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BioInnovate Ireland

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Foreword by Professor Peter McHugh, Interim President of the University of Galway

It is my honour to present to you the BioInnovate Socioeconomic impact study produced by EY.

This report serves not only as a comprehensive evaluation of BioInnovate's efforts, but also as a beacon to attract future candidates and secure continued support for the Programme's participants and their healthcare innovations.

The objective in commissioning this report was to assess and highlight the transformative effects of our training on participants, the healthcare sector, and the broader community. Through rigorous analysis and insightful findings, this report aims to demonstrate the tangible benefits and far-reaching implications of BioInnovate's work. This endeavour underscores the University of Galway and BioInnovate's unwavering commitment to excellence in education, innovation, and societal contribution.

I wholeheartedly believe that this report will serve as a powerful tool in showcasing the unparalleled opportunities and outcomes that BioInnovate offers. It is my hope that it will inspire new talent to join our ranks and encourage stakeholders to invest in future innovations from this groundbreaking Programme that are addressing unmet healthcare needs.

Thank you for your continued support and dedication to advancing healthcare innovation. Sincerely,

Professor Peter McHugh

Interim President of the University of Galway

Uachtarán Eatramhach Ollscoil na Gaillimhe





Foreword by Dr Jacinta Thornton, Associate Director, University of Galway Innovation Office

It is with great pride that we share this impact report from the BioInnovate Programme in the University of Galway. The success of BioInnovate is a testament to the University's commitment to supporting creativity, collaboration and innovation on our campus.

For over a decade, the Programme has brought together exceptional people from diverse disciplines, creating a vibrant ecosystem where ideas flourish and transformative needsled innovations emerge. BioInnovate stimulates the development of groundbreaking technologies and provides invaluable opportunities for students, faculty and partners to engage in research and innovation that addresses real-world challenges. The result is a supportive, engaged and effective entrepreneurial ecosystem. What sets the Programme apart are the University Investigators, innovation supports and funding instruments such as the Enterprise Ireland Commercialisation Fund programme which together help transform these well validated concepts into companies capable of securing investment.

BioInnovate has been a game-changer for our University, region and Ireland. The impacts speak for themselves and are a source of inspiration and a reminder of what can be accomplished through collaboration.

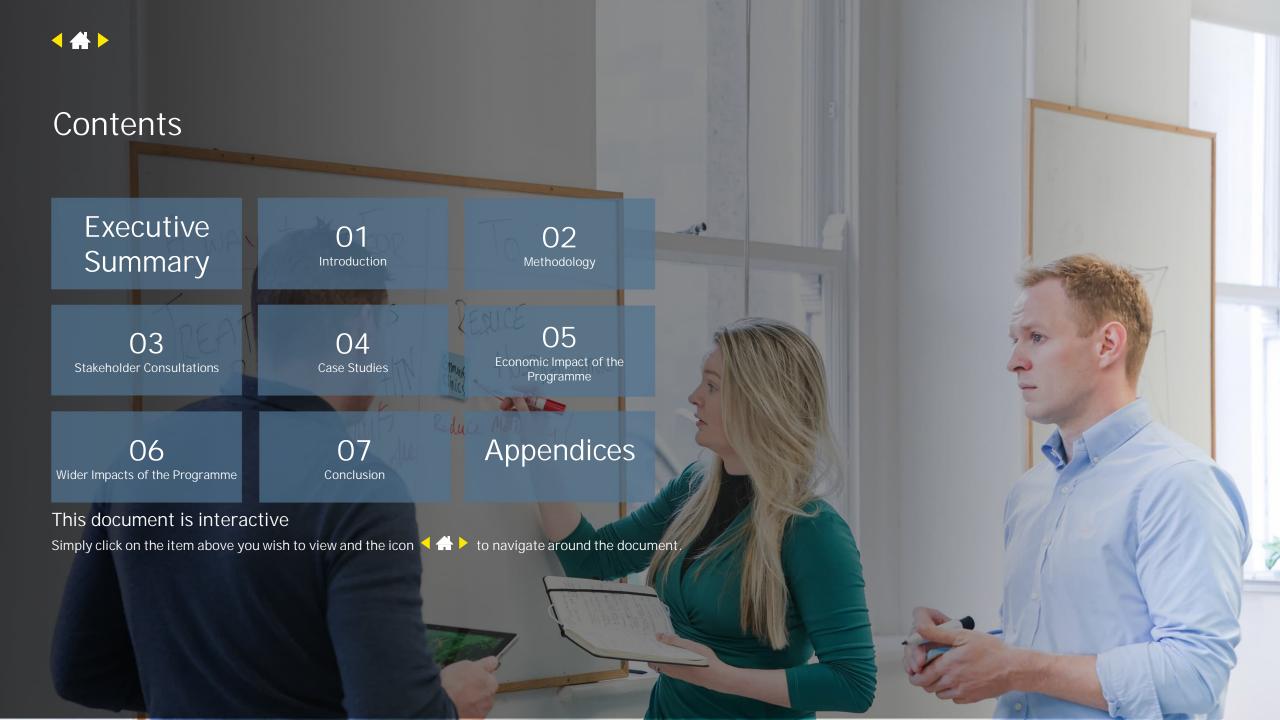
We extend our gratitude to everyone who has contributed to the success of this programme. The passion, creativity and commitment of the BioInnovate founders, management team, mentors and supporters have been a significant factor in its success and a driver of the research and innovation mission of the University of Galway.

Sincerely,

fort that

Dr Jacinta Thornton

Associate Director, Innovation Office, University of Galway Stiúrthóir Comhlach, Oifig Nuálaíochta, Ollscoil na Gaillimhe







Since 2011, BioInnovate has trained 159 Fellows and led to the creation of 35 startups, of which 24 are El Alumni-led High Potential Start Ups (HPSUs)

Programme, started in 2011, is a specialist health technology innovation programme affiliated to Stanford BioDesign. It was initiated by the late lan Quinn who saw the opportunity to anchor the medtech sector in Ireland by training innovators and leaders in this space.

▶ Affiliated with Stanford University's globally renowned BioDesign program, BioInnovate has adopted and adapted the BioDesign process as a proven needs-led innovation approach to solving previously unmet, under-met and unrecognised problems. ▮

The 10-month Programme ensures fellows and industry partners have a greater chance of creating meaningful, impactful solutions to future healthcare needs through problem-based thinking.

► The BioInnovate Programme has led to the development of 35 startup companies across Ireland who are driving and growing the health tech sector.

 Today, 1 in 8 Irish medtech companies have come from the BioInnovate Programme.

BioInnovate is globally recognised as a centre for medical technology (medtech) innovation. In recent years, with the convergence of technologies across sectors, BioInnovate has become a leader in health technology innovation, encompassing medtech, pharmaceutical and digital health solutions as well as other possible solutions. Based in Galway, one of the world's largest medtech hubs, BioInnovate enhances the future of healthcare through its programme.

► The focus of the programme is to equip fellows with the skills, network, and understanding around unmet healthcare needs to establish their own health tech startup or return to industry or clinical practice to build innovation capacity within existing organisations.

➤ To date, 159 Fellows have been trained and progressed to a diverse range of careers including Venture Capital, industry, government agencies and clinical roles. Approximately half of Alumni lead their own startup.







Factors contributing to the economic impact of BioInnovate*



Needs-led innovation

Innovation driven by identifying and addressing underserved needs in healthcare



Increased investment and funding

 Increased investment from venture capital, private equity and grants



Maturation of startups

It takes a number of years for startups to reach a stage of maturity with successful development, launches and market penetration





Lifetime economic impact of the BioInnovate Programme (2011 to 2024)

Value added to the economy by startups emerging from BioInnovate

BioInnovate | Economic Impact Assessment

€277m GVA*

- Direct GVA impact = €207m
 The value added to the economy directly from the startups' financial flows
- ► Indirect GVA impact = €29m The impact of the spending in the activity generated by suppliers, service providers, manufacturers, etc.
- ► Induced GVA impact = €42m The activity generated by the consumption in the economy by the wages received from working directly or indirectly with the startups
- ► GVA per lifetime FTE = €190k Higher GVA compared to the GVA per capita of Ireland (€82k), and the GVA of the Western region (€44k)¹

This GVA indicates that those emerging from the Programme are highly productive and efficient in creating economic value



BioInnovate's role in job creation in Ireland's medtech sector

1,460 jobs supported in Ireland

- This number represents the employment impact of the startups and is a crucial indicator of its success and economic contribution
- Due to the nature of the data, we calculate the total number of lifetime jobs supported, rather than separately identifying direct, indirect and induced
- The jobs created have a multiplier effect on the economy. Each job supports additional employment in related sectors, amplifying the overall economic impact.



This number is significant and shows the positive impact of fostering innovation and entrepreneurship on economic growth Financial contributions made to public finances by the startups

€32m exchequer revenue generated

- ➤ The exchequer impact is a crucial indicator of the broader economic benefits
- ► A strong exchequer impact can support further investment from both public and private sources
- ► It highlights the importance of the Programme in achieving fiscal and economic development goals in the region, leading to sustained or enhanced funding and resources
- ➤ This is demonstrating that the Programme's strategies and interventions are yielding positive fiscal outcomes

This positive exchequer impact equating to c.€910k per startup shows the role played by BioInnovate in generating fiscal revenue in the west of Ireland

Wages generated by the startups over their lifetime

€84m in wages

- This figure represents the total compensation paid to employees, including salaries, wages, bonuses, and benefits
- This is not only direct to the employees of the startups, but also indirect and induced through its impact on the supply chain and the wider economy
- ► Higher wages boost local economic activity by increasing consumer spending in the regions where the startups operate, strengthening regional economies



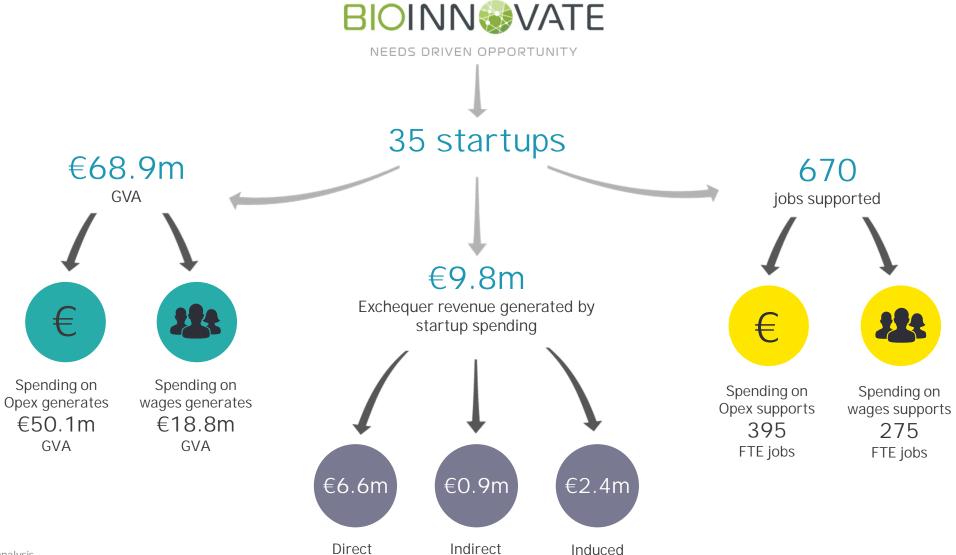
The wages generated demonstrate that the startups and innovations developed have a significant impact on fostering a stable and productive workforce

Source: BioInnovate, EY analysis

1 Bridging the Divide: 25 Years of Transformation in the Western Region - Western Development Commission

* Numbers may not sum due to rounding

In 2024 alone BioInnovate alumni-led startups generated €69m GVA and supported 670 jobs through their operational and capital investment activities in Ireland







BioInnovate's impact is far-reaching, including the positive regional impact on the west of Ireland and the critical career development for participants

Regional impact of the BioInnovate Programme



Lifetime Regional impact

- ▶ Over 70% of the startups are based in Galway. As such, a substantial proportion of the spending and impact occurs in the west of Ireland.
- ► €193m GVA has been generated in the west of Ireland, which has supported 886 jobs, €52m wages

Impact of the BioInnovate Programme on career development

Technical expertise

Hands-on experience in design, development, and testing of medtech innovations, along with the identification of unmet healthcare needs

Business and funding knowledge

Training in business development, market analysis, and commercialisation strategies, providing the fellows with the tools necessary to become a medtech founder

The BioInnovate Network

Enabling connections with key players in the medtech industry, which leads to collaboration and knowledge sharing that cannot be found elsewhere.

c.50% of alumni go into diverse careers ▶ For these alumni, the BioInnovate Network is equally as important for building on their understanding of the needs-based innovation process, and sharing this with industry and in clinical practice. They bring a new way of thinking into their roles, with some going on to embed needs-led training and embed a culture of innovation this within their respective organisations.





