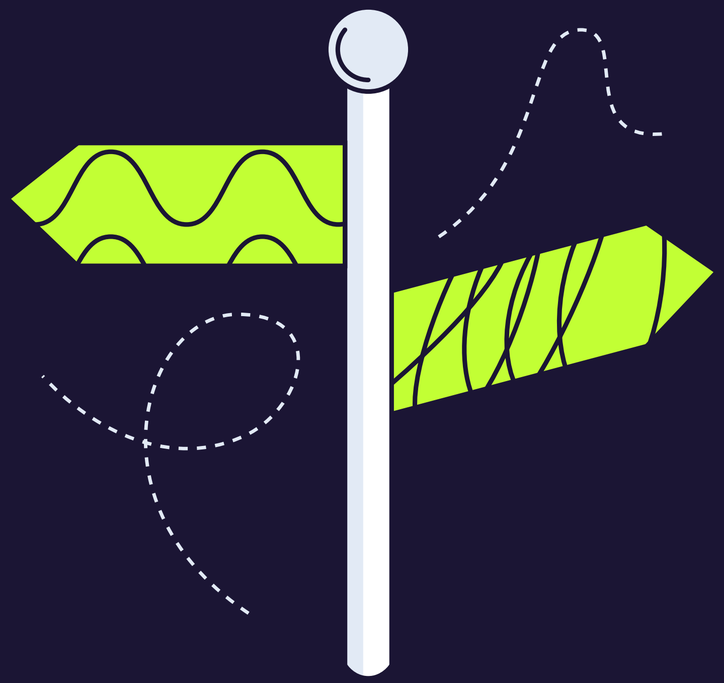
Fail fast, or prove it early:

Low cost, flexible proof of market funding for successful innovation

GROW MedTech

Contents



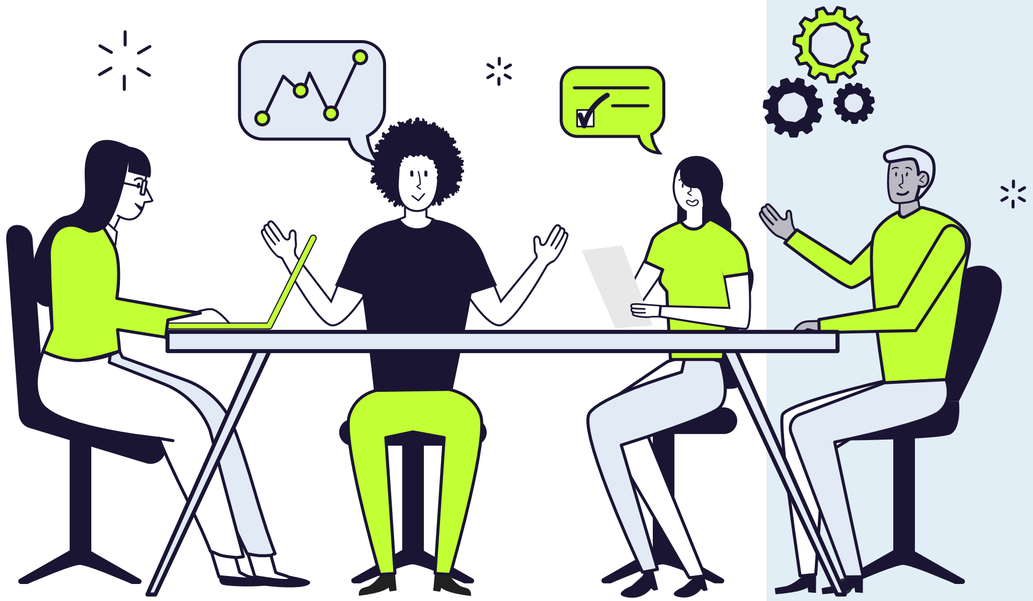
In this guide we explain the benefits of proof of market awards and how to gather the data to determine whether a technology has the potential to be successful in a given market.

By offering a funding package that could be used in a flexible and dynamic way – dependent on the needs and stages of the projects rather than a typical proof of market award – we have found that technologies stand a better chance of moving to the next stage of development and attracting further investment.

We take key learning points from Grow MedTech, a programme funded through Research England's Connecting Capability Fund. Grow MedTech has been a major UK programme providing specialist support for innovation in medical technologies, involving a consortium of six universities across the Leeds and Sheffield City Regions. Our sector-specialist innovation support has helped to put these regions at the forefront of the UK's medtech sector.

This good practice guide is for knowledge exchange and commercialisation leaders and practitioners, and will be useful for anyone with an interest in innovation translation based in a higher education institutional setting. It can be read in full or used as a reference for specific activities, and can be applied to a wide range of KE activities across sector areas.

We've included practical example documents, which can be used to deliver some of the suggested activities. There are also case studies to illustrate the benefits of proof of market awards.



IN OUR EXPERIENCE...

By investing small amounts of money into proof of market awards, opportunities can be de-risked so that the time of academics and KEC practitioners – and university budgets – are not wasted in the short to long term future.

A note to knowledge exchange and commercialisation leaders and practitioners

As a Knowledge Exchange and Commercialisation (KEC) practitioner in a Research Innovation Office (RIO) you play an important role in identifying the most promising projects for translation from a portfolio of potential opportunities. You may have academics heavily invested in their ideas and technologies, and excited about their potential applications and ability to change the world.

As a KEC practitioner you understand that to introduce and embed an idea or innovation into industry is a highly complex balance of many factors. Often, due to resource constraints, not all ideas presented to the Research Innovation Office can be progressed or introduced to an industry partner, so it's vital that the right level of due diligence is carried out to identify and support the most promising projects.

What is different about our Proof of Market funding?

Research Innovation Offices typically offer proof of market funding as the earliest support in the innovation translation journey, to assess the commercial viability of a project through market research, market testing and competitor analysis. It is often also used to assess intellectual property position and initial planning to take the project to commercialisation, including assessing costs, timescales and funding requirements.

IN OUR EXPERIENCE…

We needed to enable commercially-inspired projects to be validated and de-risked, establishing a market need and enabling further investment opportunities. We have offered a funding package that could be used in a flexible and dynamic way dependent on the needs and stages of the projects.

We believe academic project teams have benefitted from a more holistic approach to translation, which includes the dedicated, hands-on support of a KEC practitioner with sector-specific expertise and experience in innovation. In Grow MedTech, these practitioners are known as Technology Innovation Managers.

Experienced, sector-specific Technology Innovation Managers

We have taken a hands-on approach to managing our proof of market funding. We believe that our Technology Innovation Managers have been key to the success of both our proof of market funding scheme and overall programme. This specific resource, with a wealth of experience in medtech innovation – and backgrounds in academia, industry or knowledge exchange – has been invaluable support to academics in developing commercial awareness.

