Supporting Irish medtech startups and innovation in the face of global competitiveness pressures

Preparing for Brexit and international challenges

A Plan for Budget 2020 from the Irish Medtech Association
Contents

Director’s introduction from Sinead Keogh, Irish Medtech Association  2
Chair’s foreword from Conor Hanley, CEO FIRE1  4
The economic contribution of Ireland’s medtech sector  5
Executive summary  8
Rating Ireland’s startup ecosystem by medtech entrepreneurs  10

Point 1: An increase in the threshold for the reduced rate of Capital Gains Tax from €1 million to €10 million to encourage risk taking and re-investment  14

Point 2: Reform of the Key Employee Engagement Programme (KEEP), including an increase in the limit on market value of issue, but unexercised, shares under the scheme to €10 million to attract and retain talent  16

Point 3: Reform of the Employment Investment Incentive Scheme (EIIS) including an increase in the limit on investments to €2 million to drive investment  18

Point 4: Government support, backed by industry and IDA Ireland investment, for an Advanced Manufacturing Centre of scale, located in Limerick to act as a shared space to allow companies work together to develop technology and talent  20

The medtech startup cycle  22

About the Irish Medtech Association  28
Director’s introduction

Sinead Keogh,
Irish Medtech Association

Medical technology, or medtech, saves and transforms lives. These technologies are used for the prevention, diagnosis, monitoring, and treatment of disease and other conditions. There are more than 500,000 different types of medical technologies on the market ranging from glasses and wheelchairs, to pacemakers and MRI scanners.

Ireland is now internationally recognised as one of the world’s top five global hubs for medical technology. Together, Ireland has built a worldclass community of FDI multinationals and innovative startups, along with key supports such as award-winning designers, expert researchers, and partners which help startups and SMEs go the distance.

The medtech sector here now boasts more than 450 medtech businesses, including 9 of the world’s top 10 medtech companies. As many as 60% of these businesses are homegrown and four out of five are either startups or SMEs. Ireland is one of Europe’s top destinations for FDI investments and one of the largest exporters with exports worth €12.6 billion or approximately 10% of Irish goods exports.

The success of Ireland’s global medtech hub has seen €566 million in investments and 2,300 jobs publicly announced, and €180 million finance raised by startups over the past eighteen months.

Nurturing entrepreneurship is one of the strategic pillars of the Irish Medtech Association’s 2020 strategy ‘The Global Medtech Hub: How Ireland is innovating for future healthcare and economic growth’. Under this pillar, the Irish Medtech Association is working with key stakeholders and members to develop policies and conditions to ensure entrepreneurship can thrive, such as facilitating new funding opportunities, sharing best practice and networking.

The role of startups is different in the medtech community compared to other industries as these businesses have become significant drivers of innovation in recent decades.
The medtech innovation cycle is led by startups identifying an unmet clinical need and market opportunity. If the product is sufficiently innovative and differentiated from the competition, then following proof-of-concept and device development they can start to attract funding. While Ireland has a number of successful medtech focused VC firms, to ensure viable growth entrepreneurs need adopt an international perspective making them strong ambassadors for Ireland as a place to do businesses.

There are several key milestones in the lifecycle of a medtech startup with a funding injection needed at each stage to get to the next, or risk the business failing. These include seed funding at the concept stage, startup funding as the company is established and takes shape, expansion funding as it invests in clinical investigations, mezzanine funding as it drives sales and profit growth, as well as liquidity as it looks to scale or exit. The amount needed for survival can escalate from €44,000 a month to €900,000 a month as the business grows.

To ensure Ireland remains a location of choice for developing disruptive, life transforming medical technologies and help startups scale we need more funding and supports.
Medtech is arguably the most innovative sector in Europe with nearly 14,000 patents filed with the EPO in 2018. The industry is characterised by a constant flow of innovations, which are the results of a high level of research and development within the industry, and of close cooperation with the users. Products typically have a lifecycle of only 18-24 months before an improved product becomes available.

Most innovation in global medtech companies is iterative. The innovation pipeline for this dynamic industry is fuelled by startups that take on risk to drive radical innovation in the face of unmet clinical needs that represent significant commercial opportunities.