Seven start-ups at various stages of development were utilised as case studies to determine the wider social impact of the BioInnovate Programme

Organisations consulted







The role of the BioInnovate Programme



► For alumni, the network was recognised as key for the development of both the alumni and startups. It provided a full ecosystem of expertise and invaluable insights.



➤ The clinical immersion element of the Programme was a key theme across the case studies. The needs-led innovation approach allowed the need to be identified and validated, ensuring strong clinical demand.



► The information provided by the Programme was provided at the right stage. This gave the alumni a thorough understanding of the whole medtech landscape, regardless of professional background.

The impact the innovation had on healthcare and patient lives



► The needs-led innovation and clinical immersion allowed the alumni to address overlooked or underserved healthcare needs. This gives a voice to often unheard patients and their families.



► A theme throughout the case studies was also the improvement of the quality of life for patients and redefining the standard of care. This gives patients the ability and confidence to live their lives.



The innovations reduce the strain on the healthcare system through reducing the time spent recovering in hospital. This can be through providing treatments administered at home or in non-hospital medical settings.









Project background

EY have been commissioned to conduct a report to assess BioInnovate's socio-economic impact and contribution to value creation in Ireland, particularly considering the number of startup companies (and the funding therein) that have come from the Programme, the social impact of the Programme in Ireland in terms of better training, career progression, and the impact of new treatments and technologies on patients.

This study is conducted primarily using EY's Economic Impact Assessment (EIA) methodology, a multi-pronged analysis which will provide the Direct, Indirect and Induced impacts of the development of these facilities on the Irish economy. The analysis is based on a clear framework, discussed herein.

Report Layout

This report presents our findings regarding our analysis. It is laid out as follows:

Executive Summary

- 1. Introduction
- 2. Methodology
- 3. Stakeholder Interviews
- 4. Case Studies
- 5. Economic Impact of the Programme
- 6. Wider Impact of the Programme
- 7. Conclusion

Appendices

Project Scope

This report sets out the impact of the BioInnovate Programme from an economic and social perspective. It includes the following:

- 1. The economic impacts of BioInnovate, explored through the startups that have come from the BioInnovate Programme and their direct, indirect and induced economic impacts across GDP, jobs, and Exchequer revenue.
- 2. The impact of BioInnovate on the regional economy in the west of Ireland.
- 3. The social impact of the BioInnovate Programme. We have conducted multiple interviews with stakeholders related to the BioInnovate Programme, and have combined this with other online resources to establish the wider impact BioInnovate has on its fellows and on the medtech ecosystem in Ireland.





The foundation of the BioInnovate Programme

The BioInnovate Programme is a specialist medical device and digital health innovation programme and is one of two Global Affiliates to Stanford BioDesign. BioInnovate is based at University of Galway and is co-funded by Enterprise Ireland (EI). It was established in 2011 with the aim of anchoring the medtech sector in Ireland through needs-led training and creating indigenous startups.

BioInnovate Ireland was established to drive medtech innovation and entrepreneurship in Ireland. Spearheaded by Ian Quinn, in collaboration with the University of Galway and Enterprise Ireland, the Programme bridges the gap between clinical needs and technological solutions.

lan Quinn had seen industries, such as textiles and electronics, leave the region and he sought to anchor the medtech sector here. Inspired by the Stanford BioDesign model, BioInnovate was created to nurture the next generation of medical device innovators and strengthen Ireland's medtech industry.

BioInnovate was founded by a dedicated team at the University of Galway whose leadership and expertise helped shape the Programme's framework and secure institutional and external support, ensuring its success as a driver of medtech innovation in Ireland.

From the start, the Stanford BioDesign Team provided crucial mentorship, helping establish BioInnovate's structure and align it with global best practices, cementing its reputation as a leading medtech innovation hub.

Since its launch, BioInnovate has trained 159 Fellows, 260 industry-based participants from Boston Scientific, Medtronic and other industry partners, and fostered 35 startups. The Programme has seeded a vibrant community of innovators and experts across academia, clinical practice, and industry, strengthening Ireland's position as a global medtech leader.



Ian Quinn with the first cohort of BioInnovate fellows

BioInnovate Funding

The BioInnovate Programme has been co-funded by Enterprise Ireland, the University of Galway and industry partners since the Programme's inception in 2011 until 2024. This report captures the socio-economic impact of the Programme during that time.

Since 2024, BioInnovate is supported under the Innovators' Initiative programme co-funded by the Government of Ireland and the European Union through the Northern and Western Regional Programme 2021-2027.

















What is the BioInnovate Programme

The BioInnovate Programme is a highly competitive 10-month long training programme founded on the BioDesign core principles of needs-led innovation. The Programme leverages this proven Stanford BioDesign framework to develop a talented, motivated, multidisciplinary pool of innovators to shape the future of healthcare.

The BioDesign process, adopted and adapted by BioInnovate, includes three steps - Identify, Invent, Implement. This problem-first or needs-led approach aims to find the biggest healthcare problem worth solving before inventing a solution to address it.

For the Identify phase in each academic year, different clinical areas are chosen as the focus, and faculty and clinicians in that field are recruited to support the training and mentoring of the fellows. It begins with a boot camp style introduction to the clinical areas and the Biodesign process, using a learn-by-doing approach. Following this period, there is a two-month immersion in clinical practice to help identify unmet healthcare needs, usually identifying up to 1,000 clinical needs. These needs are then filtered based on potential impact, market, investor interest and other criteria. This in turn leads to the needs with the greatest potential rising to the top of the list for further investigation and innovation.

Once the top needs are identified, BioInnovate innovators begin the Invent phase. Participants brainstorm and generate potential solutions for each of their high-priority needs, before refining and evaluating these ideas.

In the Implement phase, BioInnovate teams develop a thorough business plan to commercialise their innovation. The focus of the BioInnovate Programme is to equip fellows with the essential skills, deep understanding of how to assess unmet medical needs, and a network of industry experts, enabling them to establish their own medtech startups or to enter the industry with an innovative mindset. By immersing participants in a comprehensive, needs-based process, the Programme ensures that fellows are well-prepared to identify and address critical healthcare challenges through innovative solutions. This approach not only fosters creativity and innovation but also ensures that the solutions developed are practical, relevant, and ready for market adoption.

A unique aspect of the BioInnovate Programme - Maturity of fellows

BioInnovate is focused on commercial viability of innovations emerging from the Programme, and so mid-career professionals from clinical, commercial and technical backgrounds are targeted to participate in the Programme. It was also noted that compared to those emerging directly from university, experienced clinical, technical and commercial professionals often enter with different perspectives, understandings and motives, which also drives their companies and their successful commercialisation.

BioInnovate Core Team



Prof Martin O'Halloran Executive Director



Prof Mark Bruzzi
Founder/Non-Executive Director



Prof Faisal Sharif Non-Executive Director



Dr Sinéad Walsh Director of Operations



Ailish Walsh Operations Manager



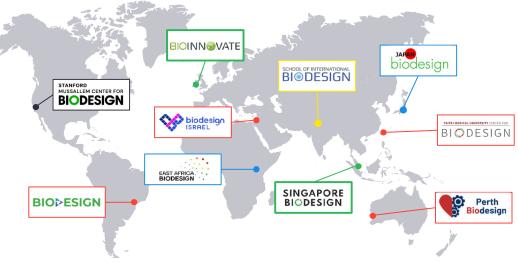
Ann Byrne Programme Administrator





BioInnovate and Stanford BioDesign

Figure 1: Stanford BioDesign Global Partnerships and Affiliations¹



- Original Stanford BioDesign Programme
 Active Programme Development Partners
- BioDesign Global affiliates

Other Programmes

"Graduated" Partners

The original BioDesign innovation process developed by Dr Josh Makower and Prof Paul Yock at Stanford University has been replicated around the world through affiliation and Stanford's Global Faculty Training. BioInnovate is one of only two global affiliates and is the only European affiliate of Stanford BioDesign.



The Stanford Mussallem Centre for BioDesign and BioInnovate share a common set of values and processes that link them together in a way that transcends geographic distance. We're proud of having BioInnovate as one of our few Global Affiliates and have enjoyed a positive, collaborative relationship from its founding.

> Dr Josh Makower. Co-Founder of Stanford BioDesign



I have huge admiration for the University of Galway and the BioInnovate Programme... It is a very good example of the university working closely with the technology community. In fact, I'd say our two universities, Galway and Stanford, stand out in this respect.

> Prof Paul Yock Co-founder of Stanford BioDesign



Prof Paul Yock (left) and Dr Josh Makower (right) receiving their honorary doctorate from University of Galway for their contribution to medtech.





Key Enablers of the BioInnovate Programme

Clinical Access and Engagement

Through the BioInnovate Programme, fellows have accessed more than 150 different hospitals, both nationally and internationally across more than 30 clinical areas. The Clinical Champions and their teams at these hospitals provide the gateway to healthcare innovations. These clinicians and patients openly engage with the fellows to help them understand their most important and pressing healthcare needs.

The clinical access and time afforded to fellows is one of the most important factors for fellows to gain insights into the clinical areas and their standards of care, as understanding the right problem to solve is the key to successful innovation.

Enterprise Ireland Commercialisation Fund

The BioInnovate Programme benefits from the funding opportunity and support of the EI Commercialisation Fund, which assists in translating research into innovative and commercially viable products, services and companies.

This aligns well with the Programme's emphasis on derisking the commercial pathway through a needs-led approach. For alumni who successfully secure a Commercialisation Fund, this affords them time and resources to continue planning, identify potential solutions and develop technologies to address unmet healthcare needs.

Supportive University Environment

A key enabler of the successful innovations from the BioInnovate Programme is the availability of world class academic researchers at University of Galway and other universities throughout Ireland, and their willingness to support the research and development of innovative technologies. These academics often take on the role of Principal Investigator in projects that emerge from the Programme.

University of Galway's Innovation Office supports this journey to develop a technical and commercial plan and achieve a university spin-out. This usually involves a 2-3-year period of further research, securing funding, IP protection and building the technology and investor readiness level to successfully launch a spin-out.

Creating a Community

Since the start, BioInnovate has leaned into the external expertise within Ireland, inviting serial entrepreneurs, investors and experts with significant industry expertise to deliver workshops of relevance to the fellows. In this way, BioInnovate acts as a facilitator to open doors in the medtech community.

Additionally, while other countries, such as the USA, have a more established approach to entrepreneurship (and failure), the BioInnovate Programme, through its leadership development coaching, fosters belief in fellows that they too can have an impact on the world. Galway is now recognised as one of the top 5 global medtech hubs.



Collaborating with fellows from the BioInnovate Programme showcases their strong entrepreneurial spirit and drive for success. Their perseverance and determination enable them to navigate the commercial journey through the University's support system post-programme, in company formation, achieving investment readiness, HPSU status, and scaling their ventures. The exceptional talent emerging from this programme is evident, and the Innovation office is always delighted to support this group achieve commercial goals.



Fiona Neary, New Ventures Manager, University of Galway Innovation Office





BioInnovate Programme Mentors and External Advisory Board

BioInnovate fellows have access to mentoring, offering invaluable assistance throughout the whole timeline of the Programme. The mentors are domain experts with significant clinical and commercial experience, including serial medtech entrepreneurs, who understand the Programme and provide fellows with advice, guidance, and support on their programme journey. Mentors will listen and ask questions that will challenge fellows to uncover unique insights into healthcare problems, define real commercial opportunities and identify the course of action they need to take regarding their own development and progress through the Programme. They provide significant mentorship and expertise on a weekly basis, acting at the later stages of the Programme like a 'Dragons' Den' Investor Panel, providing a vitally important contribution to help identify investable business opportunities.

The BioInnovate External Advisory Board also provides an important advisory function, made up of industry leaders, healthcare innovators, and academic experts who bring a wealth of experience and insight to ensure that BioInnovate adapts to the fast-changing landscape of heath technology innovation, poised to deliver not just on today's needs but also future healthcare needs.

