An academic's guide to medtech translation

Welcome to this online guide to the medtech innovation process, designed for academics and researchers in STEM subjects in the UK.

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1) About this guide

This online guide is designed for academics and researchers, and will be useful for anyone with an interest in medical technologies innovation and translation, with a focus on those innovators based in higher education or research institutions. Throughout this guide, we will provide an overview of the medtech innovation pathway, common hurdles and pitfalls, and case studies of successful translation to equip you with the right skills and information to support you on your translational journey.

Our expertise in this field was developed through the Medical Technologies Innovation and Knowledge Centre (IKC) established by the University of Leeds in 2009, and through Grow MedTech, a consortium of six universities set up in 2018. Through these programmes, and working with our industry partners, we've progressed over 250 projects (proof of concept or technology development and demonstration), of which 84 have gone beyond Technology Readiness Level (TRL) 5 – with over 50 products or services reaching the market.

How this guide can help you

As an academic and researcher, your career ambition may well be to make an impact. Partnering with a company, working with patients to develop solutions, or setting up a business can be a way of achieving this long-term impact. The reason you choose to translate your research may not always be for financial returns: it can be an effective way to enhance and sustain research activities after initial funding ends. Commercialisation of your developments can be the most effective way to ensure innovative technologies and treatments maximise the benefit for patients and health services by making those innovations widely available and sustainable.

Translating research can distinguish you and your work from your peers, while also making an extensive, positive impact on society.

Translating research in medical technologies is complex, with many phases, challenges and regulatory considerations. It takes a team, with involvement from many specialists to successfully translate research into a new product or service for patient benefit.

This guide provides practical advice to help you navigate the innovation pathway for medical technologies and will signpost you to appropriate support and resources available for each stage.

Develop your business case

The guide is broken down into accessible units, relevant to the different stages of your innovation journey. You can start at the beginning and work to the end or select where you are in your innovation journey and learn from there.

In each chapter you will find learning outcomes, learning materials, advice, guidance and further resources relevant to academics in the UK. The guide has been co-funded by the University of Leeds, so there's also specific guidance for participants from Leeds to follow.

There is a section named "Develop your business case" at the end of each chapter to help build your business plan. Business plans are an essential tool that can be used in a multitude of ways – in funding applications, to attract collaborators, commercial partners, and investors. Information from this section can be used to inform the development of your business plan, which will become a living document and asset as you navigate your innovation journey.

2) What is a medical technology?

This chapter covers:

- How do you define a medical technology?
- Further reading

How do you define a medical technology?

Medical technologies are products, services or solutions used to improve or save people's lives.

Regulatory frameworks use the term 'medical devices' which includes in vitro diagnostic (IVD) medical devices.

According to the EU Regulation on Medical Devices 2017/745 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease.
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability.
- Investigation, replacement or modification of the anatomy or of a physiological or pathological process or state.
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations...

…and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

Plus:

- Devices for the control or support of conception.
- Products specifically intended for the cleaning, disinfection or sterilisation of medical devices.

The term ‘medtech’ or medical technologies has become popular in recent years to describe a broadening scope as digital technologies and medical devices converge. The new regulations have clarified the status of such products as medical devices and thus fall within the regulations.
IVDs are tests on biological samples that can detect disease, conditions and infections to determine the status of a person’s health. IVD include products such as self-tests for pregnancy, covid19 tests and blood glucose tests for diabetics, to sophisticated diagnoses performed in hospitals and clinical laboratories.

Further reading

The definition of medical devices, along with in vitro diagnostics and software as a medical device is further covered in section 12, Regulatory considerations.

3) What is translational research?

This chapter covers:

- What is translational research?
- The innovation pathway
- Teamwork
- The innovation process and why ideas fail
- Further resources

What is translational research?

Translational research, or translational science, is an activity aimed at progressing basic research into results that benefit people, patients and society. This guide focuses on translation of technologies rather than policy impact.

The UKRI Medical Research Council (MRC) say: “The aim of MRC’s clinical and translational research is to support and fund innovation that will speed up the transfer of the best ideas from discovery research into new interventions that reach patients, and improve the return on investment in fundamental research.”

