 0.3% ( $n = 34$ ) of foreign patent applications were Irish in origin, placing it 16th amongst all countries. In 2015, Japan was displaced jointly by the UK and Israel as the leading foreign country applying for patents, both of which contributed to 3.2% of applications each. The share of Irish origin patent applications decreased to 0% ( $n = 0$ ) in 2015.

The proportion of foreign origin patents granted increased by 4.7% between 2005 (29.2%) and 2015 (33.9%). Japan had the largest foreign origin patents granted at 7% of total patents granted in 2005 and 7.1% in 2015. The other major contributors to foreign origin patents granted from 2005 to 2015 were Germany (5.4%), the UK (2%) and Israel (2.1%), with Ireland placed 20th of all countries (0.3%). The number of Irish medical device patents granted represented 0.4% ( $n = 25$ ) of all medical device patents granted in 2005, which decreased to 0.3% ( $n = 58$ ) in 2015. The share of medical device patents amongst all Irish patents granted decreased also from 2005 (16%,  $n = 156$ ) and 2015 (12.3%,  $n = 473$ ) (Figs. 6, 7, 8 and 9).

Data from the EPO found that in 2016 US patent applications accounted for the largest number of patents filed at 38%, followed by EPO member states accounting for 33%. Similarly, the USA was the dominant contributor of patents granted, accounting for 40.6% of all granted patents over the past 10 years. Germany and Japan were the other major contributors, accounting for 13.5% and 10.2% over the 10-year period respectively. Countries where there was substantial growth in the number of patents granted over the past 10 years included Israel, the Netherlands and Japan, who in 2016 accounted for 2.1%, 3.7% and 10.6% respectively. The share of Irish patents granted by the EPO has increased steadily from 0.23% in 2007 to 0.4% in 2015. Of all medical device patents granted, the proportion of patents of Irish origin have increased from 0.7% ( $n = 22$ ) to 0.9% ( $n = 73$ ) over the 10-year period, remaining in 15th position in overall rankings. Amongst all Irish patents granted, medical technology industry accounted for more patents than any other industry. The

**Fig. 5** EPO patents granted per million population from 2012 to 2015 in the field of medical technology



proportion of medical technology patents granted increased from 17.6% in 2007 to 18.9% in 2016. In 2014 and 2015, the number of medical technology patents granted peaked, accounting for 27.5% and 27.4% of all Irish patents granted. This is at the higher end of the international breakdown, with only four other countries having a higher percentage of medical technology patents.

When analysing the EPO data per population, Switzerland ranks first for medical device patents granted followed by Sweden, Israel and the Netherlands, with Ireland in 5th position. Ireland’s medical device patents have increased dramatically when calculated per head of population, from 4.1 per million population in 2012, to 15.3 in 2016. The USPTO patents granted places Israel as the highest number of medical device patents granted per head of population, with Ireland ranking 5th.

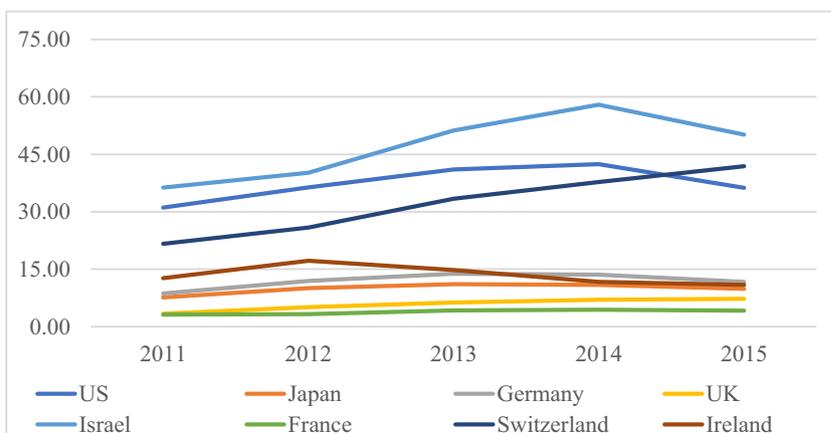
**Discussion**

The medical technology industry is a growth industry, with global growth rates of 4 to 5% predicted annually over the next 5 years [8]. Medical technology, encompassing medical devices and patentable processes relating to medications and