BioInnovate Programme Mentors



Paul Gilson Medical Device Professor, University of Galway



Prof Aoife Lowery Associate Professor. Entrepreneur & Adjunct University of Galway, Consultant Breast & Endocrine Surgeon Galway University Hospital



Dr Barry McDermott Pipeline Lead. Luminate Medial



Dr Conor Judge Consultant Nephrologist Galway University Hospital



Dr Fimear Dolan Research Fellow and Assistant Professor. SFI Royal Society University



Tony Roe Quality Management Consultant, **TROEMED**



Prof Leo Quinlan Lecturer and Researcher University of Galway



Dr Eoghan Dunne Senior Post-Doctoral Researcher University of Galway

External Advisory Board -----

- John MacNamara Chairman of the BioInnovate Advisory Board, VP for Research and Development, Medtronic
- Jonathan Bouchier-Hayes CEO, Endowave Ltd
- Caroline Gaynor Partner, Lightstone Ventures
- Prof Walter Gear Dean of Science and Engineering, University of Galway
- ▶ Paul Gilson Medical Device Entrepreneur
- Emma Callinan Director of Commercialisation, Enterprise Ireland
- Dr Maura Glennon Commercialisation Specialist and Relationship Manager, Enterprise Ireland
- Eoghan Ó'Faoláin Director of Irish MedTech Association
- Dr Ian Purdy Senior Vice President, Regulatory Affairs and Quality Assurance
- John McSweeney Commercialisation Executive, Innovation Office, University of Galway
- Dr Jacinta Thornton Associate Director, Innovation Office, University of Galway
- ▶ Dr John O'Dea CEO, Palliare
- John O'Brien Executive Chairman & CEO at S3 Connected Health
- John O'Sullivan General Partner, ACT Venture Capital
- Maureen Timlin VP of Medical Technologies for US Mid-West IDA Ireland Life Sciences Division
- Prof William Wyns SFI Professor of Interventional Cardiology, University of Galway
- ▶ Robert (Chip) Hance CEO, Regatta Medical







Our methodological approach to this study

We have utilised a three pronged methodological approach



During this phase data from 35 startup companies and projects started by BioInnovate alumni and directors was gathered. This included revenue, funding, employment, capital spending, and operational costs.

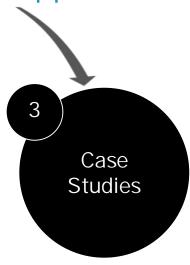
The methodology, assumptions, and considerations are explained in detail on the following pages. The resulting EIA includes total impact on the economy both nationally and regionally.



To best determine the wider societal impact of the Programme, key stakeholder interviews were conducted.

This qualitative analysis provides a deeper understanding of the BioInnovate Programme that potential funders, potential candidates, and the general public may not be aware of.

14 interviews were held, consisting of alumni of the Programme along with various stakeholders close to the Programme.



7 case studies of diverse startups from the Programme emerged from the stakeholder consultations conducted. These aim to represent the diverse range of startups and their stages of development, and have been outlined in Section 4 of this report.

The impact the BioInnovate Programme had on the startups and the impact of the innovations on the lives of patients and the healthcare system is discussed. These aim to provide further insight and tangible examples of the impact of the Programme.







Overview of economic impact methodology

Any spending by the startup companies which have resulted from the fellows coming through the BioInnovate Programme will have a multiplier effect on the economy. There is an economic supply chain being supported by the development of these startups, as well as their spending. Not only do these startups generate spending in research and development, but they also contribute spending to a wide range of sectors such as the rental, manufacturing and marketing sectors.

It is therefore important to estimate the total economic impact of the activities of those who have emerged from the Programme, rather than just showing the total amount that they, and their supplier base, will spend directly in the economy.

The basis of the methodology is Input-Output (I-O) Analysis, working with the Central Statistics Office's (CSO's) IO Tables of the Irish economy. These capture the economic relationships between the main sectors in the economy and can be used to measure the impacts from activity in a particular sector.

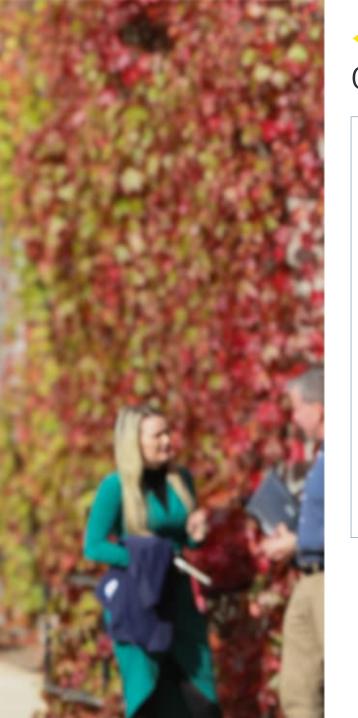
Economic Multipliers

Every time there is an injection of new demand into the economy there is a multiplier effect. This is because an injection of extra income leads to more spending, which creates more output, and so on. The multiplier effect refers to the increase in final output arising from any new injection of spending.

The IO methodology can be used to calculate three different types of multipliers:

- 1. Output multiplier: This shows the total output across all sectors of the economy associated with an €1 increase of output.
- 2. Gross Value Added (GVA) multiplier: This shows the total impact on GDP. GDP is comprised of GVA plus taxes. The GVA multiplier is lower than the output multiplier due to output multiplier having an element of double counting.
- 3. Employment multiplier: This shows the total impact on employment and is calculated by dividing the value-add multiplier by average productivity. Productivity improves year on year, and this means that fewer people are required to support the same amount of output. To allow for this a productivity growth forecast is included in the model.







Key considerations

Economic approach overview

We assessed the economic impacts on national GDP of the 35 startup companies and projects which have been started by fellows and directors of the BioInnovate Programme.

We assessed the GVA, jobs and wages generated in Ireland from these startups through assessing the combined funding, operations and expenditures of each.

This impact was relatively higher at the regional (West NUTS III region) and local (County Galway) levels, where it represents a proportionately larger boost to total economic activity than at the national level.

The economic analysis was conducted over two periods:

- 1) The latest year (2024) which is based on data from the startups from their latest year of operations
- 2) The lifetime impact, which is based on the total value of funding that all the startups have received.

Number of startups

We have assessed 35 startup companies¹ which have been started by alumni and directors of the BioInnovate Programme.

The focus of the Programme is equipping fellows with the skills, the network, and the understanding around unmet medical needs to establish their own medtech startup, or to go back into industry or clinical practice.

Accordingly, as was ratified in stakeholder consultations with the alumni, the startups would not exist or have been as successful in attracting funding without the Programme. However, it is worth noting that this does not necessarily translate to the economic impact of Biolnnovate, as Biolnnovate is not directly benefitting from the funding raised, nor the economic activity generated by these startups.

Nevertheless, without the Programme these startups would not be contributing to their current levels of economic activity.

Impact considerations

- ► The growth of these startups necessitates the hiring of additional staff, from research and development to sales and administration. This job creation increases household incomes, which can lead to higher consumer spending and a boost in economic activity.
- Successful startups from the Programme can attract both domestic and international investment. Venture capital and government grants flowing into these companies can increase the financial capital within Ireland, as well as regionally.
- ► The operation of these medtech startups can have a multiplier effect on the economy. As these companies grow, they require services from other local businesses such as suppliers, logistics, and professional services, thereby stimulating economic activity across various sectors.

There are several intangible impacts these startups have on the economy. These have not been quantified in the report, but they would lead to additional economic value.

- ► The commercialisation of the innovations created from these companies can lead to increased productivity in the healthcare sector and potentially create new market segments. This, in turn, stimulates economic growth and positively impacts the Irish Gross Domestic Product (GDP).
- BioInnovate's training component equips individuals with high-level skills and knowledge, enhancing the human capital. A more skilled workforce can increase the country/region's productivity and competitiveness.
- ► The lives saved, or the quality of life given back to patients who utilise the technology created by the startups has not been quantified or taken into account in this study.

¹ 28 of these startups are spin-outs from University of Galway, with several spin-outs also involving other universities in Ireland including TCD, UCD, UCC, and UL; and four others involving the Mayo Clinic, USA. These projects and startups emerged from a collaborative agreement where the Fellows spent time at the Mayo Clinic, Rochester, Minnesota, USA, interacting with clinicians and validating clinical needs. The IP emerging from this collaboration was shared between the University of Galway and the Mayo Clinic, and the Commercialisation Fund grants were supported by Enterprise Ireland. These 35 startups are at various stages of development and 24 of them are designated by El as alumni-led HPSUs. This is defined as having the potential to develop an innovative product or service for sale on international markets with the potential to create 10 jobs and €1m in sales within 3 years of starting up. So far, two startups have achieved successful exits; EMBO Medical was acquired by C.R. Bard in 2015; Vetex medical was acquired by Surmodics in 2021.









Stakeholder consultation process

EY conducted a series of interviews with various stakeholders involved with the BioInnovate Programme. These included interviews with alumni, affiliates of the Programme, as well as other stakeholders (including funders, past and present Directors of the Programme and University of Galway leaders). For the interviews with BioInnovate alumni, we centred around the impact the Programme had on the individual, their company and the product they developed. We then explored the impact their business has on patients and society.

For others affiliated with the Programme, we asked around the success of BioInnovate, and the impact the Programme has on fellows and on wider society. Other consultation material was provided by BioInnovate through video interviews and clips with other alumni in preparation for their upcoming recruitment campaign.

Interviewees

Alumni of the Programme:

- Dr Andrew Cameron (FeelTect)
- Annette Kent (Endowave, formerly Fire1)
- Conor Harkin (ProVerum Medical)
- Fionn Lahart (LUMA Vision)
- Dr Kevin Kelleher (Ostoform)

Stakeholders close to BioInnovate:

- Dr Maura Glennon (Enterprise Ireland)
- Gillian Buckley (Western Development Commission)
- Dr Majella Giblin (University of Galway)
- Dr James Browne (University of Galway)
- Prof Mark Bruzzi (Director and cofounder of the BioInnovate)
- Dr Josh Makower (Stanford BioDesign)
- Prof Martin O' Halloran (Executive Director BioInnovate)
- Dr Faisal Sharif (Non-Executive Director, BioInnovate)

Consultation material

Additional source material featured the following Alumni:

- Dr Alison Liddy (Relevium Medical)
- Liam Mullins (Perfuze)
- Caroline Gaynor (Lightstone Ventures)
- Irial Conroy (BlueBridge Technologies)
- Sarusha Pillay (pHetalSafe, Stryker)





Lessons from the stakeholder interviews

Highlights from the Programme

The BioInnovate Programme was revolutionary for Galway. It is a product of good strategy and vision from many people working together."

> Dr James Browne, former President of University of Galway

Key reasons for the success of the Programme:

Network & Community

The network and community aspect of the Programme is a key to its success

The culture of giving back and collaboration, and the spirit of perseverance and determination in pursuit of ways to improve the lives of patients is embedded deeply into the Programme."

Dr Josh Makower, cofounder BioDesign

Needs-based solutions

BioInnovate provide access to hospitals and clinics, which enables a targeted, needs-based approach to medical solutions.

// The clinical immersion was fantastic. I'd worked with doctors, industry, etc. but this is a different experience where it was a lot more organic"

Dr Alison Liddy, alumni, CEO Relevium Medical

Medtech ecosystem

There is a large medtech ecosystem in the west of Ireland. BioInnovate provides an opportunity for fellows to tap into this ecosystem, facilitating access to industry experts, funders, hospitals, etc.

Being part of BioInnovate means you're one step away from investors and successful entrepreneurs"

Dr Kevin Kelleher, alumni, co-founder Ostoform

Key takeaways regarding the Programme Career Development Network The process of the Programme, affiliation The close-knit community created to BioDesign, the implementation in a university setting, and the knowledge and by BioInnovate was identified by skills the fellows gain help them excel in the alumni as the one of the key their future career, whether that's influences on their careers. starting their own companies, or going innovations and companies, as it into other sectors/firms. provides a wealth of expertise for each step of their journey. Clinical Access The Programme's access Commercialisation to clinicians and patients & funding allows fellows to better identify underrepresented BioInnovate offers three advantages through the healthcare needs. funding journey: It also breaks down the 1. Learning how to connect long-standing barriers with potential investors between clinicians and 2. The BioInnovate link industry, enabling with Enterprise Ireland collaboration in the 3. The reputation and high 'neutral territory' of an teaching standards of academic setting. the Programme enable the alumni to better Support of Alumni access funding The self-sustaining support system Medtech ecosystem and community the Programme provides is invaluable. A mutually beneficial relationship exists between BioInnovate and This was seen by alumni as a "pay it the Galway medtech cluster. The fellows get access to a longforward" system, as the help one gets

established ecosystem and decades of learnings, whilst the sector

gains a diversification of products produced, people trained in the

needs first innovation process, and inspired alumni willing to

venture into the space as entrepreneurs or in the industry.



from this informal network was so

pivotal that it is important to give

back whenever possible.