For medtech, it is a complex, highly regulated process. The exact process is dependent on the technology being developed, the risk associated to its use and the benefit to the patient. Lower risk products or products predicated on other marketed products have simpler, faster development pathways. High risk products or first in-man products have longer more rigorous development pathways requiring extensive clinical investigations.

So, the development process depends on the technology, disease and risk or benefit to patients. But it can be generalised as an innovation pathway.

The innovation pathway

Watch a video about the innovation pathway

Video transcript

This graphic demonstrates a generalised process and in the real world it is not that simple.

In this game, unfortunately there are more snakes than ladders. Translational research is rarely linear and it is often iterative.

The innovation pathway is sometimes generalised into Technology Readiness Levels or TRLs.

TRLs are a widely used method for tracking the maturity of technologies, developed at NASA during the 1970s.

Here is the same diagram with some specific activities you might expect during the medtech innovation pathway. Some institutions use alternative Commercialisation Readiness Levels that acknowledge various indicators, which influence the commercial and market conditions, beyond just the technology maturity.

For the purpose of this guide, we will refer to TRLs. You will need a plan, and assume that it won't go according to plan, but it is crucial nonetheless to have a clear framework and to use this as your guide. The innovation pathway is lengthy for medical technologies. The timescales to develop a medical device depends on the type of device being delivered, but expect it to take over ten years to get a medical device to market.

Professor Ruth Wilcox, Director of the Medical Technologies IKC explains the importance of translational medtech research to our society, and lessons learned in translating technologies.

Select the video below to play.

Watch a video in which Professor Ruth Wilcox explains the importance of translational medtech research to our society.

Candy McCabe, Professor of Clinical Research and Practice at UWE, Bristol describes translational research in her own words and give tips to academics considering commercialising technologies.
Select the video below to play.

Select the video below to play.

Watch a video in which Professor Candy McCabe discusses what translational research is

Peter Culmer, Associate Professor in Healthcare Technologies at the University of Leeds, describes translational research in his own words and give tips to academics considering commercialising technologies.

Watch a video in which Professor Peter Culmer discusses what translational research is

Teamwork

Multi-disciplinary teamwork is essential for the translation of medtech research. No one is an expert in everything.

As well as expertise in the area of the underpinning research, you will need specialists in manufacturing processes, product commercialisation, regulatory, quality management, and a multitude of other disciplines.

Plus, many activities can be delivered in parallel, so you will need lots of hands on-deck to be as efficient as possible.

The innovation process and why ideas fail

The following film looks at innovation in healthcare, including steps along the innovation pathway, why ideas fail and the barriers to medtech innovation.

Watch a video about the innovation process and why ideas fail

Further resources

Engineering and Physical Sciences Research Council (EPSRC) Health technologies impact and translation toolkit provides an overview of some of the barriers research may face when applying their research to solve challenges in human health and wellbeing.

EPSRC Technology readiness levels: from basic research to adoption and diffusion diagram shows activity typically associated with each TRL, from a theoretical case at one end of the scale through to commercialisation at the other.

The University of Leeds has a general process for evaluating and progressing commercial opportunities to market. See more at: Our commercialisation process

Our University Strategy, Universal Values, Global Change: University of Leeds Strategy 2020 to 2030, provides a blueprint for a values-driven university that harnesses its expertise in research and education to help shape a better future, working through collaboration to tackle inequalities, achieve societal impact and drive change.

Focusing on three core themes – Community, Culture, and Impact – it sets out our ambition to offer a collaborative, supportive and safe environment for the entire University community and emphasises the importance of teamwork and diversity. Our Statement on Research Culture reflects these values.

4) Have you completed the underpinning research?

This chapter covers:

- Judging if you are ready to embark on translational research
- Steps to develop your business case

- Further resources

If you are reading this, you may well already have a medical technology idea and thoughts on what it will be used for. Your underpinning background research for the technology should be complete to enable the technology to be ready for translation.