Many startups are born as spinout of Irish universities where they’ve fostered collaboration-based research between healthcare professionals, engineers and leading academics. NUI Galway, Trinity College Dublin, University College Cork, UCD, RCSI and DCU are among the top performers for cultivating successful spinouts with many companies born in these universities developing novel technologies that make it to market faster.

This is in part thanks to their access to experienced mentors operating in the Irish medtech community who reinvest funds and their time back into ecosystem to drive future growth. Programs like BioInnovate Ireland help ensure these companies identify unmet patient needs and bring together multidisciplinary teams to address them, while the Health Innovation Hub Ireland helps innovative solutions reach the Irish health system.

The presence of a rich pipeline of medtech startups in Ireland is an important component of our attractiveness as a location of choice for FDI and also fuels Ireland’s image as an innovation powerhouse, and a place for international startups. Medtech startups are transforming lives, and those who succeed are acquired to manufacture their technologies to meet global demands.

Nurturing a strong startup community here helps ensure that following acquisition, should the startup wish to do so, the technology is scaled and further developed here and in many cases supports job growth.

That’s why we’re calling for reform to the Capital Gains Tax system, reform of the Key Employee Engagement Programme (KEEP), changes to the Employment Investment Incentive Scheme (EIIS) and government investment in a new Advanced Manufacturing Centre to drive innovation, attract and retain talent and encourage risk taking and reinvestment.
Ireland and its medtech industry is well positioned to capitalise on global medtech market, which is forecast to grow to €530 billion by 2024. Consider our story:

- A global medtech hub with 9 of the world’s top 10 medtech companies having a base here
- The number one location for medtech foreign direct investment in Europe
- Spans 450 medtech companies, including leading contract manufacturers, designers and service providers
- 60% of businesses are homegrown and 80% are either startups or SMEs
- Ireland is the second largest exporter of medtech products in Europe with €12.6 billion in exports
- The highest employer of medtech professionals in Europe, per capita, with many as 38,000 already working in the sector and 4,000 jobs to be added by 2020
- Ireland has the most Shingo Prizes for operational excellence of any country, per capita, in the world
- 68% of FDI companies do R&D and spend circa €181 million on R&D annually
- Nearly two out of three medtech companies have commercial capabilities here and a third of FDI multinationals plan to expand or introduce new commercial operations
Executive summary

The prospect of Brexit in October of this year looms large on all sectors of the Irish economy. For the medtech sector, however, the problems it poses for Ireland are particularly acute. We are already faced with a near neighbour whose tax treatment of entrepreneurs is more beneficial than that in Ireland. This gap is only likely to widen in the years, possibly the months, that follow Britain’s exit from the European Union.

We believe the Government should use the opportunity of Budget 2020, just weeks from the UK’s exit, to state clearly to its entrepreneurs, including those in our sector, who create such value to the economy, that it wants us to stay, to start businesses and to thrive here.

For Ireland to compete as an international location for medtech startups, it must have a mix of the right policies and conditions for startups to thrive here. While there are many essential elements for success, we have focused on the most important policy requirements in order to help medtech companies thrive in Ireland.

These policies relate to tax, share options, investment incentives and investment in high-tech manufacturing.
The Irish Medtech Association believes Budget 2020 should see the implementation of our Four Point Plan:

• **Point 1:** An increase in the threshold for the reduced rate of Capital Gains Tax from €1 million to €10 million to encourage risk taking and re-investment.

• **Point 2:** Reform of the Key Employee Engagement Programme (KEEP), including an increase in the limit on market value of issue, but unexercised, shares under the scheme to €10 million to attract and retain talent.

• **Point 3:** Reform of the Employment Investment Incentive Scheme (EIIS) including an increase in the limit on investments to €2 million to drive investment.

• **Point 4:** Government support, backed by industry, and IDA Ireland investment, for an Advanced Manufacturing Centre of scale, located in County Limerick, to act as a shared space to allow companies work together to develop technology and talent.