BioInnovate Programme case studies

To showcase the wider social impact of the Programme, case studies from a cross-section of seven start-ups and their healthcare innovations are highlighted in this section. The companies included in these case studies were co-founded by BioInnovate alumni. Problem-based thinking, clinical immersion, and the availability of support networks played a pivotal role in the development of the innovations and success of these startups.

The following startups founded by BioInnovate alumni were divided into three categories based off their stage of development and their diverse patient-focused approaches:

Development Fionn Lahart Dr Christoph Hennersperger RELEVIUM MEDICAL Life thenging transportion O'Halloran



their stage of development and their Commercial Brian Shields David Townley Dr Kevin Kelleher Rhona Hunt

Each of the case studies showcases the respective journeys of the founders and their innovations, allowing insight into the mechanisms through which the BioInnovate Programme catalyses innovation, fosters entrepreneurial spirit, and ultimately contributes to socioeconomic development through the needs-based approach to medical solutions.

It is discussed how they have leveraged the BioInnovate Programme's resources and problem-based thinking to innovate, addressing critical healthcare needs and improving patient outcomes.

The support provided by the Programme, including access to expert mentors and state-of-the-art research facilities, has been instrumental in overcoming the challenges associated with medical device development and regulatory approval. These case studies not only highlight the innovative products and solutions developed but also underscore the instrumental role played by the Programme in nurturing these ventures from inception to market readiness.





Development

Advanced Cardiac Imaging

LUMA Vision

Fionn Lahart (pictured) founded LUMA Vision, formerly OneProjects, alongside Dr Christoph Hennersperger following their graduation from BioInnovate in 2016.





The role of the BioInnovate Programme

- Fionn credits BioInnovate with having a significant impact on his life and the development of LUMA Vision.
- ► He highlights the community's willingness to share experiences and support the growth of the company.
- ▶ He also credited the branding and label of the Programme to allow LUMA Vision to be taken seriously by funders and hospitals.

The impact the innovation has on healthcare and patient lives

- LUMA Vision has developed a cardiac imaging platform called VERAFEYE that deploys a sensor in the heart during surgeries.
- This provides reliable and intuitive intracardiac and endovascular navigation, allowing for easier navigation in heart surgeries. This platform enables the reconstruction of accurate heart data, allowing for real time image recreation of the heart for surgeons.
- ► The societal impact of this innovation:
 - ▶ Patients often come back 4+ times for repeat procedures. Using this imaging technology, successful surgeries have increased, resulting in lower cost and burden to patients and healthcare systems as cardiac patients spend 70% longer in hospital.
 - ▶ It allows patients to come off medication sooner, removing cost and allowing a return to their normal, often increased quality of life.
 - ▶ Detailed analysis of the patient's heart allows for more accurate and individually tailored treatments. This impact is for future usage of the technology but current indications for this application are positive.

Development

Pain Management Solutions

Relevium Medical

Relevium Medical is a pharmaceutical company founded in 2019 by Dr Alison Liddy (pictured) following her completion of the BioInnovate Programme at the University of Galway.





The role of the BioInnovate Programme

- ▶ During the clinical immersion element of BioInnovate, Alison identified chronic pain as an urgent clinical need with a lack of effective treatments.
- Relevium Medical developed the first concept through extensive research, supported by a Science Foundation Ireland award of €1.2m, before spinning out of the University with investment from Biotech Angels, Enterprise Ireland, Y Combinator and an EIC Transition grant of €2.4m.

The impact the innovation has on healthcare and patient lives

- Through innovative research and development, Alison and her team have created a range of novel pharmacological hydrogel treatments that integrate natural biopolymers with active agents, offering superior efficacy compared to existing treatments.
- ► The treatment developed offers patients immediate long-lasting pain relief and reduced progression of knee osteoarthritis, a disease which is incurable and progressively worsens over time.
- ► Knee osteoarthritis is the fastest-growing cause of disability, with its prevalence globally doubling in the past 50 years.
- ► The company has been awarded €4.6m in government funding to develop it's second generation treatment for osteoarthritis. The funding, provided through the DTIF, will support the numerous activities in the company's pipeline product development plan.
- ▶ In 2024, Relevium Medical opened its Series A investment round to complete a tech transfer to a manufacturing partners facility.
- ► This will allow them to produce the product to scale and ultimately complete a clinical trial in patients, bringing the product closer to market.





Clinical

Smart Pressure Monitoring for Wound Care

FeelTect

FeelTect was founded by Dr Andrew Cameron (pictured), Dr Darren Burke, and Professor Garry Duffy, and was launched in May 2019.





The role of the BioInnovate Programme

- Andrew completed the clinical immersion aspect of the BioInnovate Programme in the Mayo Clinic, where he encountered patients suffering from venous leg ulcers (VLU) using intermittent pneumatic compression. This unmet need would not have been identified if it were not for the ability to partake in clinical immersion.
- Andrew noted that as CEO of a young company, BioInnovate gave him and his cofounders the opportunity to speak to people in similar situations.
- ▶ He remarked that the BioInnovate brand opens doors and allows the opportunity to lean on an ecosystem full of expertise and insights giving them access to a wealth of knowledge and expertise.
- The initial two-year development phase of their technology was supported by €460,000 in commercialisation funding from EI.

The impact the innovation has on healthcare and patient lives

- FeelTect is a connected-health platform for improving the application, maintenance, and self-management of compression therapy. This is supported by a digital platform, a secure cloud database and remote dashboard.
- Its goal is to redefine the target and standard of care.
- ▶ The product allows for effective and tailored treatment for each individual which provides significant improvements in quality of life through improved healing times and reduced need to return to clinics. Ineffective compression results in delayed healing and places a burden on healthcare systems.
- This innovation has turned a chronic condition into a healable condition. The digital platform allows for monitoring of patients overtime, and allows informal carers to perform the wrappings at home, reducing the need to attend hospitals/clinics.

Clinical

Better Cancer Care for Patients

Luminate Medical

Prof Martin O'Halloran (pictured), the Executive Director of Biolnnovate, co-founded Luminate Medical alongside Dr Bárbara Oliveira and Aaron Hannon.





The role of the BioInnovate Programme

- Martin highlighted that the level of patient and clinical involvement throughout the Programme allows for innovations to be developed that both address clinical needs and give a voice to some of the lesser heard voices in medtech, including patients and their families.
- The concept behind Luminate's solution, to reduce the side effects of chemotherapy, was identified through the BioInnovate Programme. Subsequently, Bárbara and Aaron came on board to bring this concept through development to commercialisation.

The impact the innovation has on healthcare and patient lives

- Luminate Medical develops products to reduce the side effects of chemotherapy, including hair loss and peripheral neuropathy. 68% of all chemotherapy patients develop some form of peripheral nerve damage as a result of their treatment.
- ► Through consultations with oncologists, the founders of Luminate Medical learned that oncologists did not view these side effects as a primary issue during chemotherapy. Indeed, oncologists often considered it to be a sign of a justified, effective, and good treatment process.
- However, conversations with patients revealed that there was a psychological impact of hair loss and loss of sensory and motor function, adding trauma to them and to their families. Patients also highlighted that they were paying for inefficient solutions, such as trying retain their hair or to get wigs during treatment to hide their illness.





Clinical

Treatment for Benign Prostate Hyperplasia

ProVerum Medical

Conor Harkin (pictured) completed the BioInnovate Programme in 2013 before co-founding ProVerum Medical with Dr Ríona Ní Ghriallais.





The role of the BioInnovate Programme

- Conor noted that the network, exposure and structure of the BioInnovate Programme, is the reason ProVerum Medical exists.
- ► The information required for FDA approval and funding was new, and PerVerum would not have had the required knowledge to go through the process without BioInnovate. The Programme facilitated in translating every aspect of the legal and financial systems' language.

The impact the innovation has on healthcare and patient lives

- ProVerum Medical created the ProVee device for patients suffering with Benign Prostatic Hyperplasia (BPH), receiving €40m of funding to date.
- ► The ProVee device is a stent that is inserted into the urethra, opening up the passage and restoring the channel. This requires no incision or surgery and can be administered in a doctor's practice rather than invasive transurethral intersection surgery in hospital.
- The main benefit of the device is to the patient is quality of life, allowing patients to return to normal life and rapid recovery from the procedure.
- While the device is not currently commercially approved, the PROVE feasibility study has reported promising outcomes including:
- No damage to the prostate or urethra
- Symptom relief
- Improved urinary flow rates
- No negative sexual side effects
- A clinical investigational device exemption study started in June 2021 and concluded in March 2024 with 221 patients enrolled. FDA approval is the current goal.

Commercial

Neuromodulation for Rhinitis

Neurent Medical

Neurent Medical is a medical device company cofounded by Brian Shields (pictured) and David Townley, who met during the BioInnovate Programme in 2014/15.



NEURENTMedical

The role of the BioInnovate Programme

- During the Programme, Brian and David identified rhinitis as a severely underserved need with a growing demand from patients.
- They developed their concept at University of Galway through a €495k Enterprise Ireland Commercialisation Fund, before spinning out of the University and raising €9.3m (\$11m) in a Series A round, one of the largest raises in Europe for a University medtech spinout.
- ▶ Brian was named Enterprise Ireland's High Potential Start-Up Founder of the Year in 2019, and received one of the first DTIF awards.

The impact the innovation has on healthcare and patient lives

- Through extensive research and development, Brian and his team have developed a low risk, single-use device that enables patients with rhinitis to be treated in a doctor's office under local anaesthetic.
- This innovation is significantly lower risk to previous interventions that required invasive surgery.
- ▶ In 2021, Neurent Medical received FDA clearance for their NEUROMARK[™] device, a novel multi-point nerve disruption treatment for chronic rhinitis.
- ▶ Neurent Medical are now commercially operating in the USA. They have raised over €60m in total, employing 50 staff, which has enabled them to bring this innovative treatment to thousands of patients.
- ▶ In an exciting development in 2024, Neurent Medical established a manufacturing facility locally in Galway that will allow them to produce their devices for the market for the coming years.





Commercial

Innovative Ostomy Care Solutions

Ostoform

Ostoform was co-founded by Dr Kevin Kelleher (pictured) and Rhona Hunt, following their completion of the BioInnovate Programme and the awarding of Commercialisation Funding from El. Ostoform is now run by Dr Kevin Kelleher.





The role of the BioInnovate Programme

- ► Kevin credited BioInnovate with being the genesis of the company and stated that this innovation would not exist in the Programme's absence.
- The innovation arose during the clinical immersion portion of the Programme where they developed a new ostomy product that protects the skin from corrosive output.
- ► Through the needs-based approach, the BioInnovate Programme illustrated the high incidence of skin complications among ostomy pouch users and the effect this has on patient healing.

The impact the innovation has on healthcare and patient lives

- ► It was determined that a contributing cause of skin problems was the absorbency and resulting adhesive breakdown of ostomy appliances.
- This led to the design of the Ostoform product, which was an innovatively designed product in an area of medicine which hadn't experienced innovation for 20 years.
- Ostoform's new ostomy product allows for a dramatic improvement on the patients' quality of life through the protection from peristomal skin complications.
- ▶ This gives patients the ability and confidence to live their lives, which was the main inspiration and motivation for Kevin. The drastic quality of life increase has been attested to by their users, with an American customer noting that they went from having multiple leaks per day to getting 5-7 days wear time with the product.
- Ostoform has five published clinical studies in peer reviewed journals involving seventy-two patients. Over 1,000 patients are currently using the product.



Patient testimonials

This product has changed my life. I don't say that lightly. Prior to finding this seal, there were times I had changed a bag up to 10 times in a day! I was afraid to leave my home for fear of breakage. I couldn't work, couldn't enjoy the simplest of life's joys, let alone do basic life tasks without fear of a bag break while in public. With your seal I am able to get an entire week's wear without ANY leakage! My life in the last three weeks has changed and I am hopeful for the first time in months!



Nurse testimonials

Ostoform is the only new GAME CHANGER in ostomy care in recent memory. This has been my go-to for all problematic stomas. I recommend it all the time.

Ostoform has been a game changer for every patient I have tried it on. I keep it in stock at the hospital now. I have shared this product with our local WOC community because I have been so impressed with the outcomes!