Their role in the proof of market funding scheme has included:

- identifying what is needed – understanding the stage of the technology, gaps in knowledge and what activities are required to fill the gaps
- co-developing application forms
- reviewing applications as a team, subsequently contributing to refining and optimising the direction of the project
- drafting requests for quotation from consultants
- managing kick-off meetings and delivery of the project
- helping the academic team to analyse and process results.

Flexible funding

We have offered a package with small amounts of money to allow the project teams to:

- understand market opportunity, potential commercial value and viability
- understand professional user needs (clinical and healthcare professional needs for us, and fit in the clinical pathway)
- understand user needs (patients, for us, and fit in the patient pathway) and ensure users are involved in these early stages of development
- understand the technology development roadmap and commercialisation strategy, including the IP and regulatory strategy pathway.

Proof of market funding scheme outcomes

As a result of our holistic approach, over three years we have delivered over 50 proof of market funded projects across six universities. These have:

- de-risked and validated ideas
- shaped technology development roadmaps
- initiated and developed collaborations with co-development partners
- developed knowledge of market and fit within it
- prioritised technical and commercial development risks - which to tackle first
- shaped the technology to produce a commercially viable product
- improved understanding of development timescales and costs
- helped teams to identify next steps
- strengthened future and follow-on funding applications.

10

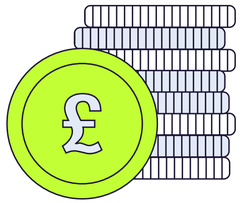
reasons to introduce low cost, flexible proof of market awards

1

A SMALL PRICE TO PAY

A small investment (typically £5k– £15k) boosts confidence to invest time and money into the technology and potentially patent

Case study: A small grant provides substantial support



2

ANALYSE THE COMPETITION

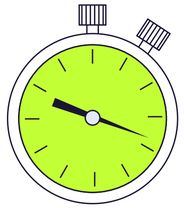
Understand what is available already and if the new technology has advantages, disadvantages, or offers benefits over the existing alternatives. Plus, insights can help tailor the technology to provide maximum benefit over an existing technology.

Case study: Using light for accurate diagnosis

NO WASTE OF TIME

Prevents time and effort being wasted if a technology has no market or poor commercial viability and prioritises the most promising technologies.

Plus, by commissioning external consultants to complement in-house expertise, time in the team is saved, helping with any capacity issues.

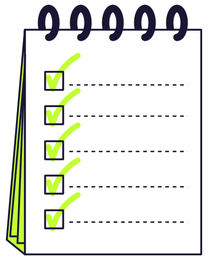


3

4

ACCESS REGULATORY EXPERTISE

In highly regulated industries such as medical technologies, regulatory approval can be a difficult and expensive process. To enable successful translation it is important to determine the class of a technology as well as its regulatory pathway, and it is vital that appropriate expertise is sought as early as possible.



5

UNDERSTAND USER NEEDS

A small amount of proof of market funding can go a long way to organise user focus groups, providing insight into end-user opinion.

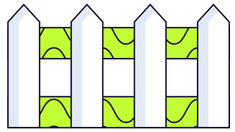
IN OUR EXPERIENCE...

While user engagement is important across all areas of research and innovation, it has specific importance for healthcare.

UKRI EPSRC says: "People's interactions with healthcare technologies can be amongst the most personal, intimate and invasive of all the interactions with technology that they will experience during their lives. The nature of those experiences and people's reactions to them can have profound effects on the success rates of the associated interventions and by extension the success or failure of your technology. The most effective way to understand the concerns, questions and requirements of these potential users of your technologies is to embed their perspectives at the heart of your project from its inception."

Case study: Virtual Physiotherapist could improve stroke recovery

6



BREAK DOWN BARRIERS TO ENTRY

Insights allow the academic team to pivot the technology to overcome any barriers to entry – or stop the project ('fail fast').

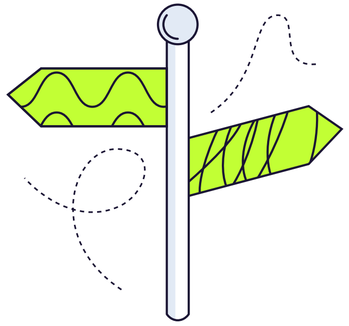
IN OUR EXPERIENCE...

In healthcare industries we must also uncover any perceived barriers in the healthcare setting, or barriers preventing adoption of a new technology in the NHS that may have been unknown by the academic or Research Innovation Office. External experts in the field are able to identify the 'unknown unknowns' and we have found that preliminary health economic work can help to overcome these challenges.

Case study:
Breaking down barriers in medtech

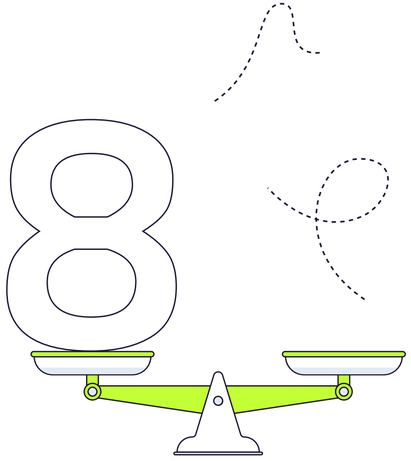
ROAD MAP THE TECHNOLOGY'S DEVELOPMENT

Prioritise which technical and commercial risks should be tackled first, as well as developing a commercialisation strategy and potential business models, identifying industry partners and determining the IP position.



7

8



GET AN UNBIASED OPINION

By using an external consultant to complement in-house expertise, you gain independent validation and an additional, non-biased insight into the technology.

9

UNCOVER OPPORTUNITIES NOT YET CONSIDERED

This is especially true in converging technologies. Market analysis can reveal opportunities to pivot research into market or (for healthcare industries – clinical) areas of need.

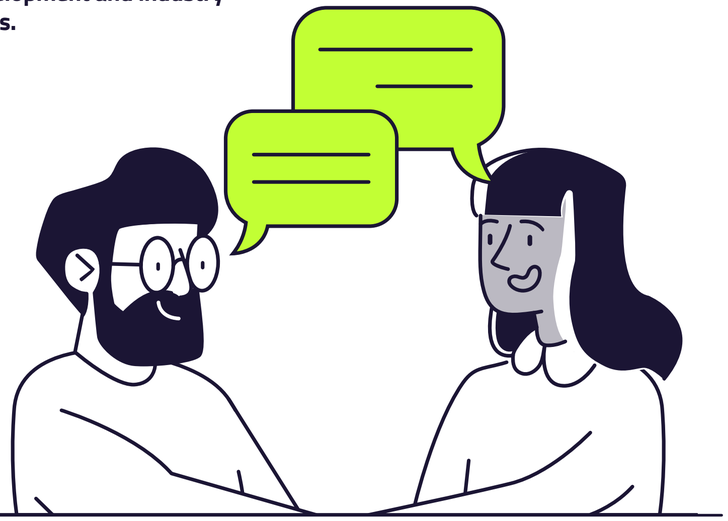
10

MAKE INTRODUCTIONS

Translating research without 'real-world' expert input from expert users or industry can lead to difficulties later. Proof of market funding can also lead to identifying and brokering collaborations with co-development and industry partners.