It is often quite difficult to define what is basic, what is applied and what is translational research. In the real world it is a continuum between basic research to applied and translational research.

A definition may help to better understand these terms and there are numerous definitions available online. Our definitions below are framed for medical technologies, but translational research can be applied across multiple areas of science and engineering.

Basic research

This type of research is often focused on fundamental science, engineering and knowledge creation where there is not a defined application or output other than the knowledge generated. For medtech, this might be understanding the biological process or mechanism of a disease, screening for and identifying biomarkers related to a condition or developing models to simulate in vivo processes, these could be molecular, cellular, biophysical, computational or animal models.

Translational research

This has a defined end point and is a part of applied research that is focused on developing research with the particular output for the treatment of medical diseases and conditions. Its goal is to 'translate' existing knowledge developed and apply it to techniques and treatments to address medical needs. It has been labelled as the process from 'bench to bedside'. It is often the first stage in developing new technologies and the initial stages in the product development commercialisation processes.

The work that occurs within translational research can be varied and is highly dependent on the technology or application, however proof of concept is often seen as a critical step in translational process.

Examples of translational research include concept development, development of technical prototypes, in vitro and in vivo safety testing and understanding and preparing for regulatory stages. It is defined as TRL 2-5 and bridges the gap between basic and clinical research.

Develop your business case

Before embarking on research translation think about the following areas:

- Has the underpinning basic science and research been demonstrated?
- Who has funded this work and how much funding has the technology received so far?

- Are there any commitments required to the funders?
- Do you have any data to support your concept?
- What is the maturity of your research/technology/intervention in TRL terms?
- Do you have any knowledge already of the clinical impact, the patient benefit and the impact of healthcare provision?
- Has there been any industry support or interaction for this project? Have you engaged with key stakeholders to determine potential impact/ benefit/ unmet need?
- What experience and achievements do you and your team have that are relevant to the development of the technology? Have you any prior experience in commercialising a technology, product, process or service or running a business?

Further resources - UK

UKRI is a non-departmental public body sponsored by the Department for Business, Energy and Industrial Strategy (BEIS).

The organisation brings together the seven research councils, Research England, which is responsible for supporting research and knowledge exchange at higher education institutions in England, and the UK's innovation agency, Innovate UK.
UKRI provide funding to:

- Researchers
- Businesses
- Universities, NHS bodies, charities, non-governmental organisations (NGOs) and other institutions.

Funding is provided for every stage of research, from fundamental research to applied and translational research that develops new products and services. Search funding opportunities

Further resources – Research Innovation Service, University of Leeds

- Applying for research funding includes developing your research proposal, costing and pricing, approvals, systems and what happens after submission.
- Managing awards includes project set up, contracts, and managing live awards.

For further information on funders please refer to the Funding for translational research and innovation section, within section 15, Support from your Research Support Services.

5) Building a business case

This chapter covers:

- What is a business case?
- How do you use it?
- What should it include?
- Business plan template to download

- Further resources

Ensure you have prepared a confidential disclosure agreement before talking about your technology. For further information please refer to **topic 10, Novelty and intellectual property.**

What is a business case?

A business case or plan is a written document that describes your technology and how you intend to take it forward to commercialisation. It will help you to clarify your idea, uncover any potential barriers, and measure your progress.

Your business plan will evolve throughout the development pathway and develop over time.

How do you use it?

You'll need to refer to it when you apply for funding, it will help build the confidence of potential collaborators or investors to support you, allow you to measure progress, and ensure you and your team are all working towards the same goal.

What should it include?

Your business plan should include all the elements described through this course: the product concept, the clinical need and value of the idea, the clinical engagement planned or completed, the market opportunity, the intellectual property status, your IP strategy, regulatory considerations, etc.

Develop your business case

Before building your business case, you will need to download the business plan template [accessible Word doc] and populate it as you work through the guide.

Further resources

The British Business Bank - tips for developing a business plan

6) What is the clinical need for your idea?

This chapter covers:

- Technology push and market pull
- Identification and characterisation of unmet clinical needs
- Steps to develop your business case
- Further resources

Technology push

Research and development in science and technology can lead to new discoveries, which can be used to develop new products or improve existing ones. This is known as 'technology push', and it happens before there is market demand for the product.