The total cost of these proposals is: €109 million

This cost is not small, but the cost of doing nothing could be far higher. While Brexit has generated much uncertainty, it seems certain that post-Brexit Britain will do all it can to attract new investment to recoup that it will lose, or has already lost, from exiting the EU.

Ireland’s medtech investment will be a target.

The implementation of these measures will help work against this and enable Ireland to compete on better terms with the UK in attracting and retaining medtech investment and growing the sector.
Rating Ireland’s startup ecosystem by medtech entrepreneurs

Talent and skills

1 in 2 rate access to talent as good, 1 in 4 say it’s very good

1 in 4 rate access to talent as average

Innovation supports and clinical expertise

1 in 2 rate the availability and ease of access to innovation supports as good

2 in 5 rate the availability and ease of access to innovation supports as average

2 out of 5 rate access to technology centres as good, 1 out of 8 rate it as very good

1 in 8 rate access to technology centres as very poor

Gaps the Government could address include the availability of clinical research capabilities, health economists, and more engineers

Gaps the Government could address include better early stage clinical trial facilities and first-in-human capabilities
1 in 2 rate the availability and access to business supports as good, while 1 in 8 rate it as very good.

1 in 4 rate the availability and access to business supports as average.

1 in 8 rate access to technology centres as very poor.

Nearly 2 out of 5 rate the availability and access to accelerators as very good or good.

Nearly 2 out of 5 rate the availability and access to accelerators as average.

Nearly 2 out of 5 rate the availability and access to accelerators as poor.

Gaps the Government could address include supports beyond early stage companies or spinouts notably incentives to invest and make medtech funding easier with more VCs, seed funds and angel funders.

Gaps the Government could address include more rounded supports for commercialisation, reduce the tax burden on startups and simplify the process for government supported incubation centres.
Gaps the Government could address include measures for connecting the ecosystem more effectively, better supports for startups unconnected to universities, and more funding intermediate size projects.
1 in 2 rate the regulatory environment as good and rate access to regulatory expertise in Ireland as good

1 in 8 rate the regulatory environment as average

2 in 5 rate the regulatory environment as poor

1 in 2 rate access to regulatory expertise in Ireland as good

More than 1 in 4 rate access to capital and reliefs as good while 1 in 8 rate it as very good

1 in 2 rate ease of exiting and attracting acquirers as average

More than 1 in 4 rate access to capital and reliefs poor while 1 in 4 rated it as very poor

1 in 4 rate ease of exiting and attracting acquirers as good while 1 in 8 rate it as very good

1 in 8 rate ease of exiting and attracting acquirers very poor

Gaps the Government could address include more clarity around the new EU Medical Devices Regulation is needed and it risks restricting both innovation and startup numbers

Gaps the Government could address include improving CGT relief, lower the tax burden for early stage startups and attract medtech specific VCs
Point 1
An increase in the threshold for the reduced rate of Capital Gains Tax from €1 million to €10 million to encourage risk taking and re-investment.

Ireland currently has the third highest rate of CGT amongst OECD countries at 33%. While improvements were made to the entrepreneurial relief in the 2016 Financial Act, reducing the rate of CGT to 10% for the first €1 million of lifetime gains, the scheme remains uncompetitive compared to other jurisdictions such as the UK. This discourages serial entrepreneurship, which is an important facet in the medtech ecosystem.

HOW THE UK COMPARES

Entrepreneurs’ relief in the UK means a lower CGT rate, charged at 10% on the first £10 million of gains, when selling a qualifying business.

Higher or additional-rate taxpayers, who pay 20% on most assets, are effectively charged half of the usual rate, saving up to £1 million.

This compares to a lower threshold of €1 million in Ireland.
Our recommendations for the Government are to:

• Change the limit at which the lower 10% rate of CGT is charged from €1 million to €10 million for high tech companies.

• Expand CGT entrepreneurs to passive investors, such as equity investors and venture capitalists, in high-potential and high-risk, high-tech companies to increase the supply of equity for highly mobile Irish companies.