IN OUR EXPERIENCE...

Academic project leaders do not always know where to find external expert input or have the right connections particularly in health-related industries where the NHS is difficult to navigate. Unless there is a known contact, KEC practitioners and Research Innovation Offices can find it challenging to identify the correct person to speak to. A proof of market award can effectively make these introductions, particularly when a dedicated sector-focused practitioner (such as our Technology Innovation Manager) has built a strong network of contacts.



Tips for KEC practitioners

How to lead a successful proof of market awards scheme

Proof of market awards have the most benefit when they are carried out as early as possible. The earlier a technology is de-risked, the earlier confidence is built for investment.

Proof of market awards carried out at later stages (e.g. TRL 3-5) can still be invaluable - de-risking technology is a continuous process throughout development. This could be a late award on a well-developed research project or a second award carried out as the technology develops. Second proof of market awards can be very effective to either find a commercial partner to invest in the technology at a later stage in the TRL or for further commercial refinement of a technology as it moves from a lab-based prototype to a more commercially focused product.

How you manage or fund proof of market awards will depend on the budget available and the external contacts that you and your organisation have.

Proof of market reports from an external consultant - which generally focus on market analysis and identifying contacts in the relevant market for a technology – may cost around £10k.

IN OUR EXPERIENCE…

We established a framework of relevant external consultants with sector-specific expertise and secured excellent value for money through Grow MedTech and the collective experience of six Research Innovation Offices and associated high flow of potential projects.

For our proof of market awards scheme, we allocated £5k per award, expecting opinions from several key stakeholders (clinical and industrial), market analysis and also regulatory advice. The reports received have been of excellent quality. Clinical introductions have been effectively made leading to long term relationships. Regulatory advice has been found to be accurate and helpful and insight into markets has been of the standard expected and of high value to project teams.

Project managing and supporting the proof of market award requires dedicated support, including:

- Leading kick-off meetings with academic project teams to refine project scope and interim meetings to monitor progress, pivoting work depending on interim findings
- Leading end of project de-briefs and initiating end of project reports – compiled by the academic team rather than the consultant – to understand what value they bring to KEC practitioners and project teams
- Tailoring the writing style required for a commercialisation application. Academic writing (e.g. for a publication) generally requires a very different writing style to a commercialisation application and is not necessarily a writing style academics receive training for. This support involves:
  - Lay explanations of technical ideas
  - Focusing on benefits compared to current market holders
  - Initial views on pathways to market
  - Thinking in terms of developing a product rather than continuing academic research.

IN OUR EXPERIENCE…

Academics may consider developing a five-page application for £5k funding a poor use of their time. It is in the Technology Innovation Manager's remit to explain that the proof of market award application is the foundation of a business case that can put an academic team in the correct mind-set for a successful commercialisation project.

> A business case, no matter how embryonic, is a valuable asset and should not be underestimated, even for TRL1-3 projects.

Case study:
Cloud-based monitoring could help prevent stroke

Case study:
A small grant provides substantial support

IN OUR EXPERIENCE…

Technology Innovation Managers make the proof of market funding scheme – and the overall programme – successful. This specific resource, with a wealth of experience in medtech innovation and backgrounds in academia, industry or knowledge exchange, has been invaluable in supporting academics to develop commercial awareness.

Read more about the role of the Technology Innovation Manager in the introduction.

It is important to dedicate time with the consultant for a kick-off meeting, and a de-brief when the report has been delivered after the KEC practitioner and academic have had the opportunity to read the report in detail.

The kick-off meeting ensures the consultant understands the project and has the opportunity to ask any questions. It is also a good time to set expectations for objectives, deliverables and timescales.

The de-brief should be an honest appraisal of the technology from the consultant, and a frank discussion of any issues that arose.

IN OUR EXPERIENCE...

The direction of the project depends on the specific outcomes of the proof of market funding award, but common themes are:

- A lack of identifiable market: consider dropping commercial project (fail fast) or realigning to meet market demands identified in proof of market report
- A strong market: identify possible contacts and collaborations, and work with them to develop commercially viable product
- Identification of significant barriers to entry:
  - Yes: insurmountable - close project
  - Yes, but can be overcome: pivot project to overcome barrier and reassess commercial goals
  - No: continue as planned, with surveillance by KEC practitioner for any new barriers.

User feedback is a vitally important aspect of many proof of market funding scheme reports. There are a number of ways this can be collected with increasing levels of engagement for each, including mass survey, focus group or one-to-one conversations.

IN OUR EXPERIENCE...

Professional users (for example in healthcare industries, clinicians) are exceptionally well informed and their input can greatly improve a project's success by opening up contacts in NHS Trusts, and by offering practical knowledge and testing capability. Caution should be applied if only a small number of professional users are approached, as strong opinions could direct the project down a suboptimal path.

Public end-users are an under-valued resource for feedback in product development. In healthcare industries, patient and public involvement (PPI) can improve the development process of a technology by preventing the development of a tool that is inaccessible or unusable by the patient.

Case study:
Decision tool gets to the heart of the problem

Once the proof of market funding award is complete – what are the next steps?

In most cases you will be applying for the next stage of commercialisation funding, perhaps proof of feasibility (PoF) or in further developed cases, proof of concept (PoC).

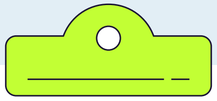
Your goal is to develop a more advanced prototype of the device, aligning with the recommendations and outcomes of the proof of market report.

External funding may be appropriate and often this is much larger than a Research Innovation Office can offer.

IN OUR EXPERIENCE...

Technology Innovation Managers should continue to provide valuable assistance once the proof of market funding award is complete - taking the technology into the next stages of innovation. This includes, but is not limited to: supporting the writing of further funding applications, knowing which contracts to use when, terms of contracts, advice on engaging with industry, negotiating licences, pitching to investors, helping with business planning, spin-out documents, and company formation.

Activities that can form all or part of a proof of market funding award



- ☑ End-user and public consultation workshops
- ☑ Identifying industry and co-development partners
- ☑ Professional-user consultation workshops: **Case study: Assessing international markets for a new test for Alzheimer's**
- ☑ Industry consultation or technology showcase workshops
- ☑ Developing technology road maps and routes to commercialisation
- ☑ Market, opportunity and competitor analysis: **Case study: Plant biologists join war on fungal infections**
- ☑ IP landscaping and advice on IP protection
- ☑ Regulatory pathway guidance.