Market pull

But the ideal innovation journey starts with an unmet need. Responding to the demands of the market or users (patients, public, clinicians and healthcare workers etc) is the most effective approach to innovation in healthcare. This is called ‘market pull’.

What are unmet needs?

Unmet needs are those that do not have products or services to address them, or the solutions on the market do not adequately serve the need. These unmet needs may create more convincing opportunities for innovation compared with needs that are already addressed, or which have multiple competing solutions

Why are they important to successful innovation?

Determining which unmet needs represent the best opportunities for innovation is a challenge in itself, but is it important to understand the unmet need in depth to avoid pursing phantom opportunities and missing others.

Understanding unmet needs

To understand unmet needs, the obvious thing to do would be to ask users what they need. However, customers can easily describe a problem they’re having, but not the best solution. Henry Ford is widely quoted to have said:

“If I had asked people what they wanted, they would have said faster horses.”

Identifying these unarticulated unmet needs is the critical challenge and area of opportunity for an innovator.

Identification and characterisation of unmet clinical needs

The following Translate MedTech film looks at various approaches that can be used to understand and define unmet clinical needs.

Watch a video about the identification and characterisation of unmet clinical needs

Develop your business case

As you continue building on your business case, think about the clinical value of your idea and include the following:

What is the clinical opportunity/unmet clinical need and how have you arrived at this insight?

What is the clinical benefit to the patient/clinician/healthcare provider/payer?

Could you benchmark your development against current market solutions and/ or competitor products, considering the clinical, technological and financial advantages?

Are you aware of a current 'gold standard' treatment/service, what is it, and how does your idea fit within?

Is there a need for an external opinion on the clinical value (consultancy work)? Who, and why are they the best fit? What questions will they address?

Further resources

Select a tab for further relevant resources.

UKRI have published a useful guide to engaging with healthcare professionals: UKRI Stakeholder engagement guidance.

NIHR signposting service can connect you with experts who can collaborate on clinical and health research in order to help develop a potential therapeutic or technology.

Working with innovation support organisations provides access to key clinical networks and promotes the application of academic research to real world problems, maximising the impact of your work, for example:

- NHS Innovation Hubs, e.g. Medipex, HealthTech Enterprise, Trustech, Midtech
- Academic Health Science Networks (AHSNs) across England. As the only bodies that connect NHS and academic organisations, local authorities, the third sector and industry, the AHSNs are catalysts that create the right conditions to facilitate change across whole health and social care economies, with a clear focus on improving outcomes for patients.
- NIHR Medtech and In vitro diagnostics Co-operatives (MICs).

The NIHR experimental medicine infrastructure enables researchers to develop clinical applications from scientific breakthroughs, to translate these discoveries into new treatments for patients NIHR Experimental medicine.

Funding for early commercial/clinical/user need evaluation is available through UKRI Impact Acceleration Account/Welcome Trust Institutional Translational Partnership Award funding Translational activities supported.

Research and Innovation Development Managers and Officers can support University of Leeds researchers identify consultants for an external opinion on clinical value (consultancy work).

7) Working with clinicians

This chapter covers:

- How can clinicians help?
- What about clinical specialist organisations
- The process
- How much of an understanding of the clinical pathway is required for funding proposals?
- Steps to develop your business case
- Further resources

Ensure you have prepared a confidential disclosure agreement before talking about your technology, or that you have adequately protected your IP.

How can clinicians help?

Clinicians are crucial to the development of new medical technologies because they can help ensure that innovations are designed to meet defined clinical needs from an early stage. Often, however, clinicians have limited time available to commit to this process and may lack experience of the innovation process.

What about clinical specialist organisations?

Working with a specialist organisation, such as an NHS innovation hub or Academic Health Science Network can make clinical engagement as efficient and as effective as possible. This approach will help develop a more viable business case for your innovation, speeding up the technology development process and helping to secure investment because clinician involvement will boost a technology's credibility.