BioInnovate has led to

35 startup companies











































































Factors contributing to the economic impact of BioInnovate

product development

contributions for the exchequer

| Factor | Description | Impact on GVA/employment/exchequer revenue | The role of BioInnovate |
|----------------------------------|--|---|--|
| Needs-led innovation | Innovation driven by identifying and addressing underserved needs in healthcare | The Programme supports startups in carefully developing solutions that directly address healthcare needs, ensuring high market relevance and impact This creates jobs to develop, produce, and market new products, anchoring the medtech sector in Ireland | The BioInnovate Programme provides a 'neutral territory' for industry, academia and clinicians to come together and collaborate This approach fosters creativity and innovation but also ensures that the solutions developed are practical, relevant, and ready for market adoption |
| Increased investment and funding | Increased investment from venture capital, private equity and grants in 2024 28% of funding (€86m) was received in 2024 | Investment allows startups to scale operations and increase market presence. This capital drives investment in new technologies, expansion of production capabilities, and new market entry This drives workforce expansion as well as their supply chains, contributing to employment of the wider economy 40.6% of funding from international sources adds value to the economy that would not be there otherwise This also enables additional spending on their operations, the expanded supply chains and throughout the economy, resulting in greater exchequer revenue | Throughout the course of the Programme the fellows are focused on the necessity to become investment-ready During the stakeholder consultation, it was clear "pitches from BioInnovate companies demonstrate an acute awareness of potential barriers and thoughtful consideration of challenges ahead" (Caroline Gaynor, Lightstone Ventures) The network supported by the Programme allows startups to connect with potential investors and funders they would have otherwise struggled to get an audience with, increasing their chances of securing substantial investment |
| Maturation of startups | It takes a number of years for startups to reach a stage of maturity with successful development/launches and market penetration | Significant increase over time in production and sales leads to higher GVA This expansion of operations (characteristic of mature startups) results in more staff required as teams are built upon in other areas e.g. marketing, customer service, and | BioInnovate's alumni have successfully applied for Enterprise Ireland's Commercialisation Fund, allowing them to develop their innovations and grow during an incubation phase, based at a local university, prior to needing to scale and generate sustainable revenue |

▶ This increase in revenue and payroll leads to increased tax



▶ This results in startups emerging from the Programme being

set up for long-term success



Total economic impact of BioInnovate startups

€277m lifetime GVA impact

| | Lifetime |
|-------------------------|----------|
| Direct GVA €m | 207 |
| Indirect GVA €m | 29 |
| Induced GVA €m | 42 |
| Total GVA €m | 277 |
| Total lifetime FTEs | 1,460 |
| Total lifetime wages €m | 84 |
| | |

Note: Numbers may not sum due to rounding

Overall, the 35 startups received a total of €310m funding. This funding has come from local public and private stakeholders, as well as international investors.

This funding, and the spending of the startups in developing medical technologies, paying employees and contributing to innovation in healthcare, has resulted in significant economic activity in medtech and healthcare. The total economic output of the startups is $\in 376$ m.

Economic output is an imperfect measure of economic impact however, as it includes an element of double counting. By looking at the value added to the economy from the services of the startups we can see a truer reflection of their economic impact. The total GVA impact of the BioInnovate startups is €277m.

This figure includes:

- The direct GVA impact (€207m), corresponds to the value added to the economy from the startup's financial flows (i.e. funding received, wages spent, operational spend, etc.).
- The indirect GVA impact (€29m), corresponds to the knock-on effect of the spending of these startups on the rest of the Irish economy, i.e. the activity generated by the suppliers and service providers of the companies that benefited from the direct impact (for example, manufacturers, universities).
- The induced GVA impact (€42m), corresponds to the activity generated by the consumption in the Irish economy of the wages received by people who worked directly or indirectly with these startups.

It is worth noting that not all the funding has necessarily been spent by the startups and some of the value created by these startups is intangible and unquantifiable, such as the medical value of lives saved and quality of life improvements, and the benefits of innovation for the medtech and healthcare sectors. Valuing this is outside of the scope of this assignment, but if quantified we would anticipate it leading to significant additional value.

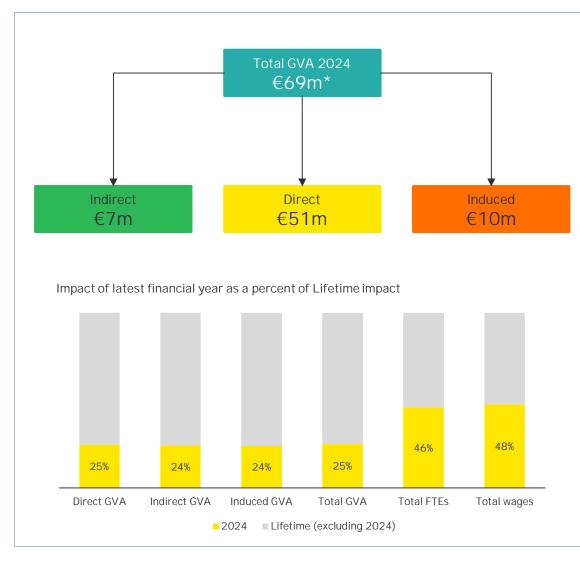
The startups have supported a total of 1,460 lifetime FTE jobs and an estimated €84m in wages.

They also generated €32m in Exchequer revenue. This is comprised of the additional payroll, profits and consumption taxes resulting from increased economic spending by the startups. This spending stems from designing and developing their products, renting facilities, paying wages, activity within supply chains and associated additional spending in the economy.





The economic impact of BioInnovate startups from the last financial year



GVA and Exchequer impact

The startups had raised €86m funding in the latest year (as of May 2024), from an array of local public and private investors, as well as international investors.

40.6% of this funding came from international investors, which means it is additional funding coming into the Irish economy.

The funding allows the startups to operate and pay wages, which altogether generated an economic output of €100m. However, economic output includes an element of double counting so is an imperfect measure of economic impact.

By looking at the economic value added to the economy through GVA we have a better estimate of the latest (2024) impact of these startups.

Overall, the total GVA impact of the 33 startups was €69m in FY24, representing 25% of the lifetime GVA.

This is broken down into a direct GVA of €51m, an indirect GVA of €7m and an induced GVA of €10m.

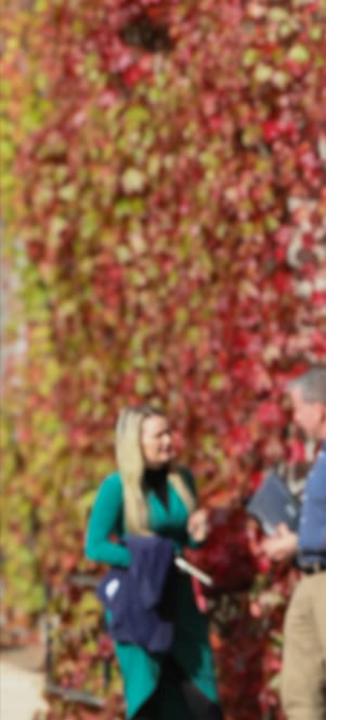
The startups also generated €14m in Exchequer revenue in FY24 through payroll, profits and consumption taxes.

The economic value from the latest financial year makes up a large proportion of the total lifetime from 2011 to 2024. This relates to the significant increase in funds raised by the startups as they grow in scale and value. It takes many years for medtech companies to get to this stage of development and growth. The increased economic impact over time also demonstrates the role played by high-value startups in creating sustained economic growth.

Source: BioInnovate, EY analysis

Notes: * Numbers may not sum due to rounding







Current employment impact of BioInnovate startups

670

Total FTE jobs supported by the spending of startups 330

People directly employed in Ireland by BioInnovate startups 70%

of direct employees involved in innovation

75%

of the direct jobs supported are outside of Dublin 62%

of the direct jobs are supported in Galway

| | Permanent FTE Jobs |
|----------------|--------------------|
| Direct | 330 |
| Indirect | 230 |
| Induced | 110 |
| Total FTE jobs | 670 |
| | |

Source: EY estimates

Overall, we have calculated that the startups supported 670 FTE jobs in Ireland between June 2023 and May 2024.

Of these, the startups directly employed 330 FTE employees. The majority of these employees are involved in innovation and research and development (R&D) of the various medtech products, meaning they are highly skilled, talented employees.

The spending by the startups supported 230 indirect FTE jobs in the wider economy, including through various suppliers and other networks which are required to operate the startups.

The wages paid to these direct and indirect employees facilitate induced spending in the economy. This induced spending supports an additional 110 induced FTE jobs across Ireland.

It is important to note that these 670 jobs are not necessarily new jobs created in 2024. Rather, these are the jobs that the startups directly have created through their operations, as well as the other additional jobs that have been supported in the economy due to spending of the startups and their employees.

This employment supported in Ireland generates a significant wage impact. The 670 FTE jobs supported in 2024 generated €40.2m in terms of total wages.*

Note



^{*} Wages have not been split across direct, indirect and induced to ensure the anonymity of the startup average salaries



The regional impact of BioInnovate

- ► The majority of these startups operate in the west of Ireland and have an important role in the regional development of the west. As such, the majority of their impact is in the west of Ireland.
- ▶ 70% of the latest GVA impact of the startups is experienced in the west of Ireland, in particular in Galway, which makes up 64% of the total impact.
- ▶ 61% of the 2024 FTE jobs supported by these companies (including direct, indirect and induced jobs) are in the west of Ireland (55% of the total in Galway).

| Regional and local impacts | 2024 |
|----------------------------|------|
| Ireland | |
| GVA €m | 68.9 |
| Employment | 670 |
| Wages €m | 40.2 |
| West | |
| GVA €m | 48.0 |
| Employment | 405 |
| Wages €m | 24.7 |
| Galway | |
| GVA €m | 44.1 |
| Employment | 370 |
| Wages €m | 22.8 |

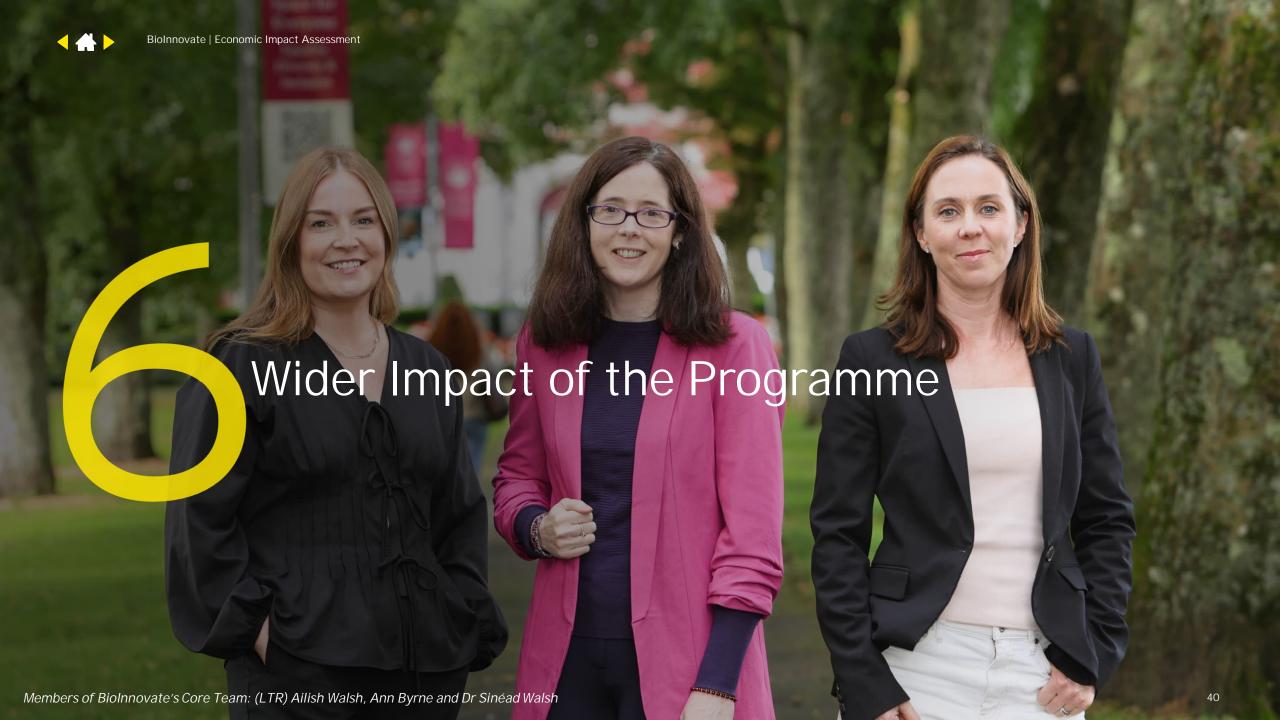
Source: BioInnovate, EY analysis



Note

^{*} The definition used for the west of Ireland for the purpose of this report is the NUTS level 3 Region IE042, encompassing the counties of Galway, Mayo and Roscommon. See more information on the NUTS classification here







Overview of what the BioInnovate Programme provides

The BioInnovate Programme has been a huge success. These faculty and fellows are implementing the BioDesign process at a level that is truly one of the best in the

Dr Josh Makower, co-founder of Stanford BioDesign

world.