IN OUR EXPERIENCE…

The type of activities specific to health-related innovation are:

- **Patient, carer and public consultation workshops**
- **Clinical consultation workshops**
- **Health economics assessment** Case study: Industry and academic experts partner to create new 3D burn imaging device for more effective treatment.

OUR PROOF OF MARKET AWARDS SCHEME

53
awards funded to date

£5k
funding available per award

3 – 6
month project duration

£254k
Total funding allocated

Rolling
responsive call – reviewed monthly

Grow MedTech – Proving the market for successful KE

Grow MedTech – funded through the Research England Connecting Capability Fund 2018–2021 – has been a major UK programme providing specialist support for innovation in medical technologies, involving a consortium of six universities across the Leeds and Sheffield City Regions. Our sector-specialist innovation support has helped to put these regions at the forefront of the UK's medtech sector.

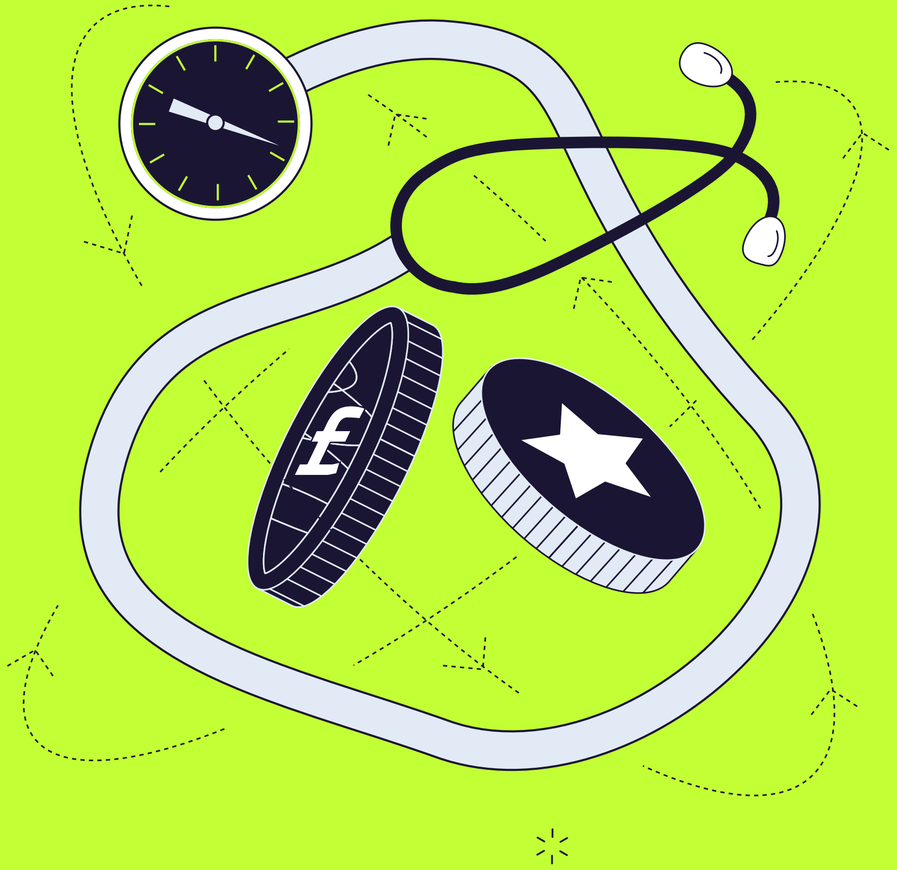
Acting as partnership brokers, we have proactively connected people from academia, industry and clinical practice to collaborate on developing new medical technologies. Our six skilled and experienced Technology Innovation Managers have been based in our partner universities but have worked collectively as a team, connecting with academics, companies and clinicians from across the regions. We aspire to involve patients at every stage of the journey.

We have provided funding for technologies from initial concepts at Technology Readiness Level (TRL) 2 and 3 through to proof of commercial concept at TRL 5. We have also provided support for projects at TLR 5+.

More importantly, academics and companies have accessed sector-specialist expertise and advice to help them progress their technologies, create effective partnerships and leverage additional funding from other sources. We have helped projects bring together different disciplines and technologies – including digital and AI – to enable our partners to access the strongest market opportunities.

Grow MedTech's collaboration between the Universities of Bradford, Huddersfield, Leeds Beckett, Sheffield Hallam and York, led by the University of Leeds, now has a track record of highly successful innovation support. Our model and processes may provide value for other sectors and regions.

Case studies



1

A small grant provides substantial support

Our proof of market awards have allowed researchers to address crucial, early-stage commercial questions. Coupled with advice and support from our Technology Innovation Managers, they have enabled one team of researchers at the University of Bradford to take some important first steps.

Professor Mohamed El-Tanani, in the University's Institute of Cancer Therapeutics, is developing a blood test to determine the likelihood of breast cancer patients developing secondary tumours – known as metastasis – based on a biomarker discovered through his research.

Simple, fast, low-cost and suitable for all breast cancer types, it would offer substantial advantages over the more expensive and complex genomic tests currently used by clinicians.

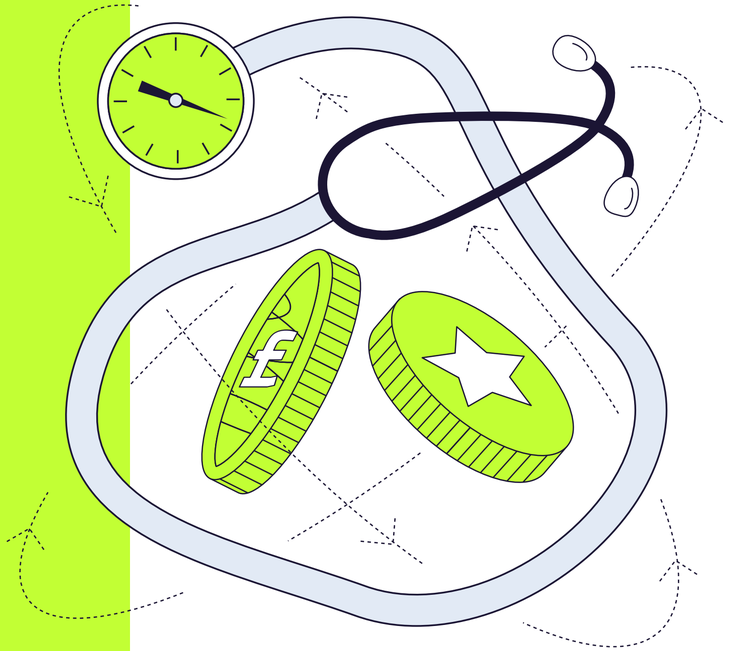
Professor El-Tanani found that one of the first questions potential investors asked about the technology related to regulatory approval – questions he and Bradford's Commercial Manager in the Faculty of Life Sciences, Dr Jason Jones, found difficult to answer. They successfully applied for a Grow MedTech proof of market award to fill this gap.