The process

The whole process starts with understanding clinical need. Many medtech innovation programmes run regular workshops with clinicians to articulate clinical needs and show where fresh solutions to improve patient care are required.

Getting the clinical perspective right from the start and involving clinicians at every stage of development is key to a smooth commercialisation pathway. You should not rely on the thoughts of one local clinician (clinician need) and ensure there is a wider clinical need for your idea. Winning buy-in from key opinion leaders will support advocacy and the adoption of your new technology, along with providing crucial advice and guidance in its development.

Academics can engage with the clinical community through NHS Innovation Hubs, Academic Health Science Networks, charities, hospital trust research and innovation departments and by attending clinical conferences and meetings.

Funding may be beneficial to engage a specialist organisation to identify clinicians with suitable expertise or run workshops on clinical needs.

How much of an understanding of the clinical pathway is required for funding proposals?

The following Q&A looks at how much of an understanding of the clinical pathway is required for proposals.

Watch a video about how much of an understanding of the clinical pathway is required for funding proposals.

Hemant Pandit, Professor of Orthopaedic Surgery at the University of Leeds gives tips on the most efficient routes to engaging with busy clinicians.

Watch a video in which Professor Hemant Pandit gives tips on effective ways to engage with busy clinicians

Develop your business case

- As you continue building on your business case think about the following:
- Is there a need for external support to advise on clinical engagement (consultancy work)? Who, and why are they the best fit? What questions will they address?
- How you have involved clinicians or healthcare professionals in developing this technology?
- How they will be involved in steering and implementing the project in the future?

Further resources - UK

UKRI have published a useful guide to engaging with healthcare professionals: Stakeholder engagement.

NIHR signposting service can connect you with experts who can collaborate on clinical and health research in order to help develop a potential therapeutic or technology.

Working with innovation support organisations provides access to key clinical networks and promotes the application of academic research to real world problems, maximising the impact of your work, for example:

- NHS Innovation Hubs, e.g. Medipex, HealthTech Enterprise
- Academic Health Science Networks (AHSNs) across England. As the only bodies that connect NHS and academic organisations, local authorities, the third sector and industry, the AHSNs are catalysts that create the right conditions to facilitate change across whole health and social care economies, with a clear focus on improving outcomes for patients.
- NIHR MICs.

The NIHR experimental medicine infrastructure **enables researchers to develop clinical applications from scientific breakthroughs, to translate these discoveries into new treatments for patients.**

Further resources – University of Leeds

A non-disclosure agreement (NDA) or Confidential Disclosure Agreement (CDA) should be put in place prior to sharing any valuable or private information, knowledge or research results with a third party (for example, unpublished research data, details about new intellectual property, or non-public costs and prices). This will ensure that the other party keeps such information secret and will allow the parties to hold open discussions, without the fear of the disclosed information being misused or shared with anyone else by the other party.

Yorkshire and Humber AHSN is one of 15 AHSNs set up by NHS England to operate as the key innovation arm of the NHS.

Funding for early commercial/clinical/user need evaluation is available through UKRI Impact

Acceleration Account/Welcome Trust Institutional Translational Partnership Award funding - Translational activities supported.

8) What is the market opportunity for your idea?

This chapter covers:

- What do we mean by market opportunity?
- Using market intelligence and developing the right solution
- Prove the opportunity early: Proof of market studies
- Developing a health economics proposition
- Steps to develop your business case
- Further resources

What do we mean by market opportunity?

'Market opportunity' means the size of the opportunity for sales of the product. With a robust market analysis, you can make more profitable decisions.
Many new innovators believe their solution or technology will have wide market appeal or have unrealistic broad expectations. As a result, they overestimate their market opportunity.
Before investing serious time, resources and effort into an innovation, you should check:

- If the problem that you have identified is widespread
- If there is already anything available that can solve the problem.

Innovate UK say your market analysis could include the following:

1. Calculating market size. Is there enough market demand?
2. Competitor analysis. Who are the major players already out there in the market?
3. Market growth opportunities. Is this the best market for your innovation?
4. Identifying any barriers to entry. What are the potential pitfalls?
5. External environment. Are there any upcoming technology updates, policy and regulatory developments or social influences that could affect your success?