• Charge CGT for earn-out and similar arrangements only on receipt of earnings. As it stands, the current system ties up cash to re-invest for several years and can lead to high levels of debt for entrepreneurs without access to cash. The current system asks entrepreneurs to pay a bill for more than they get, asking them to pay all tax upfront is punitive.

Total cost: €60 million

Entrepreneurs’ experience of CGT

We asked entrepreneurs their views on Ireland’s current system of CGT.

The UK is seen to be “way ahead” in terms of CGT and there the UK system better “realises the risk undertaken by entrepreneurs” with a higher number of serial entrepreneurs as proof of the impact of these policies. The US, Switzerland and Israel are also considered best in class for CGT.

Medtech entrepreneurs say “without a doubt” they would reinvest in medtech if changes were made to CGT which would “help a lot”. People with experience of selling companies are “rare and valuable” and changes to CGT would help them “stick around in the industry to repeat their success”. The current system punishes hard earned success.

Startup CEOs and founders think that expanding CGT to passive investors would increase the supply of equity for the business, but there must be additional rewards to the entrepreneurs.

Freeing up cash by charging CGT for earn-out and similar arrangements only on receipt of earnings reduce debt would help entrepreneurs re-invest.

Our research suggest that 7 out of 10 entrepreneurs rate Ireland’s current policy on CGT as very poor, with 1 in 7 rating it as poor as well as 1 in 7 rating it as average.
Point 2

Reform of the Key Employee Engagement Programme (KEEP), including an increase in the limit on market value of issue, but unexercised, shares under the scheme to €10 million to attract and retain talent.

There is huge competition for talent currently, where startups are competing with Foreign Direct Investment and large multinational companies. Radical reform of KEEP is essential to help startups compete and grow. We’re calling on the Government to help startups attract experienced talent to succeed.

Our recommendations for the Government are to:

- Increase to €10 million the limit on the market value of issued but unexercised KEEP shares. The current €1 million level is overly restrictive for truly high-potential firms where early rounds of investment may place the company’s valuations at many multiples of this level.

- Remove the restrictions on employer share buy-backs under KEEP. Given the low liquidity in the market for equity in Ireland, this is unreasonably onerous and can render the scheme unusable for many workers.

- Ensure better guidance is given for firms around the definition of holding companies and excluded activities under KEEP. If necessary, amend regulations in this area. These issues create significant challenges for several sectors.
• Introduce an agreed ‘safe harbour’ approach to share valuation. As it stands it is
difficult for many early-stage companies to value their companies. The cost of doing
this for the operation of KEEP alone is disproportionate and a major impediment for
many early-stage companies.

**Estimated costs: €5 million**

### Entrepreneurs’ experience of share options

Medtech entrepreneurs have had a mixed experience of attracting talent, with half of
businesses saying it was an issue. Entrepreneurs say that we need a way to ensure
employees have “skin in the game”.

The speed at which startups grow and scale has been hindered by their ability to attract
talent. The only way to get the “high quality people” is to “pay attractively” according to
one entrepreneur.

Their greatest competition for talent is large global multinationals, notably those from
the USA, Germany and the UK. Some entrepreneurs also find themselves competing with
other startups and public bodies for talent.

Most entrepreneurs we spoke to said that that the tax treatment of share options is
punitive, costly and too complex to make such options attractive.

Best in class, flexible and easy to use share options would help by giving employees a
sense of “ownership”, creating an added incentive for employees to work for startups
and reducing the risk of them leaving the business.

The UK and US are seen as best in class by entrepreneurs for share options, followed
by Israel, Switzerland and Germany.

3 in 4 entrepreneurs rated Ireland’s current policy on share options as poor or very poor
with 1 in 4 saying it was average.
Point 3
Reform of the Employment Investment Incentive Scheme (EIIS) including an increase in the limit on investments to €2 million to drive investment.

The Employment and Investment Incentive Scheme is a tax relief incentive scheme which provides all income tax relief to qualifying investors for investments in certain qualifying small and medium sized companies.

We’re calling on the Government to encourage investment in medtech startups by increasing the limit of the scheme and end uncertainty caused by the current system of split relief, based on employment levels or R&D expenditure.