> **"An important part of the Grow MedTech approach is to make those connections with other areas of expertise or knowledge that are needed for translational work."**

Specialist advice

The funding covered the costs of a specialist consultant, who provided a detailed report on the regulatory challenges involved in taking a test such as this to market. This included quality assurance of manufacture and putting the latest In-Vitro Diagnostic (IVD) regulations into plain English, to provide clear steps to regulatory approval.

"We can now go into investor meetings with confidence and answer these key questions," says Dr Jones. "To make a proposition like this attractive to investors, you need to show there can be low-cost market entry, with the infrastructure and quality procedures required kept as simple as possible."



Making connections

Funding is only part of the support that the project has received from Grow MedTech. Former University of Bradford-based Technology Innovation Manager, Kieran Perkins, was continually on-hand to provide advice and useful contacts for the team. This included an introduction to the National Institute for Health Research Leeds In Vitro Diagnostics Co-operative (NIHR Leeds MIC) and clinicians at Bradford Royal Infirmary.

"An important part of the Grow MedTech approach is to make those connections with other areas of expertise or knowledge that are needed for translational work, but that may be unfamiliar to some academics," says Kieran.

Professor El-Tanani agrees: "Developing a clinical technology has to take into account the opinion of patients and the NIHR Leeds MIC will help us do this, as they have active PPI groups. They're also going to work with us on the health economics aspects, so we can quantify cost savings of the test to the NHS."

The close working relationship between Kieran and the University's commercialisation team has been as productive as the grant itself, welcome as the funding always is, according to Dr Jones:

"The concept of having Grow MedTech people with specialist expertise based in each University has worked really well at Bradford," he says. "Having Kieran on hand to answer questions, provide advice and review grant applications has been invaluable."

2

Virtual Physiotherapist could improve stroke recovery

A system developed by researchers at Leeds Beckett University aims to offer a 'Virtual Physiotherapist' service to patients recovering from stroke.

Through support from a Grow MedTech proof of market award, the research team has been able to make critical connections with healthcare professionals and patient groups, carry out market scoping and competitor analysis activities, and begin developing a commercialisation and implementation strategy for the technology.

Rehabilitation following a stroke can be extremely tough for patients, both mentally and physically. Physiotherapy sessions can help regain strength and movement – but regular exercise is key to success and this can be hard if patients struggle to attend clinics, or if they have to motivate themselves to maintain an exercise regime at home.

The Virtual Physiotherapist enables patients to carry out simple arm exercises, and using the system is as simple as sitting in front of a computer and carrying out the prescribed task, such as lifting a glass to drink.

Artificial intelligence in the computer's software tracks the movements, building up a picture of progress over time.

> **"The sort of technology employed by the Virtual Physiotherapist is likely to become increasingly available within healthcare settings."**

Direct access to clinicians and patients

The sort of technology employed by the Virtual Physiotherapist is likely to become increasingly available within healthcare settings. Its success, however, is entirely dependent on whether or not patients and physicians are inclined to make use of it.

Grow MedTech's emphasis on involving end users in technology development from an early stage means the Leeds Beckett team have been able to make useful connections to guide development work.

Through Translate MedTech, Grow MedTech's predecessor programme, lead researcher Professor Dorothy Monekosso was able to make valuable links with clinicians and assistive technology experts through a network of clinical professionals.

"We had developed a prototype using funding from the Royal Academy of Engineering and the University of Malaysia that showed how patients could use the system – but what we were lacking was input from clinicians about whether they saw a use for this sort of technology, and how they would use it," says Professor Monekosso.

"Through consultations facilitated by Grow MedTech, we were able to get some really positive feedback, but also lots of development ideas.

"Through the Grow MedTech and Translate MedTech events I've attended, I now have a wide group of clinical personnel in the region who are interested in helping us take this forward.

"Grow MedTech's support goes much further than just access to funding. Without access to NHS colleagues, it doesn't matter how good the system or the technology – it just won't go anywhere!"

Expressions of interest from clinical colleagues also helped the team secure Grow MedTech funding to further test the Virtual Physiotherapist.

During this phase, Grow MedTech Technology Innovation Officer Cat Colquhoun introduced Professor Monekosso to colleagues in Assisted Living Leeds, which draws together Leeds City Council's assistive technology services and information.

"Through Assisted Living Leeds we were able to work directly with a group of stroke survivors and have them test out the system and give their opinion about how – and whether – they would use it," says Professor Monekosso.

Early investment leads to long term benefits

After confirming the clinical use and interest from patients, the team are exploring in more depth what incentives will encourage users to maintain regular use of the Virtual Physiotherapist.

The proof of market award from Grow MedTech has enabled further collaboration with Assisted Living Leeds, and new collaborations with the universities of York and Sheffield Hallam.

The academic team are applying for follow-on funding to develop their technology further, and the Grow MedTech team have provided ongoing support on care pathways, user co-design of the interface and regulatory requirements.

3

Using light for accurate diagnosis

Early and accurate diagnosis can make the difference between life and death. But for many diseases, diagnostic tools that can pick up disease at an early stage either do not exist, are imprecise or are limited to use in hospitals and specialist centres.

A Grow MedTech proof of market award has supported Dr Yvette Hancock, Associate Professor from the University of York's School of Physics and Enterprise Fellow at the Centre for Future Health, to develop a diagnostic tool with the potential to work across a range of diseases and in different healthcare settings.

Dr Hancock has been working with clinical teams and academic partners at Guy's Hospital and King's College London, as well as the instrumentation company Horiba UK, to develop a portable Raman spectrometer that could be used in a clinical setting. But with so many potential applications for the technology, the team turned to Grow MedTech to help them identify the best route for clinical application and commercialisation.

"The market analysis we gained through Grow MedTech was critical in helping us to focus our efforts more effectively."

Market analysis

Following an unsuccessful bid for proof of concept funding, Dr Hancock was encouraged to prove her technology by focussing on one clinical area. Grow MedTech Technology Innovation Manager, Clare Green, had a feel for the market and clinical needs, but suggested it could be proved legitimately with a health economics report.

Grow MedTech proof of market funding allowed Dr Hancock to commission the York Health Economics Consortium to assess the potential markets and health-benefit potential for the technology. Based on this analysis, the team decided to focus its efforts initially on prostate cancer.

"We wanted to develop the technology to have the biggest impact possible and prostate cancer is an urgent area of need," explains Dr Hancock.

"It is the second most common cause of cancer death for men in the UK, with around 48,000 men diagnosed each year, and with incidence rates on the rise.