The community and network are key in the success of the Programme

- Alumni noted the huge number of opportunities The Programme opened up for them. The community and network it provided was invaluable to the startups.
- The long-term relationship between the alumni and the Programme fosters a 'giving back' mentality, where previous alumni help out wherever possible. This means that they continue to provide support, collaborate, and exchange knowledge, even after the Programme ends.

"You get so much out of it that it is important to give back whenever you can " - Dr Andrew Cameron, alumni

► The coming together of industry, academia, and clinicians did not, or at least rarely, happened before the Programme's establishment

"Anybody can be a part of this community, BioInnovate help join the dots that are already there" – Prof Mark Bruzzi

Gap for medtech in Ireland

The growth of the medtech sector in Ireland has been a huge success. Ireland is now viewed around the world as one of the leaders in this sector, being one of the main hubs in Europe, with Galway at its centre.

This growth has highlighted the potential in Ireland outside of Dublin, and how an industry can grow through the hard-work of a committed community.

Funding

It is well documented that medtech startups need significant funding, and they tend to need it early in the startup process. This is due to the need for a high degree of testing, trials, and product development. The longevity of research, and the amount of money required for R&D are key differentiators of the sector. There are very high barriers to entry, with extensive and complex regulation. BioInnovate, through established relationships with the likes of Enterprise Ireland and the WDC, help founders navigate this complex and competitive space.

Needs-led innovation

The 'needs-led innovation' process used by BioInnovate has been recognised by the Galway medtech cluster as the key for health technology innovation. BioInnovate alumni who do not found their own companies go on to work in different areas and companies in the sector.

They bring with them the knowledge of this process and how to integrate this way of thinking and working. Some go on to work in venture capital companies, such as Caroline Gaynor of Lightstone Ventures, and thoroughly understand what a medtech startup needs to show to be viable.

Industry understands this value and actively seek out personnel and training around the process. Mark Bruzzi of Biolnnovate noted the Programme's plans to expand their educational outreach to "instil innovation methodology for a pipeline of product creation" throughout the industry.

Fungibility of medtech

Fungibility in the context of the medtech sector refers to the ability of resources, products, or technologies to be interchangeable and easily transferable within the industry. In the case of the cluster around Galway, the success of the BioInnovate Programme affects this in 4 key aspects:

1. Talent Development: The Programme trains and mentors individuals, equipping them with the necessary skills and knowledge to innovate and develop new medical technologies and businesses. This creates a pool of skilled professionals who can move between different companies and roles within the sector

- Investment: By connecting innovators with investors, BioInnovate helps in securing the financial support crucial for the development and scaling of startups.
- 3. Network: Through acting as a connector, or community facilitator, BioInnovate allows industry, clinicians and academia to come together and collaborate. This aids the exchange of ideas and best practices, making it easier for innovations to be identified and adopted.
- Inspiration: The success of the alumni can act as a catalyst for innovation in the industry, showing others outside the Programme that they too can succeed.



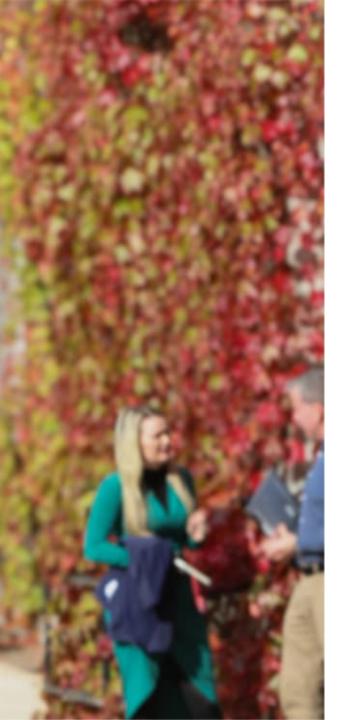




The highlight for me is working with super talented people who are really passionate about making an impact in patient care but also in terms of creating jobs and value for Ireland.

Prof Martin O' Halloran, Executive Director, BioInnovate







Highlights of the Programme

Opportunity offered by the Programme

- ▶ Fellows emphasised that without the BioInnovate Programme, their companies would likely not exist today. The Programme acted as the catalyst which gave them the opportunity to identify problem areas, learn from others, ask questions, network, and to have a community of support. In many instances, the Programme brought people together who later co-founded companies.
- It was highlighted that a key part of the Programme is the identification of key clinical problems for fellows to focus on. This needs-based problem solving provided the foundation of the startups, and ensures that the Programme helps provide solutions for currently unmet medical needs.
- ► The Programme unlocks entrepreneurial skills, arming fellows with the skillset required to manage the entrepreneurial space, speak to funders, and build critical business relationships.
- ➤ The link with Enterprise Ireland was hugely beneficial to the startups in the immediate term after they had been through the Programme.
- ► Founders also benefitted from access to hospital and university facilities, which they would not have had otherwise.
- Fellows of the Programme commented that a key attraction of the Programme was the opportunity to do something completely different from what they had previously been doing.
- Interviewees also highlighted that while the idea of starting a company is enticing, it is also daunting. BioInnovate helps to mitigate fears and provides an accessible way for founders to get started with a wide range of supports already in place.

BioInnovate contributing to improved healthcare

The wider social impact of BioInnovate and the startups they help create is the health benefits facilitated by their medical devices.

There has been an estimated 8,100 patients treated to date by BioInnovate startups, with this number expected to ramp-up significantly as companies continue to scale and go through the clinical trial processes.

Outside of startups, alumni have gone on to work in senior positions in companies that are in turn generating growth and contributing to the medtech sector by way of innovation, training, and funding.



The BioInnovate alumni are really unique and truly help each other out constantly.

Dr Maura Glennon, Enterprise Ireland



The BioInnovate Programme opened so many doors through alumni connections and the network created ... Startups can often be a lonely place, but BioInnovate provides a support system and network of people which can be leveraged.

Annette Kent, alum





Benefits of the Programme

Access to the wider medtech ecosystem

Fellows benefit from the wealth of expertise at their disposal through the Programme. This is a vital benefit as it provides assistance for those entering into both the entrepreneurial and medtech landscapes as they have access to entrepreneurs, investors, clinicians, medtech specialists, as well as other experts.

The Programme provides an understanding of the regulatory and financial landscape of the medtech industry. As such, regardless of the fellow's background it provides knowledge of the sector, and how to find an entry point into it.

Additionally, the alumni continue to receive support from the Biolnnovate community even after completing the Programme. This element of community and bringing all aspects of the industry together in one self-supportive network was a founding principle of the Programme in Galway. Co-founder Prof Mark Bruzzi stated that the high-level vision was to create a conversation between industry, academia and clinicians, as there was limited communication and collaboration in 2011. This network aspect has surpassed all expectations, with former University of Galway President Dr James Browne crediting the network and the Galway medtech ecosystem as one of the reasons for the success of the Programme.

A number of BioInnovate facilitated symposiums and events were also praised throughout the interviews, with many stating that they go out of their way to regularly attend. For those starting their entrepreneurial journey, this provides access to investors they would have otherwise struggled to get access to. These include 20+ Medtech Brew networking and knowledge share events that BioInnovate have co-hosted with the Irish Medtech Association. These events bring individuals from startups, SMEs and MNCs across the sector together on topics of relevance.



According to Mark Bruzzi, the university setting provides a 'neutral territory' which fosters collaboration between clinical treatment and industry. This is critical to get clinical engagement, as in a commercial environment it could be more adversarial around issues such as compensation for help/expertise, and potential competition.

Having clinicians involved in regular conversations with industry results in greater benefits for both parties. The knowledge from clinicians allows for industry to increase the quality of products developed in the west of Ireland.

The supportive nature of the BioInnovate network results in stakeholders being willing to lend their time and expertise in a cooperative setting free of charge.

The access to clinicians and hospitals in particular is crucial to the development of the innovations emerging from the Programme. The biggest beneficiaries for this collaboration are the fellows. It provides them with the opportunity to see the current functioning of the healthcare system, enabling them to visualise the solutions to crucial needs and often overlooked problems.

The alumni noted that this immersion was imperative allowing them to spend time with physicians, observe patients, and understand outcomes.

Diversification in products developed is necessary for the health of an industry as it aids in the protection against the ebbs and flows of the market. BioInnovate's clinical immersion, overall network of support, and the needs-based innovation, leads to a healthier medtech cluster surrounding Galway.

Dr Majella Giblin, Senior Lecturer in University of Galway and expert in the medtech sector, said "You want regions to have specialisation, but only to a point; you also need diversification to achieve regular growth".











What makes the Programme successful



There are a couple of key ingredients for the success.

- (1) We recruit highly motivated people, who are midcareer and have some experience. They typically have a bit of jeopardy in joining the Programme (leaving an established role, kids, a mortgage). This means they are super motivated to succeed.
- (2) A lot of the training and mentorship comes in from industry, with speakers in every week, from other founders, investors, etc.
- (3) Alignment between University of Galway, industry, and EI, to create and scale start up companies. This helps build innovation capacity within existing companies.

Prof Martin O' Halloran, Executive Director, BioInnovate



Driving new healthcare innovations can be a complex and difficult journey but this Programme has the support and buy-in from mentors, clinical champions, industry leaders, and the alumni at every stage of the journey, making highly ambitious goals achievable.

Dr Sinéad Walsh, Director of Operations, BioInnovate



A key to the success of the Programme is in the network and the community it provides to fellows.

We help fellows coming into the Programme access this ecosystem (other alumni, hospitals & clinics, industry and funders).

Prof Mark Bruzzi, Non-Executive Director and Co-founder of BioInnovate



It's the environment. The presence of the large number medtech companies in the region. These companies have a significant manufacturing base and drive for R&D. Co-location of the hospital and University and medtech in the same city enables very close interaction.

Dr Faisal Sharif, Non-Executive Director, BioInnovate



The Programme has been hugely successful because of the ecosystem. The Programme came in at the right time, in the right place, via good strategy and vision from many people working together in the medtech space.

Prof James Browne, former President of University of Galway



The fellows they have selected are exceptionally bright and capable, and I really think the program has the model perfectly tuned. The culture of giving back and collaboration, and the spirit of perseverance and determination in pursuit of ways to improve the lives of patients is embedded deeply into the program. There are thousands of patients who have benefitted from their work already, and millions ahead who most certainly will.

Dr Josh Makower, Co-founder of Stanford BioDesign



What sets the Programme apart is that there are willing Principal Investigators to host projects, El funding, an ecosystem, and supports provided by the University to take up these projects after the 10-month Programme

Dr Jacinta Thornton, Associate Director, Innovation Office, University of Galway





BioInnovate and The Stanford Mussallem Centre for BioDesign are all about solving problems for patient care that have not yet been solved. The BioDesign process is a way of thinking that can guide innovators towards a solution that can truly change the world.

Further, implemented in a University setting, the process also has the capability to transform careers and inspire new innovators to solve important healthcare problems, create businesses that expand opportunities for employment and investment and even drive economic growth.

Dr Josh Makower, co-founder of Stanford BioDesign







BioInnovate benefiting patient lives

Needs-based approach to treatment

A cornerstone of the BioInnovate Programme is the emphasis on a needs-based approach to innovation, where the fellows identify the critical unmet medical needs in clinics and hospitals around Ireland through clinical immersion during the Programme.

Clinical immersion ensures fellows are immersed in clinical environments over eight weeks, observing patients and healthcare professionals in a range of clinical settings. This includes spending time in specialist diagnostic clinics, surgical and interventional procedures, post-operative care, and observing patient rehabilitation. This provides the opportunity to observe and document healthcare challenges and identify unmet clinical needs.

As such, the innovations emerging from the Programme target underserved clinical needs. This needs-based approach, and the communication with staff and patients, allows the fellows to identify critical gaps in treatment and care, helping guide their potential approaches to solving these issues.

All the alumni interviewed emphasised that their treatment area arose from this clinical immersion, as it allowed them to explore the key unmet medical needs of patients in Ireland.

As of April 2024, over 8,100 patients have been treated by the innovations developed by the startups. The treatments range from venous leg ulcers to stoke care, and from the interviews and data received from the startups these treatments are contributing to a significant improvement in these patients' quality of life.



We really wanted something where we could have patient impact, and stroke is one of those areas. It's literally a lifesaving intervention.