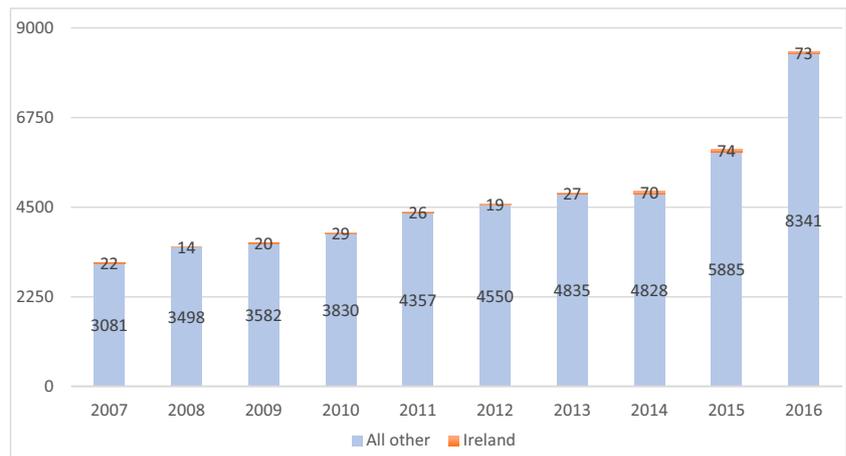
healthcare, currently accounts for the most patents of any industry filed with the EPO. It is interesting that during the period from 2005 to 2015, there was a significant decrease in the number of patent applications filed in the medical technology sector as per the USPTO data, but an increase in those granted. Those patents granted in 2015 reflect patent applications from approximately 2 to 3 years previously, the time taken for the USPTO to process a patent application and grant the patent [9]. This occurs against a backdrop of an overall increase in USPTO patent applications. It is highly unlikely that this decrease, specific to medical device applications, reflects a sudden decline in research and innovation. This trend may reflect the increasing cost and complexity of developing medical technology and the shifting patents towards specialised research and development units who may file higher quality applications with a resulting higher application success rate. The USA consistently accounts for the greatest proportion of patents granted in the medical technology fields reflecting an ongoing increased interest in innovation.

There has been a suggestion over recent years that the EPO patenting process is a more scrupulous process than its US or international counterparts. Patents are examined by three rather than one examiner [10]. A smaller proportion of patents are granted. It is generally accepted that patent quality is of

**Fig. 6** USPTO patents granted by USPTO per million population for medical devices



**Fig. 7** Total patents granted per year by the EPO in the field of medical technology and the proportion which originated from Ireland



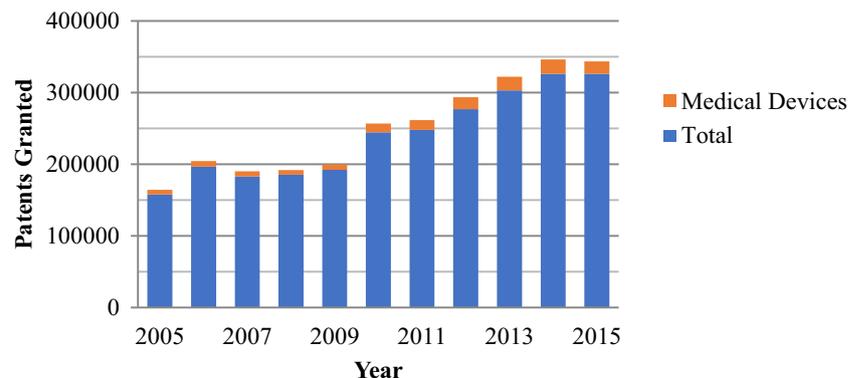
comparatively high standard in the European patent system, and it is consistently highly rated for patent quality by the world’s largest patent offices [10]. Large-scale questionable patents are not seen to the same extent as other patent jurisdictions leading to a safe and attractive marketplace for innovators [11]. Furthermore, patent-assertion entities (patent seekers who actively acquire patents solely for the purposes of prosecution or to negotiate licencing fees) are a serious concern in the USA, but are encountered less often in Europe, due to patenting practices.

There was a significant change in the US patenting system which paralleled a decrease in USPTO patent filings. Until 2013, the USA practiced a “first to invent” approach to patenting [6]. This meant that if two applications were made for the same invention, the invention was investigated to ascertain who invented it first. This approach differs from much of the rest of the world, where a “first to file” approach is used, where the patent is granted to whomever filed first with no consideration taken as to who was the first inventor [6]. In order to ease this transition, a grace period has been instigated whereby the inventor can publish his invention within 1 year of filing a patent without losing their patent right [6]. Again this differs to Europe where public disclosure of an invention renders it unpatentable [6]. Whether this has directly impacted on the USPTO decline in patent filings remains unknown. The

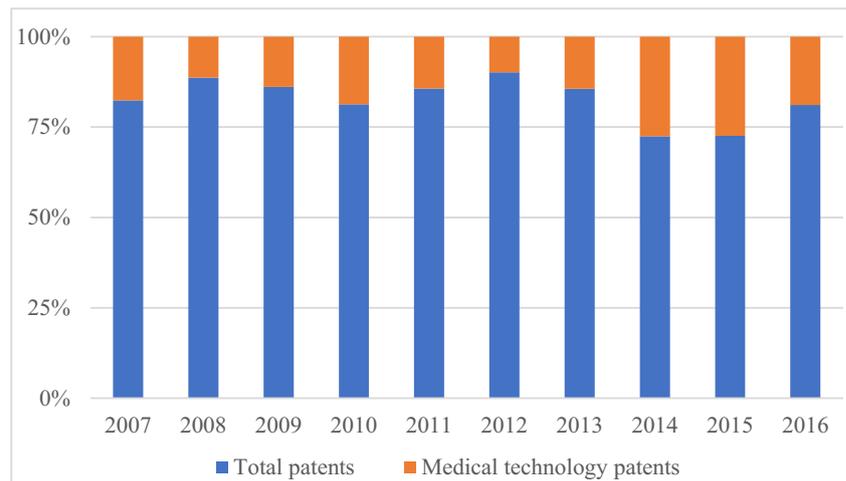
USA is also one of very few countries with no pharmaceutical price regulation. Therefore, during the period of patent protection, the developer is at liberty to charge competitive prices to recoup the research and development costs [12]. It is felt by some that this is instrumental in maintaining ongoing innovation [12]. However, one recent study disputed this school of thought [13].