"But our ability to accurately screen for it is still pretty poor, so an easy and accurate test would be a gamechanger for detecting prostate cancer at the earliest stage possible."

Following on from her successful proof of market Dr Hancock is now developing the diagnostic tool to not only accurately pick up cases of prostate cancer, but also to identify whether the cancer is an aggressive type and to what stage the disease has progressed, allowing for the best possible means of early detection of the disease.

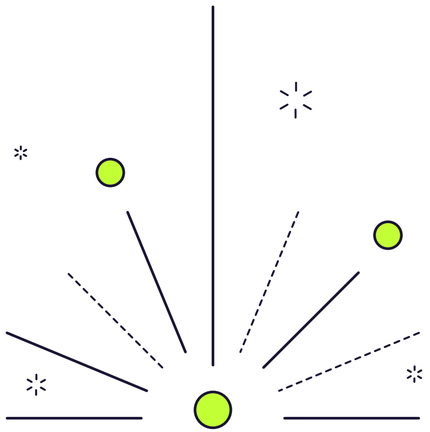
Clinical studies

Dr Hancock has already proven that the technology can accurately diagnose prostate cancer in human cells in the laboratory. Grow MedTech has helped to fund two proof of feasibility studies to validate the technology in blood samples.

The first was a clinical trial at Guy's Hospital in London, testing the technology against samples from prostate cancer patients. A parallel control study took place at the University of York with samples from healthy donors.

"Grow MedTech have been crucial in taking this project forward," says Dr Hancock. "We'd already built a strong team, with industrial, clinical and academic partners, but the market analysis we gained through Grow MedTech was critical in helping us to focus our efforts more effectively.

"The clinical trial will help us take the technology to the next stage."



4

Breaking down barriers in medtech

Digital technologies are breaking down the walls of the medtech industry, enabling companies – and academics – that are new to medtech to apply their knowledge within the sector.

This is true at all levels, from big players such as Apple (who recently appointed a senior cardiologist) and Google (who recently bought Fitbit) to the smaller companies and individual academics who are using their know-how to develop digital health technologies.

"The ability to pay is a major barrier that needs consideration along with the technology's price point."

Dr Steven Fenton from the University of Huddersfield, for example, is an electronic engineer with a research interest in audio quality in music production.

A Grow MedTech proof of market award has supported his project to create a 3D 'audio map' to help blind and visually impaired people navigate their surroundings.

A market report was carried out to confirm the market as the NHS, to establish potential market value and make contacts within the NHS and other industries. The report identified some unknown and unexpected barriers, including the fact that funding for these types of devices falls within the remit of social care, not the NHS, and so the purchase of the proposed system would fall upon the patients. The market is therefore private, and hampered by the fact that only 27% of registered blind citizens are in paid employment. The ability to pay is a major barrier that needs consideration along with the technology's price point.

This is considered a major, insurmountable barrier to entry. Using the insight gained from the market report, Dr Fenton now is considering either other markets for the base technology, using different techniques to try and reduce the price point to fit in with the identified markets.

Although the project may not seem like a typical story of success, the proof of market process has given the academic team an early insight that alternative applications should be explored – without significant time, investment and resource being wasted.

Cloud-based monitoring could help prevent stroke

5

A Grow MedTech proof of market award has helped researchers at Sheffield Hallam University investigate the market need for a new technology that uses artificial intelligence and 'Internet of Things' connectivity to predict stroke risk.

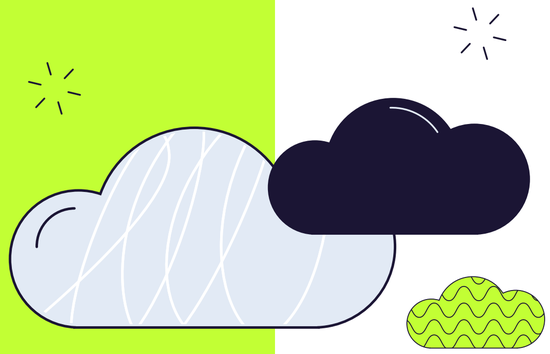
The stroke risk monitoring service helps cardiologists to diagnose an abnormal heart rhythm, known as atrial fibrillation (AF). This irregular beat can cause blood clots to form which, as they travel towards the brain, can lead to stroke.

The researchers have developed a smartphone app which relays data from a wearable heart rate sensor to a cloud-based AI system.

The AI system uses a custom deep learning model to analyse the patient's heart rate and triggers a warning within five-minutes to the patient's cardiologist if an abnormal rhythm is detected.

In the UK more than 100,000 people suffer strokes each year, costing the NHS about £3bn. More than 1.2 million people in the UK have AF and all of these are at risk of stroke.

The Stroke Association says that AF contributes to just under 20 per cent of all strokes in the UK, so an early detection system could have clear benefits to both patients and to the NHS.



> **"The team has been able to identify potential commercial and clinical partners, assess the market size and start to discuss the technology with patient groups."**

Dr Oliver Faust, the lead developer, said: "We wanted to develop a system that can reduce stroke among these patient groups – in order to reach that goal, we need to develop a business plan and establish important commercial and clinical relationships.

This will help us to find out if patients, cardiologists and commercial developers would be open to adopting this innovative approach."

Through a Grow MedTech proof of market award, the researchers have been able to secure expert advice from a business innovation consultant, as well as project guidance from Grow MedTech's Technology Innovation team.

Simon Butler, a Grow MedTech Technology Innovation Manager at Sheffield Hallam University, explained:

"We want to help researchers think more commercially, to assess potential market size and potential, for example. We've brought the project team together with a skilled business consultant with an international reputation in the medical device field.

"Through this expertise, we'll be able to help answer these key questions and guide the project's commercial development. And by doing this at an early stage in the project, we can maximise the chances of success."

Additionally, through the proof of market award, the team has been able to identify potential commercial and clinical partners, assess the market size and start to discuss the technology with patient groups.

Also important was discussing the system with device manufacturers, to ensure it works seamlessly within the Internet of Things 'ecosystem'.

Says Dr Faust: "Grow MedTech provides the necessary expertise in all these areas and with their support, we can ensure we are developing a service that will bring genuine benefit to both overburdened clinicians and at-risk patients. The Proof of Market award gave us confidence in its commercial and clinical potential to engage further with these groups."

The academic team have since been awarded further funding to conduct a small-scale patient trial with their system and have identified and established an industry co-development partner.