Dr Liam Mullins, alum, co-founder Perfuze



The BioInnovate Programme is great place to solve unmet problems in healthcare... this is huge for innovation, competitiveness and resilience of the medtech sector in Galway

Dr Majella Giblin, Senior Lecturer, University of Galway



Relevium is a spinout from the BioInnovate Programme, and it came about by identifying there was a very big clinical need in the chronic pain space, which we narrowed down into knee osteoarthritis pain. Our treatment provides pain relief for up to 6-months without the need for damaging oral medication.

Dr Alison Liddy, alum, co-founder Relevium Medical



The Ostoform Seal with FLOWASSIST has dramatically improved the quality of life of patients. It gives people their lives back, it gives them the confidence to go outside again and live their lives without worrying about leakages... BioInnovate is directly responsible for the company emerging.

Dr Kevin Kelleher, alum, co-founder Ostoform





The BioInnovate ecosystem - A virtuous cycle

The BioInnovate Programme is part of the wider medtech ecosystem in Galway.

Each aspect of the ecosystem relies on the others, and their shared interests is what drives innovation and growth in the region.

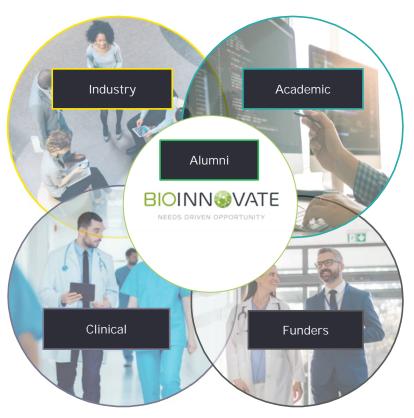
Aligning interests

The medtech ecosystem in Galway is one of the major success stories in Ireland since the turn of the millennium. It is the result of significant work and co-operation from many different stakeholders.

The vision to put a platform in place to allow high-performing startups to spawn, and the tools for them to grow is not an accident. It comes from the aligned interests of many who recognise the potential and capacity for growth if you are able to nurture and enable it.

There are four key stakeholders in this ecosystem, with each of their interests aligning with the success of BioInnovate.

The nexus of stakeholders which BioInnovate brings together



The medtech sector in the west of Ireland has been described as a virtuous cycle, which BioInnovate has helped to reinforce. The sector, and by extension the Programme, is supported by five key stakeholders examined:

Alumni: Alumni are at the centre of the BioInnovate Programme; the Programme enables the fellows to explore problem-based thinking and to grow as entrepreneurs, founders, and experts. The Programme relies on the excellence and commitment of the fellows, as well as their extensive network to support a new group each year.

Funders: Funders (and industry) play a vital role in sustaining the medtech ecosystem. Their operations foster innovation and growth and provide opportunities to founders. BioInnovate's close ties with MNCs, SMEs, EI and the World Development Commission (WDC) are a testament to the importance of funders to the sector.

Industry: Industry collaboration is a cornerstone of the BioInnovate ecosystem, providing real-world market experience, expertise and pathways to commercialisation.

Academic: The University of Galway provides the platform for BioInnovate to operate. It provides the centre for operations along with crucial facilities needed for the Programme. The College of Medicine, Nursing and Health Sciences, College of Science and Engineering and the J.E. Cairns School of Business and Economics all contribute substantially to the Programme. Universities across Ireland also provide a breeding ground for researchers, and fellows after the Programme, who receive funding from the Commercialisation Fund.

Clinical: Hospitals are where unmet healthcare needs are first identified and where one hopes to see the long-term benefits of the Programme truly come to life. Hospitals support the Programme by helping with the education and experience of fellows, supporting product development by allowing clinical trials, and ultimately derive benefits from the innovative creations of the various startups.







A key to the success of the Programme is in the network and the community it provides to fellows.

We help fellows coming into the Programme access this ecosystem (other alumni, hospitals & clinics, industry and funders).

Prof Mark Bruzzi, Non-Executive Director and Co-founder of the BioInnovate Programme





BioInnovate and Enterprise Ireland

Enterprise Ireland

Valuing innovation is absolutely central to Enterprise Ireland's thinking. The companies who research best, innovate best, and raise funds best.



Dr Maura Glennon, Senior Commercialisation Specialist, Enterprise Ireland

Background

Since its establishment in 2011, BioInnovate has been co-funded by and worked closely with Enterprise Ireland. They have provided funding to the fellows during the Programme. The EI Commercialisation Funding won by the alumni to develop their technologies within the universities has enabled the translation of their research into innovative and commercially viable products and companies.

A major focus for Enterprise Ireland is to support the development of HPSUs spinning out from Irish Universities and ensuring these are put in the best position to succeed. They are committed to supporting the medtech sector and its partnership with BioInnovate has helped facilitate the growth in this sector. It has provided significant support to the medtech sector and has helped facilitate the growth in this sector. BioInnovate Programme is an opportunity to prime the system, as it acts as a fertile intersection of universities, hospitals, clinicians, and industry.

Key considerations

Alignment with El vision

El plays a crucial role in fostering the development of Irish innovators. El seeks to support Irish enterprises in creating solutions for global challenges, thereby delivering sustainable prosperity throughout Ireland. BioInnovate are a key player in delivering on this vision through the success of its health technology innovation programme and by its deep engagement with national and international clinicians, engineers, and business experts. Additionally, El provides further funding and supports to help Irish businesses grow and scale.

Benefits

During their Commercialisation Funded project the alumni have the time and money to develop their technologies and associated business case before and raising further capital in the future HPSU.

At present, 22 of the 24 alumniled HPSUs have come through the commercialisation fund (91.6%).

them to work in and with the Universities and their Innovation Offices. These combined State supports from the Universities and El allows the fellows alumni to accelerate the development and growth of an investible proposition during an incubation phase.

Commercialisation Fund

Upon completion of the Programme,

Commercialisation Fund to enable

alumni can apply to El's

The Commercialisation Fund requires the university to submit a detailed proposal which is evaluated by a group of independent experts before being ratified by EI.

Wider impact

El has established a new 'Innovators Initiative Programme', based on the success of BioInnovate. This brings a similar style Programme to three other sectors, looking to replicate BioInnovate's achievements. This speaks to the success that the Programme has had in establishing startup companies, raising the innovation capabilities of the participants and creating an enabling environment for innovation in Ireland.

11

The Programme would not exist without the support of Enterprise Ireland. The stipend support for fellows, followed by access to the Commercialisation Fund are unique and attractive for talented people to join the Programme.



Prof Faisal Sharif, Non-Executive Director, BioInnovate

11

El is committed to supporting the development of Irish-owned companies on their journey to achieving their globa ambition

A really important element of this is helping to foster the development of Irish innovators who are driving transformation around the world, and programmes like BioInnovate and facilities like the Ian Quinn Centre are key to that.



Marina Donohoe, Head of Research, Innovation and Infrastructure at Enterprise Ireland







The benefits are far reaching. Economically creating new jobs and exports. Creating a culture of innovation, new startups linking in with larger MNCs, and of course, new treatments for unmet clinical needs.

Prof Faisal Sharif, Non-Executive Director, BioInnovate





Impact of BioInnovate on career development

Our consultations illustrated that the BioInnovate Programme has a significant impact on the career development of its fellows. The Programme provides fellows with the tools to succeed in the medtech sector, both as company founders and throughout the wider sector. These tools include:

- Technical Expertise: The Programme allows hands-on experience in design, development, and testing of medtech innovations, as well as the identification of unmet healthcare needs.
- Business and funding knowledge: The Programme includes training in business development, market analysis, and commercialisation strategies, providing the fellows with the tools necessary to become a medtech founder in Ireland and abroad (particular note was made on the knowledge and help given on the US FDA approval process)
- The BioInnovate Network: The Programme facilitates connections with key players in the medtech industry, including executives, researchers, and clinicians. This leads to collaboration and knowledge sharing that cannot be found elsewhere and gives an enormous advantage over competition.

Furthermore, all the alumni interviewed stated that their company would either not exist or not have achieved the current level of success without being on the Programme.

The Programme attracts individuals from diverse geographic, cultural, professional, and academic backgrounds, each bringing their own unique motivations and goals for participating, along with unique perspectives and opinions. For example, some entered with the explicit purpose of starting their own medtech startup, looking to engage with other entrepreneurs in the area and looking for their own niche to target, while others entered to have better access to high-potential medtech startups or just for a career change.

Part of the Programme assigns fellows into groups to work together to identify a need in a clinical setting. Due to the diversity in the fellows, this group work fosters diversity of thought, offering ideas and solutions that would have been beyond the capability of tackling the problems alone.

As approximately half of the alumni go on to diverse careers outside of founding their own startups, the knowledge and skills gained from the Programme are highly valuable. For these alumni, the network is equally as important for understanding the needs-based innovation and share this with industry. They bring this BioInnovate process, and more importantly, way of thinking, into their roles, some go on to teach this within their companies.



Cathy O'Boyle, Chief of Staff at Luminate and BioInnovate alum



Joining the BioInnovate Programme was obvious for me. It provided opportunities to spend time with physicians, observe patients, and understand outcomes. These experiences have been formative and continue to influence future decisions for Perfuze



BioInnovate let me combine business with medicine... the need for the technology came out of the Programme... Proverum would not be a company without it

Conor Harkin, alumn and co-founder of Proverum Medical







Prateek Dixit, Senior Technical Officer at the University of Galway's Medical Device Prototype Hub and BioInnovate alum



Impact of BioInnovate on career development (cont.)

Evidence from alumni

Annette Kent, Clinical Director Endowave, formerly Fire1, joined the Programme with the intention to spark a career change from working in the pharmaceutical sector. She credited the depth of experience she received from the Programme in such a short time, as well as the skills, knowledge and mentality needed to be successful in medtech. She highlighted that the Programme puts a large emphasis on developing the ability to market the fellows and their businesses, which was invaluable for developing her career.

"The Programme opened so many doors, through alumni connections, network, etc. BioInnovate provided a huge range of opportunities, and actually introduced me to my role in Fire1 through the network"

Dr Andrew Cameron, co-founder of FeelTect, credited the Programme for developing his confidence and versatility to overcome problems within the medtech ecosystem. The Programme provided him with experience in the ecosystem, which allowed him to identify a medical problem to focus on, develop the technology to solve the problem, start a business, and ultimately commercialise.

"The Irish medtech ecosystem puts a lot of support into this industry and especially into innovation – BioInnovate gave me the opportunity to join this ecosystem"

Furthermore, he highlighted the most challenging, yet rewarding part of the Programme was being in a group of people with diverse backgrounds and ways of thinking. The group pushed him out of his comfort zone and opened him up to different ways of thinking and solving problems that he would not have gained otherwise.

Caroline Gaynor, Partner at Lightstone Ventures, like others, did not create a startup but rather went into venture capital funding upon finishing the Programme in 2013. She noted the substantial impact the Programme had, not only on herself, but the wider medtech sector, given that the Programme content is widely applicable across the sector. Caroline notes that the companies and people emerging from BioInnovate that she deals with have an acute awareness and understanding of the barriers to be faced and how to overcome them.

Conor Harkin, co-founder of Proverum Medical, came from a venture capital background working in an EU investment fund and went into the BioInnovate Programme as a way to access Irish startups in life sciences. He also thought that the course was intellectually stimulating and had met alumni who highly recommended it.

"BioInnovate gave us the opportunity – it gave us access to tap into the experts and encouraged us to go and actually do it. This network, the exposure to hospitals and other fellows, and structure of the Programme, it is why Proverum exists"

He described himself as a 'reluctant entrepreneur' as he would have never thought of starting his own medtech company before the Programme.



Wider impacts of the Programme

The BioInnovate Programme focuses on identifying and addressing unmet clinical needs. Over 8,100 patients have been treated technologies developed by the startups.

These treatments provide a wide range of social benefits, including:

- Improved quality of life for patients
- Cost saving for the healthcare system
- Fewer people needing to go to hospital (decreased bed days)



BioInnovate startups have led to over 40 unique medtech technologies. The BioInnovate alumni have been supported by over

€23.9m in Commercialisation Funding from Enterprise Ireland, allowing for the establishment of the startups. Overall,

these companies have raised a total of £310m

"BioInnovate and The Stanford Mussallem Centre for BioDesign are all about solving problems for patient care that have yet been unsolved. The BioDesign process is a way of thinking that can guide innovators towards a solution that can truly change the world. Further, implemented in a University setting, the process also has the capability to transform careers and inspire new innovators to solve important healthcare problems, create businesses that expand opportunities for employment and investment and even drive economic growth."

Dr Josh Makower, co-founder Stanford BioDesign

"It's an incredibly rewarding Programme. My co-founder identified the need. The current standard of care is very challenging, and we were looking for a way of doing things better."