HOW THE UK COMPARES
The main difference between the Irish and UK EIS schemes relates to the limits to which they apply.

The limit in the Irish scheme for individual investors is €150,000 annually. In Britain it is £2 million per year for a married couple or £1 million individually.

The UK EIS also allows for losses to be offset against tax, the Irish EIIS does not.
Our recommendations for the Government are to:

- Increase the €150,000 limit on EIIS investments to €2 million. The current level is severely restricting the flow of capital to firms.
- In line with the recommendations of the Indecon review, losses on EIIS investment should be allowed for CGT purposes and any capital gains on the sale of shares are taxed as capital gains rather than as income, as is currently the case. The current system makes potential entrepreneurs more risk adverse.
- Remove the current system of split relief based on employment levels or R&D expenditure. This introduces a level of uncertainty for the investor over which they have very little control. Full relief should be given in the investment year.

Estimated cost: €20 million

Entrepreneurs’ experience of EIIS

Medtech founders experience of availing of the Employment Investment Incentive Scheme is mixed. Some have never used it, with some saying that the EIIS limit and uncertainty caused by the current system are a disincentive to investing in medtech startups.

Most entrepreneurs have considered investing in alternative countries. The main reasons are more attractive and efficient taxation systems, better interest rates and CGT. One startup CEO said that they are relocating to mainland Europe because “the business environment here is anti-startup”.

Nearly 9 out of 10 entrepreneurs said that they had considered relocating their or their businesses to another country. Most have considered relocating to the US which is seen to have more supports and a more favourable environment. This is followed by the UK which has “more entrepreneur friendly tax policies”. Other countries identified are Switzerland, France, Malta, China and India.

Removing the current system of split relief based on employment levels or R&D expenditure, with full relief in the year, would help entrepreneurs but more needs to be done.

Medtech entrepreneurs agree that losses on EIIS investments, for CGT purposes, being taxed as capital gains, rather than income, would make a difference to their businesses and help make EIIS more tax efficient.

More than 7 out of 10 entrepreneurs said that Ireland’s current policy was average, while 1 in 7 said it was either poor or average.
Government support, backed by industry and IDA Ireland investment, for an Advanced Manufacturing Centre of scale, located in Limerick to act as a shared space to allow companies work together to develop technology and talent.

Manufacturing accounts for nearly a third of Irish GDP. To fully realise the sector’s potential and sustain and build our vital manufacturing mandates we need the right infrastructure and business environment. Otherwise, Ireland risks losing out to competitor economies that are already investing aggressively in this space.

IDA Ireland recently announced a new Advanced Manufacturing Centre to support companies in the de-risking, deployment and commercialisation of advanced manufacturing and digital technologies within their operations.

This initiative will be a key enabler of the skills uplift needed for the future, and a natural home for collaboration between SMEs, FDI companies and technology providers. To be competitive long term, Ireland must take a leadership position in this space.

The Irish Medtech Association are calling on the Government to act now and lead on the delivery of this critical national infrastructure.
HOW THE UK COMPARES

The Catapult centres are a network of world-leading centres, established by Innovate UK, to transform the UK’s capability for innovation and help drive future economic growth.

They are a series of physical centres where the very best of the UK’s businesses, scientists and engineers work side by side on late-stage R&D – transforming high potential ideas into new products and services to generate economic growth.

Each Catapult centre does this by providing access to expert technical capabilities, equipment, and other resources required to take innovative ideas from concept to reality.

Our recommendations for the Government are to:

• Invest strategically in a discrete Advanced Manufacturing Centre of scale. A funding model the same as or similar to the 1:1:1 funding model, like a Research Technology Organisation (RTO) should be adopted. The focus should be on the higher Technology Readiness Levels (TRL) levels (5 – 9) to address the gap that currently exists in the research, development and innovation ecosystem.

Estimated cost: €30 million on top of the €12 million already committed by IDA Ireland

Entrepreneurs’ experience of the advanced manufacturing ecosystem

In a recent Irish Medtech Association survey, more than four out of five Irish Medtech Association members said that automation of manufacturing was critical and two thirds of members we surveyed said that their company were implementing some form of automation.