As of 2015, Ireland’s ranking for overall patent granting is 25th and 22nd according to the USPTO and EPO respectively. Specific to medical technology, Ireland ranks 17th and 15th respectively, which has remained static since 2007. The medical technology industry in Ireland has grown significantly since the 1970s when the medical technology industry was first introduced to Ireland [14]. The medical technology industry is one of Ireland’s largest industries, exporting over €12bn worth of product annually, and employing 29,000 people [15]. Ireland is the second largest employer per capita in Europe in the medical device industry, behind Switzerland in first place [16]. Eighteen of the world’s top 25 medical technology companies have a base in Ireland [14]. While medical technology represents the second largest employer per capita, Ireland ranks only eighth for research and development spending within Europe [17]. This mismatch may reflect the fact that the many medical technology companies that manufacture and are tax-based in Ireland conduct research and

**Fig. 8** EPO total patents granted the proportion in the field of medical technology



**Fig. 9** EPO total Irish patents granted and percentage relating to the medical technology industry



development overseas. Indigenous companies also contribute greatly to the industry; this includes companies such as Creganna, Trulife, Vistamed and Steripack. Many of the indigenous companies are sub-suppliers of the larger global companies [14]. Ireland is now responsible for 80% of the world's cardiovascular stents, one third of all contact lenses sold globally and a quarter of all diabetic patients are reliant on products manufactured in Ireland [15].

Ireland has created a competitive environment for the medical technology industry. This has been largely attributed to three variables. Firstly, third-level education has been state funded since the 1990s creating a talented and well-educated labour pool. Secondly, the comparatively low corporate tax rate has been hugely important in piquing interest of international companies. Thirdly, as an English-speaking country within Europe, it is attractive to large global medical technology companies. Ireland has also now established itself as a location of excellence, having built up skills specific to the sector and experience with regulatory agencies such as the Food and Drug Administration (FDA) and the European Medicines Agency (EMA) [14]. The Irish Medical Devices Association has recently outlined a 4-year strategy to maintain Ireland's position as a medical technology hub [18]. The focus of this strategy is largely on drug delivery systems requiring collaboration of medical technology and pharmacology corporations [16]. Finally, a culture of industry-facing regulatory processes and access to the EU market have been cited as contributors [17].

Switzerland ranks first when considering patents granted by the EPO in medical technology field per capita. It also ranks highly according to USPTO data. Similar to Ireland, its success in the medical technology industry has largely been ascribed to its well-educated labour pool, a favourable tax environment and ongoing government technology development programmes [19]. In analysing the USPTO data, Israel is responsible for the most patents granted per head of population for medical devices. Several factors have been

postulated to contribute to this high level of innovation. Israel is known to have a high number of academic and medical centres of excellence in a relatively small geographical area and serving a relatively small population [20]. There is also a high number of engineers graduating every year from the Israeli Defence Forces [21]. The governmental has been continuously supportive, providing grants and financial support to encourage research and development. It is therefore unsurprising that a large number of global medical technology companies have set up local research and development centres [20].

A limitation of this study is lack of sub-categorisation within medical technology patent filing reports, either by product type (such as implantable device, drug delivery system), or by speciality (such as surgical, cardiology, interventional radiology). This precludes further analysis and limits interpretation and discussion to broad overview. Furthermore, it should be noted that while country of origin of a patent is typically reflective of patent origin and of site of research, it is possible that national data is skewed by off-shore patent filing and by filings from multinational groups.

## Conclusion

The medical technology sector is a growth industry. The USA remains the major contributor to patent filings and patents granted relating to medical devices across the two major patent offices examined, with further major contribution to the medical device industry that was also made by Germany, Japan, the UK, Switzerland and Israel. There was a decrease in medical device patent applications to the USPTO in recent years; however, the percentage of submitted patent applications approved has increased. Ireland consistently demonstrates high levels of medical device patent filing per head of population. An analysis of national trends over time provides an overview of the performance of the research and

development of medical technology in Ireland, and benchmarking against other high-patenting small nations such as Switzerland and Israel may facilitate national planning to ensure continued national competitive advantage.

### Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflict of interest.

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