Decision tool gets to the heart of the problem

6

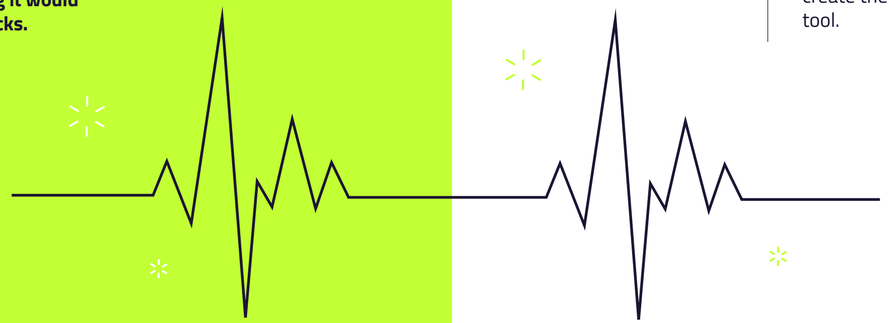
Patients making choices about healthcare treatments need to fully understand their options, but unfortunately this does not always happen as well as it should in clinical practice.

A Grow MedTech proof of market award has funded the development of a commercialisation pathway for a digital tool to help patients with heart disease to make more informed decisions about their treatment.

The new device is based on funded research led by Professor Felicity Astin from the University of Huddersfield. The research team studied the way the process by which patients opted for a treatment called coronary angioplasty happened and surveyed the views of patients and cardiologists at ten NHS Trusts in England.

Coronary angioplasty (CA) is one of the most common medical procedures worldwide and involves opening up partially blocked arteries in the heart. When this treatment is given to people with stable heart disease unpleasant symptoms of angina can be relieved.

Professor Astin discovered that these patients were often opting for this treatment without a clear understanding of the risks and benefits – often mistakenly believing it would reduce their risk of future heart attacks.



"Involving end users, both the patients and the clinicians, in the design of the tool is a critical part of the project."

Crucial funding

The multidisciplinary team – working with the Mid Yorkshire NHS Foundation Trust and the NIHR Devices for Dignity MedTech Cooperative – decided to develop a digital decision aid that could be used by patients and health professionals to work together to ensure that patients are making informed choices about CA.

However, they struggled to find a funding source to cover the crucial gap between research findings and a prototype device – until they discovered Grow MedTech and contacted Technology Innovation Manager, Dr Luke Watson.

"The support, contacts and commercial advice we've had from Grow MedTech has been fundamental in helping us to take the project forward," says Dr Emma Harris, Research Fellow in Patient Education and Communication at the University of Huddersfield.

With the help of Grow MedTech, the team set up a working group involving expert patients, doctors and nurses working in cardiology, academics with expertise in cardiology care and decision aid development and Devices for Dignity with their technological expertise. They've run several workshops, with patients who've undergone CA and the other with cardiology healthcare professionals, to co-create the content and working of the decision tool.

Gaining commercial understanding

The proof of market funding and support has demonstrated a clear market opportunity for the tool: allowing the team to understand the market opportunity, size and stakeholder needs, enabling them to recognise additional potential benefits of their tool and user acceptability, and get a clear picture of its competitors. It also provided them with next stage development recommendations and potential commercialisation routes.

"Involving end users, both the patients and the clinicians, in the design of the tool is a critical part of the project," explains Dr Harris. "Ultimately this tool can help them both – ensuring clinicians are able to do their job well in terms of informed consent and that patients make the best decision for them personally.

"It's been really helpful to have Dr Luke Watson, our Grow MedTech Technology Innovation Manager, to go to for advice on the commercial side. He's worked directly with Devices for Dignity on issues such as IP and copyright, freeing us up to do what we do best – the research and work with stakeholders."

Professor Astin agrees: 'We want to ensure that the research has an impact on clinical practice to improve patient care and the Grow MedTech support is helping to make this happen."

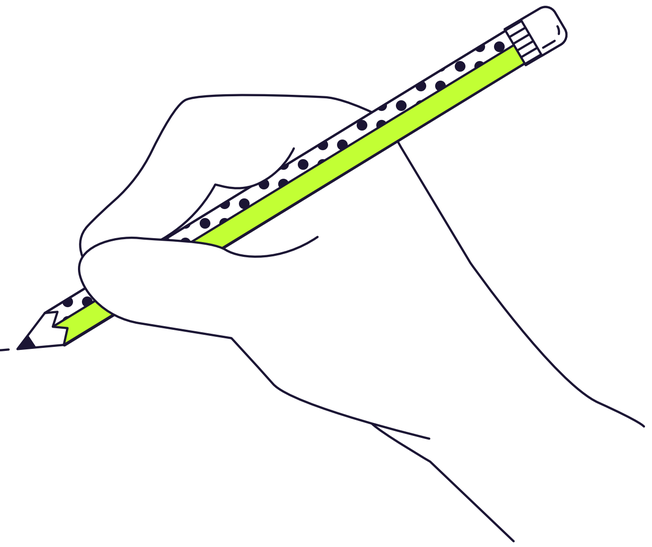
The team have since been awarded two Grow MedTech proof of feasibility awards, enabling them to further develop and validate their prototype device, and have had interest in commercialisation from the private sector.

7

Assessing international markets for a new test for Alzheimer's

A new test that uses an existing clinical drawing task will enable clinicians to provide an early and objective assessment of Alzheimer's and related conditions.

The technology uses machine learning to identify subtle differences in patients' pen movements that can indicate cognitive decline.



"We're confident there's a need for this technology and with Grow MedTech's support we're able to test the market both in the UK and overseas."

Through a Grow Medtech proof of market award, the academic team at the University of York has established the potential market in the USA, China and UK & Europe. The funding has also allowed them to prove the clinical need for the device through workshops in three contrasting territories, the UK, USA and China: highlighting common clinical needs and those specific to the respective demographics, health systems and cultures. The award has been essential for understanding the markets for these countries and will significantly influence the design, implementation and deployment of the intelligent medical device.

"It's really important to involve different stakeholders early on," explains Professor Stephen Smith, who leads the research.

"All our work is clinically led – we're working with consultants who understand the condition; a nurse specialist, who has expertise in managing patients; and, importantly, the patients and their carers.

"We're confident there's a need for this technology and with Grow MedTech's support we're able to test the market both in the UK and overseas. Our team has led workshops in the UK and China with experts from Leeds and Shanghai hospitals and held discussions with medical device companies worldwide. The next step is to use Grow MedTech funding to arrange a similar event in America."

Grow MedTech Technology Innovation Manager, Clare Green, supported Professor Smith in the earliest stages of application for funding, and throughout the project. She says:

"I supported Professor Smith with an application for a no cost extension as there had been significant holds on the project, coordinating with partners overseas. Sometimes fixed timescales of projects can't account for the variations in individual projects. The scope to be flexible with our proof of market awards paid dividends."

"The single greatest advantage of the Grow MedTech programme is the local Technology Innovation Manager support, which helps shape applications and the implementation of projects so that the most efficient use of time, resources and opportunities is achieved," said Professor Smith.