Sarusha Pillay, alum

"Thanks to the Programme, there are so many businesses out there who are generating new products and contributing innovation in the medtech sector."

Annette Kent, alum

"My company would not exist without BioInnovate. I met my cofounder through the Programme, and identified the problem we wanted to solve."

Conor Harkin, alum



Regional funding and development



BioInnovate has played a crucial role in what has been an important sector for WDC. They have been extraordinarily successful and have created a virtuous cycle for the medtech sector, particularly in the west of Ireland.

Gillian Buckley – Head of Investment, Western Development Commission

Western Development Commission

BioInnovate has had a significant impact on regional growth in Galway and the west of Ireland.

The emphasis on regional growth is highlighted by their close relationship with the regional evergreen fund, the Western Development Commission (WDC). The WDC is an investment fund which supports business, community, social enterprises and creative industries in the Western Region of Ireland.

The fund, worth approximately \in 90m - \in 120m, made its first medtech life science investment in 2003. They have made investments in 45 medtech startups since then, 12 of which have been BioInnovate companies, and it has proved to be an immensely successful industry for them.

In order to apply for WDC funding, startups must be based in the west of Ireland and must comply with state-aid rules. WDC also generally choose to fund HPSUs that are spinning out of the EI Commercialisation Fund.

This accentuates the long-term impact that BioInnovate can have on startups - it provides them with the pathway to success in terms of receiving funding from EI and the WDC and provides access to an enabling network and the skills and knowledge to execute on clinical needs.



Regional focus

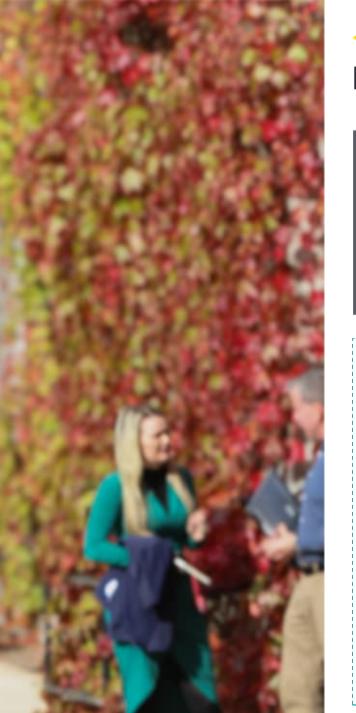
With the majority of development, startups, and growth in Ireland being centred around Dublin, the growth of the medtech sector in the west of Ireland has been highly influential in showcasing the success regions outside of Dublin can achieve.

The BioInnovate Programme has played an important role in positioning Galway and Ireland as leaders in the medtech industry globally. The people involved have given huge commitment, doing an excellent job in developing the sector in less than 30 years. This commitment has transformed into a network and ecosystem which has placed the west of Ireland at the centre of the Irish hub. This only aids in encouraging growth of other sectors too.

BioInnovate has also directly contributed to the creation of hundreds of jobs in the region, attracting talent from all over the world, including positions within startups, established companies, and research institutions. The Programme continues to provide a steady stream of startups and talented alumni each year, most of whom stay in the region.

With the help of the established medtech eco-system in Ireland, BioInnovate will continue to encourage grassroots regional growth. This will keep socioeconomic benefits derived from the HPSUs in the west of Ireland.







BioInnovate's wider impact on training in the medtech sector in Ireland

Separate to the Programme, BioInnovate also offer a 10-day industry training course for industry employees that takes place over 20 weeks.

The aim of the industry training programme is to embed innovation into the SME and MNC sector, by adding significant indigenous R&D capacity and anchoring these companies in Ireland for decades to come. It offers a deep dive into the needs-led innovation process, equipping them with the skills and knowledge necessary to drive innovation within their organisations.

The training programme includes elements of BioDesign's 'Process of Innovating Medical Technologies', with the course content capturing the following:

- Identify: Needs Finding
- Invent: Concept Generation and Development
- Implement: Business Plan Development

This course allows participants gain a thorough understanding of the needs-led innovation process, enabling them to identify and address unmet medical needs within their businesses and organisations. Addressing underrepresented and unmet healthcare needs through this process has the following effect on Ireland's medtech sector:

- Enhanced innovation capabilities the training fosters a culture of innovation, developing solutions that are insightful and practical
- Competitiveness Both the organisations and the wider sector gain from having a well trained workforce that are well-versed in the latest innovation methodologies and capable of driving growth in the medtech sector
- Reputation The success and visibility of the Programme contribute to the overall reputation of the medtech sector in Ireland, positioning it as a hub for cutting-edge medical technology development
- Diversification According to Dr Majella Giblin, there has been very little incremental innovation in the Irish medtech sector before BioInnovate. The needs-led innovation allows for the diversification of products enhancing the region's medtech portfolio, making it more resilient and adaptable to changing healthcare demands and international developments

"You want regions to have specialisation, but only to a point; you also need diversification to achieve regular growth... Diversification and reputation are the two biggest impacts for the region" – Dr Majella Giblin

The course teaches participants several key skills and experiences, including:

Demonstrating awareness of the process for innovating medical technologies Identifying unmet medical needs

Appreciation of concept generation and brainstorming

Awareness of issues surrounding clinical trial design

Experience pitching a product concept

Teamwork in a multi-disciplinary setting

Over 260 individuals have completed the training programme since 2011, which is seen as a key agent for innovation culture change in the medtech sector. Also, this training has led to the generation of new IP and pipeline products within the companies.

Further Training



In collaboration with Irish Medtech Skillnet, BioInnovate have developed and offer two further courses that focus on supporting increased RD&I in Irish organisations:

- 1. BioInnovate 101: Essentials of Health Technology Innovation a 3-day programme which emphasises the tools, language and philosophy of the process of innovating health care solutions while minimising the risk of project or commercial failure. This programme is targeted at companies who are considering investment in innovation and want their team to embrace the BioInnovate process for innovating health technologies.
- 2. Strategic Innovation for Senior Executives a 3-day immersive programme designed specifically for senior leaders, equipping them with the core skills and strategies required to develop and implement an innovation strategy tailored to their business. This programme focuses on equipping decision makers to identify and maximise opportunities within the ever-evolving healthcare landscape, driving needs-led innovation at an organisational level.





What alumni from different professional backgrounds say about the Programme

Clinical



Advice, guidance and expertise is needed on everything if you are to start your own company, BioInnovate provided this. Regardless of your background, you get a credible understanding of the entire industry, as well as the regulatory and financial landscape.

Conor Harkin, Proverum Medical



The Programme has a special place in my heart. I saw it as an opportunity to do something completely different with my career, and BioInnovate opened so many doors through alumni connections and the broader medtech network.

Annette Kent, Endowave, formerly Fire1

Clinical - Commercial



The impact BioInnovate has had on the Irish ecosystem is really quite substantial. Pitches from BioInnovate demonstrate an acute awareness of potential barriers, and thoughtful consideration of the challenges. The companies that emerge tend to have a leg up on their counterparts in Ireland and Europe.

Caroline Gaynor, Lightstone Ventures

Commercial - International



As somebody that's come from another country, I would strongly encourage international students to consider the Programme. It was an incredibly rewarding Programme. I think the thing that stood out the most was the methodology and the science and the validation that what we were doing was embedded in.

Sarusha Pillay, pHetalSafe, Stryker

Technical



Everyone in the BioInnovate Programme was always more than happy to help, offer their expertise and give you their time

Dr Alison Liddy, Relevium Medical



The BioInnovate Programme provided opportunities to spend time with physicians, observe patients, and understand outcomes. These experiences were formative for the creation of Perfuze, and continue to influence the future decisions. The network BioInnovate provides is key and contributed to their success and the maturation of the medtech sector in Ireland



Liam Mullins, Perfuze

BioInnovate is the genesis of the company, the kernel, it is directly responsible for the company emerging at all

Dr Kevin Kelleher, Ostoform



The exposure was incredible – Access to an important network of current, past and future entrepreneurs – as well as potential investors

Fionn Lahart, LUMA Vision







Conclusion

BioInnovate has had a significant positive impact on the medtech sector, on innovation and startups, on research and development, and on patients. It has promoted regional growth in the west of Ireland, and Galway in particular, and is now acting as the model for new Programmes in other sectors.

The startups which have spun out of the Programme have generated €277m GVA in Ireland.

These startups have also supported 1,460 lifetime jobs, generating €84m in wages. This has also resulted in €32m revenue for the Exchequer.

Regionally, BioInnovate spinouts are mainly in the west of Ireland, with 73% of the startups located in the west of Ireland. As such, the majority of the GVA impact and jobs supported is in the west of Ireland.

However, this economic impact is one story of the much wider impact that the BioInnovate Programme has. This wider social impact of the Programme has been highlighted across extensive interviews with stakeholders. BioInnovate has helped grow a culture of innovation and growth, the effects of which Ireland will continue to benefit from for years to come.

To date, over 8,100 patients have been treated by products and innovations developed by BioInnovate alumni, with the number rapidly growing as startups' products created by the alumni become operational and as the number of startups continues to grow each year.

Lifetime impact of startups

€277m

1,460

Total GVA impact

FTE lifetime jobs supported

€32m

Exchequer revenue generated

Over 8,100

Patients treated

€310m

Revenue and funding generated

70%

Total GVA impact occurs in the West NUTS 3 region

41%

International funding

61% **Employees in Galway**







Economic Impact Methodology

Overview of the approach

The economic impacts are considered at three levels:

Direct

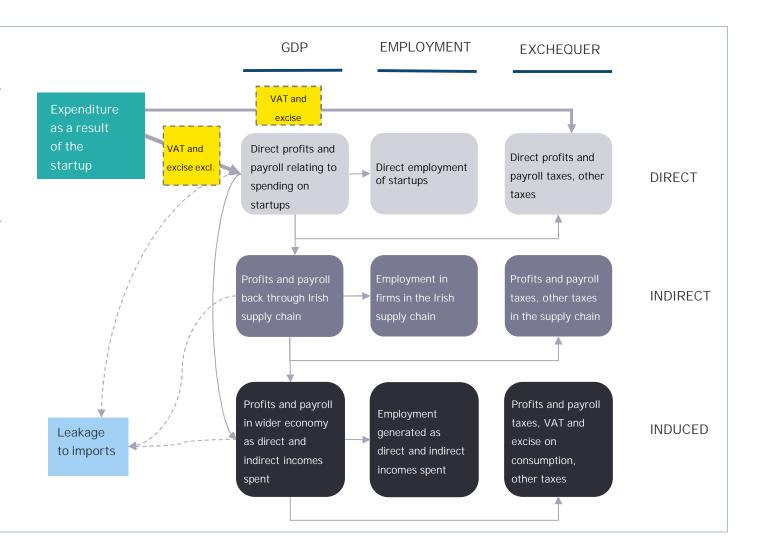
These consist of the spending generated by the startups, the number of direct employees and contract staff employed by them, the wages they are paid and the Exchequer revenue this generates. It also looks at these impacts for the incremental revenue and employment generated as a result of the capital expenditure.

Indirect

These consist of the impacts of the purchases made by the startups to Irish firms (excluding imported materials), the people employed in these firms, the wages they earn and the Exchequer revenue they contribute. For example the purchase of Irish-based machinery and professional services, back through the Irish supply chain.

Induced

These impacts arise when those employed directly by the startups, and the employees of Irish suppliers spend their wages in the wider economy. This creates demand for consumer goods and services, which generates further economic activity, employment, wages and Exchequer revenue.









There are 24 alumni-led HPSUs included within the data of this report

- Amara Therapeutics
- Aurigen Medical
- Capri Medical
- Embo Medical
- Endowave Ltd.
- FeelTect Limited
- InVera Medical
- Kite Medical
- Loci Orthopaedics
- ► LUMA Vision (formerly OneProjects)
- Luminate Medical
- MindSave

- Neurent Medical
- NUA Surgical
- Ostoform Limited
- Perfuze
- ProVerum Medical
- Relevium
- RugbySmarts
- Selio Medical
- Signum Surgical
- SymPhysis Medical
- Tympany Medical
- Versono







Abbreviations

ВΙ BioInnovate CSO Central Statistics Office ΕI Enterprise Ireland ΕIΑ **Economic Impact Assessment** FDA Food and Drug Administration Full Time Equivalent FTE **Gross Domestic Product** GDP GVA Gross Value Added

HPSU High Potential Startup

I-O Input-Output

NUTS

MNC Multinational Company

Nomenclature of Territorial Units for Statistics





Supporters & partners of the BioInnovate Programme























