As many as 57% said their approach to adopting new technologies was business driven, but one of the greatest barriers identified by 49% of respondents is difficulties integrating new technologies.

Ireland is recognised as a leader in manufacturing with the greatest number of Shingo Prizes for operational excellence, per capita, in the world but as we look to the future we need to embrace new technologies to remain global leaders.

In particular, 92% of respondents identified robotics as important, 83% identified AI and data analytics, with 79% focusing on additive manufacturing and 3D printing. The group has identified this as a major gap in the advanced manufacturing ecosystem. Recent investment in manufacturing research centres are a positive step to drive innovation in this space, but it does not go far enough.
The medtech startup cycle

There are a number of key milestones on the road to success for medtech startups from identifying an unmet clinical need and commercial opportunity, to attracting funding, then getting to market and driving sales. This journey takes time and money; some startups run out of both along the way. Those who succeed can either grow their business by adding new markets and products or exit and start all over again with a new startup.

1. **Identifying an unmet clinical need and commercial opportunity**
   When starting a medtech business, entrepreneurs must first identify an unmet clinical need and commercial opportunity. If an entrepreneur has a good idea for a technology it must be innovative, addresses patient needs and add economic value to stand out. They need to consider the clinical commercial context to understand the financial drivers behind the technology and the associated risks. Their product must be clearly differentiated to compete.

2. **Getting the leadership team right**
   Once they have a good idea, they can start to build a business around it. For medtech entrepreneurs there are two key streams - technology development and attracting funding to help the business reach key milestones. To grow entrepreneurs, create jobs by building a team which includes subject matter experts and add experience with their board who can help de-risk new businesses as well as reassure potential investors.

3. **Addressing clinical need and device development**
   When developing a new technology, first entrepreneurs need to develop a prototype as proof of concept. Then as they continue to design and develop the technology, they need to identify any potential risks and ensure technological feasibility.

The medtech startup cycle: Medtech innovation pipeline

![Medtech Innovation Pipeline Diagram]

**01** Identifying an unmet clinical need and commercial opportunity

**02** Getting the leadership team right

**03** Addressing clinical need and device development

Supporting Irish medtech startups and innovation in the face of global competitiveness pressures
4. The business plan
   Along with developing the technology, entrepreneurs need to build a business plan to help them on their journey to market and raise funding along the way. They need to understand how much they need to raise to support R&D, clinical investigations, regulatory approval, market access, distribution costs and still make a return on investment in an acceptable time frame. When they’ve identified which country they’re going to market in first they need to understand the implications of this, such as regulatory pathways and the reimbursement strategy that works for different health systems.

5. Intellectual property
   Medtech is arguably the most innovative sector in Europe with nearly 14,000 patents filled with the European Patents Office in 2018. As startups begin to grow entrepreneurs need to do a review of the IP landscape to ensure their position in the market is not already taken and to protect it. There are three different ways to do this notably, patents, trademarks and registered designs. Early strategic work with IP experts can help avoid problems down the road and increase the technology’s attractiveness with investors.

6. Financing
   As entrepreneurs begin on their startup journey the company’s worth is low, it’s high risk and raising money can be expensive. Pre-money valuation will give an early indication of its worth by checking the leadership team, similar companies, reviewing the market size along with key players, and identify how much money it needs to reach key milestones. As startups move from one milestone to the next, raising money gets less expensive if technical and commercial milestones are well managed as the risks are reduced for investors. There are a number of key funding milestones startups need to reach to move from one stage to the next or risk failure.
The medtech startup cycle / continued

- Concept (seed funding)
- Establishing a startup (state grants, venture capital and business angels)
- Testing the safety and efficacy of the technology with clinical investigations (expansion funding from venture capitalists, family, investment banks, and corporate investors)
- When the startup’s technology has gone to market, had its first sale and are trying to drive profits (mezzanine funding stage underpinned by debt and equity)
- Once they’ve achieved liquidity, they may look to scale the business or exit by being acquired

7. Clinical investigations
Once startups have developed the technology, they must begin to test it for safety and initial efficacy with pre-clinical validation. Early engagement with clinical and ethics experts can help startups successfully manage clinical studies. When they’ve had success in this stage, they may move on to first in human clinical investigations to gather more data and build clinical experience of the product in use. After the technology has been successfully used in the pilot trial and clinical endpoints have been reached, then it can get clinical validation.