8

Plant biologists join war on fungal infections

Plant biologists at the University of Leeds are applying their expertise in medtech for the first time with support from Grow MedTech.

1.5m

deaths globally each year could be prevented

Working in partnership with researchers at both the Leeds and Sheffield Teaching Hospitals Trusts, the team is developing a new generation of tests to detect fungal infections such as candida or aspergillosis. These can be extremely dangerous – particularly to patients with weakened immune systems.

Current tests are inadequate, costly, and frequently lead to false diagnoses, meaning effective treatment can be delayed.

A Grow MedTech proof of market award has helped the team investigate the competitor landscape, identify potential industry co-development and commercialisation partners, develop a patient and public involvement plan, and assess the scope to launch a novel diagnostic. The team now have evidence that their antibody test has the potential to be successful, with a renewed understanding of the best ways to maximise opportunities in the market.

"A new test for fungal infections could prevent up to 1.5 million deaths globally each year," says Dr Yoselin Benitez-Alfonso, of the University of Leeds.

Grow MedTech Technology Innovation Managers helped the academic team identify what questions needed answering to understand if the technology was commercially viable and supported their application for a proof of market award. Once the project had been funded, support was given to draft a request to quote, and shortlist suitable consultants.

The project team have since secured additional funding from Grow MedTech for proof of feasibility and have identified a number of promising antibodies currently being tested on patient samples. The ongoing work has attracted interest from a major international pharmaceutical company after the project was featured in the Grow MedTech annual report.

Dr Benitez-Alfonso also credits her engagement with Grow MedTech activities and support from Technology Innovation Managers as being instrumental in her recent award of a UKRI Future Leaders Fellowship. "Thank you for your work in making interdisciplinary science possible and for your support in lifting the impact of this part of my research," she said. "Our Technology Innovation Manager was invested in the project, making sure it ran smoothly and keeping in touch with how everything was going."

9

Industry and academic experts partner to create new 3D burn imaging device for more effective treatment

A Grow MedTech-funded partnership between University of York academic Prof Roddy Vann, and industry partner Sylatech is developing a new technology capable of capturing 3D imaging of burns.

This will result in more comprehensive mapping of burn severity, more targeted treatments, and reduced healing times and scarring.

Accurate, rapid and repeated assessment of a burn injury is crucial for choosing an effective treatment course for the best patient outcomes.

Currently, a procedure called Laser Doppler Imaging (LDI), which measures blood flow in the wound, is considered best practice for assessing burns, but a major limitation of LDI is that it can only provide an accurate assessment after a burn has stabilised. Cost and usability issues can restrict the use of LDI and so in many cases, a visual inspection of burns, where healthcare professionals rely solely on their own experience to assess the severity of the burn and decide the best treatment, is carried out instead.

> **"Clearly demonstrating the market potential of the technology has been key to attracting onward investment and development funding."**

The solution

A team led by Professor Roddy Vann, in the York Plasma Institute at the University of York, is currently working on a prototype device that is capable of producing accurate 3D images of burns by measuring microwaves naturally emitted by the body.

If successful, this device could greatly advance research into burn progression through direct imaging of the damaged area.

Scientists from industry partner Sylatech are co-inventors of the technology, working alongside Grow MedTech and the York team to commercialise the technology.

Working closely with industry from an early stage is always important and the link with Sylatech is particularly strong, having grown from its early days as a Knowledge Transfer Partnership.

The partnership has been dedicated to creating an impactful technology for end-users, having brought in clinicians from specialist burns centres at the Queen Elizabeth Hospital in Birmingham and Pinderfields Hospital in Wakefield – as well as Patient and Public Involvement groups – to guide their work.

A proof of market award from Grow MedTech has been used to provide a Health Economics study to de-risk and accelerate the burn imaging device towards commercialisation and clinical adoption. The model produced has enabled the team to determine which parameters are key to economic viability, allowing them to identify the potential economic savings for different patient groups, and therefore the likelihood of clinical adoption from a cost-benefit perspective.

Clearly demonstrating the market potential of the technology has been key to attracting onward investment and development funding. Following on from their successful proof of market project the academic and industry team were successful in securing further Grow Medtech funding to develop the mathematics and software components required for a portable prototype.

Resources

We have provided examples of the documentation we used to run our scheme for reference, which can be adapted by using your own branding and refining for your sector.

Guidance for applicants

The guidance document sets out our proof of market scope, eligibility, assessment criteria and how to apply. Our guidance document was hosted on the Grow MedTech website for ease of access for applicants.

Application form

The application form provides an example of the questions asked of the academic team to be assessed for suitability for funding.

Scoring criteria

The scoring criteria outlines how we assessed applications for their suitability for the funding.

Request for quotation template

The request for quotation template sets out the framework which our Technology Innovation Managers used to identify and contract expertise in medtech development to support funded projects.

Final project report form

This template sets out a framework for reporting project outputs and outcomes, future plans, and reflections from the academic team on what went well, what could be improved and on the funding scheme process.

All documents can be downloaded from the Fail fast or prove it early good practice guide webpage.

Acknowledgements

If you found this guide or our resources helpful – please let us know: info@growmed.tech

Process development lead:

Dr Danielle Miles

Author and editorial team:

Dr Luke Watson

Rowan Grant

Grow MedTech Team

Dr Jo Dixon-Hardy,
Director of Grow MedTech,
University of Leeds

Dr Danielle Miles,
Programme Lead &
Technology Innovation Manager,
University of Leeds

Dr Luke Watson, Technology Innovation Manager, University of Huddersfield

Dr Graeme Howling,
Senior Technology Innovation Manager,
University of Leeds

Dr Cat Colquhoun,
Technology Innovation Officer,
Leeds Beckett University

Dr Jillian Newton,
Technology Innovation Manager, Sheffield Hallam University

Dr Clare Green,
Technology Innovation Manager,
University of York

Rowan Grant, Communications and Engagement Manager, University of Leeds

Nick Chester,
Reporting Officer,
University of Leeds

Kelly Broadbent,
Senior Communications and Events Officer,
University of Leeds

Sara Liptrot,
Administrative Assistant,
University of Leeds

Former team members:

Kieran Perkins,
Technology Innovation Manager,
University of Bradford

Simon Butler,
Technology Innovation Manager,
Sheffield Hallam University

Dr Alice Bullas,
Technology Innovation Manager,
Sheffield Hallam University

Victoria Turner,
Administrative Assistant,
University of Leeds

Kaeyo Kelly,
Communications and Engagement Coordinator, University of Leeds

Joe Drake,
Technology Innovation Officer,
University of Leeds

Mohua Siddique,
Innovation Development Officer,
Translate MedTech, University of Leeds

Contact us

www.growmed.tech

info@growmed.tech

@growmedtech

linkedin.com/company/grow-medtech