8. Identifying the right regulatory pathway
For the product to get to market, it needs regulatory approval. To get regulatory approval entrepreneurs need to demonstrate product safety, efficacy and clinical benefit. The Food and Drug Administration is the regulator in America, the channels for regulatory approval are either the 510(k)-pre-market submission demonstrating equivalence to another legally marketed technology or premarket approval (PMA) to go to market by demonstrating sufficient scientific evidence to provide assurance. In Europe the regulations are set by the European Union and companies are held to a high standard to achieve a Conformité Européenne (CE) mark. While the EU set the regulations CE marks can be granted under these rules by any one of 58 notified bodies.

Achieving regulatory approval is not only an important step for selling a medtech product, it’s required for most companies that may wish to exit. The majority of startups are acquired post-commercialisation, and entrepreneurs must plan ahead to make it to this milestone. Once the technology has gone to market and is in use post-market surveillance begins. At this stage there may be further product updates to improve clinical as well as cost-effectiveness of the technology.
9. Breaking into the market
The first sale is an important step on the road to success. The most common market medtech startups pursued first are either the USA which is the largest medtech market (43% of the global market) or the European Union (28% of the global market). As both the largest global market and a single market, the USA is an attractive first destination. To get there entrepreneurs need to identify the right distribution channels. Then as startups look to grow they develop sales and marketing strategies to drive sales and break into new markets.

10. Exiting or scaling
When they’ve achieved significant market penetration, startups can either develop a strategy to scale the business or look to exit by being acquired or go public with an IPO. Many startups pick the acquisition route with entrepreneurs using the experience to then start new companies, but competition is getting tougher with changes in M&A.

Global medtech firms are becoming more strategic making fewer, larger deals, the value of mergers and acquisitions grew 178% globally and were worth €49 billion in the first half of the 2017 alone. This activity is complemented by divestments as companies refine their business plans. Only 1 in 4 medtech acquisitions occur within six years of a company’s existence. For many VCs these first six years are focused on building and growing portfolios. Finding the right VC at the right time to invest in your business is a major driver of success. The following four years then focus on portfolio maintenance and realisation of investments. Sometimes, funds have a one or two year extension.

An acquirer’s willingness to pay depends on profits and how the startup can strategically enhance its portfolio by expanding either its product range or creating a gateway into new markets. The average time-to-exit for medtech startups is 7-9 years. By this time companies have spent an estimated €40 million growing their business. Nearly one in five medtech M&A deals are around the €45-€90 million valuation range.
While startup founders may take different paths to start and grow a medtech business, here we’ve set-out the most common milestones that signpost your journey to success.
Identify an unmet clinical need and commercial opportunity

Do you have an innovative product that stands out from competition?

Develop initial business plan

Build core team and add expertise with strong leadership

Design and develop product prototype

Protect IP

Attract startup funding (grants, VC and business angels)

Pre-clinical validation to test for safety and efficacy

Attract expansion funding to support clinical trials and company growth (grants, VC, investment banks and corporate investors)

Review IP landscape
About the Irish Medtech Association

The Irish Medtech Association is the business association within Ibec representing the medtech sector.

The Irish Medtech Association has more than 250 members and represents over 90% of the employment in the sector. The Irish Medtech Association’s vision is that Ireland will be a global leader in innovative patient-centred medical technology developments, products and solutions.

- Ireland will be a globally significant medical technology hub and the location of choice for the industry due to our expertise and pro-business environment.
- Irish medical technology developments, products and solutions will be major contributors to global healthcare and the global economy.

The Irish Medtech Association is led by a Board of Industry CEOs and Executive Leaders. Strategy implementation is coordinated through working groups and taskforces.

www.irishmedtechassoc.ie