Using market intelligence and developing the right solution

The following Translate MedTech film describes in further details how to define the market opportunity, critically review existing solutions, scope and evaluate new solutions and appraise ideas to take forward.

Watch a video about using market intelligence and developing the right solution.

Prove the opportunity early: Proof of market studies

Research Support 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-house expertise

(commercialisation support services) or external consultants can be contracted to complete proof of market studies.

10 reasons to utilise proof of market awards

1. A small price to pay. A small amount of funding (typically £5-£15k) ensures confidence to invest time and money into the technology and potentially patent.
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.
3. Reduces time wasting. Prevents time and effort being wasted if a technology has no market or poor commercial viability and prioritises the most promising technologies
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 patient or public opinion.
6. Break down barriers to entry. Insights will allow your team to pivot the technology to overcome any barriers to entry – or stop the project ('fail fast').
7. Roadmap the technology's development. The study will help your TTO 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.
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' clinical or industrial 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.

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

- Patient and public consultation workshops.
- Identifying industry and co-development partners.
- Clinical consultation workshops.
- Industry consultation or technology showcase workshops.
- Developing technology road maps and routes to commercialisation.
- Market, opportunity and competitor analysis.
- IP landscaping and advice on IP protection.

- Initial health economics proposition.
- Regulatory pathway guidance.

Developing a health economics proposition

Health economics seeks to facilitate decision making by offering an explicit decision-making framework based on the principle of efficiency. It is not the only consideration but it is an important one and practitioners will need to have an understanding of its basic principles and how it can impact on clinical decision making (taken from Introduction to health economics for the medical practitioner, D P Kernick.).

Health economics assessments help to ensure decisions are made transparently and fairly in an era of limited resources and an increasing range of intervention possibilities. This specialised cost-benefit analysis robustly assesses whether the benefits gained by introducing an intervention outweighs the benefits of current interventions.

Proof of market type award

Using a proof-of-market type award at an early stage to develop an initial health economics proposition will be beneficial in building a case for further funding to develop the technology.

Preliminary discussions

For new technologies that are not directly comparable to existing solutions, then health economic analyses can be challenging, so preliminary discussions with specialist organisations or pilot studies are recommended before commissioning a full analysis.

Full health economics analysis

A fully defined health economics analysis can be developed within a proof of concept study to build a case for further investment.

Develop your business case

As you continue building your business case, think about market opportunity for your idea or solution and include the following points:

- Who are the customers for this opportunity?
- If there are existing commercial products or services, what are the price point for these?
- What is the market size?
- How is this development innovative/unique?
- What issues/technical problems does it overcome?
- How will your product compare to existing products on price?
- Does this development have health-economic/cost benefits to the health service provider?
- Is there a need for an external opinion on the market opportunity (consultancy work)? Who, and why are they the best fit? What questions will they address?

You probably have some basic ideas of how your innovation might be preferable over current solutions, but this will need to be proven. Health economics analysis and/or clinical consultation might be beneficial as part of a proof of market type award, using a specialist organisation or consultancy. Proof of market studies usually take 1-6 months and require around £5-10k of funding.

Further resources – UK resources

External support might be worthwhile: Market intelligence report could be beneficial as part of a proof of market type award using a specialist organisation or consultant. Proof of market studies usually take 1-6 months and require around £5-10k of funding.

ClinicalTrials.gov is a database of privately and publicly funded clinical studies conducted around the world, using this is useful to understand technologies in clinical development: Clinicaltrials.gov.

Innovate UK explain how to identify market opportunities: How to identify market opportunities.

The NIHR Research Design Service provides support to health and social care researchers across England on all aspects of developing and writing a funding application, including research design, research methods, identifying funding sources and involving patients and the public. Advice is confidential and free of charge: NIHR Research Design Service.

Consulting with a health economist can have significant benefits in supporting this evaluation. A health economist can identify potential benefits and/or costs, and could provide a projection of the impact your proposed innovation could have on the clinical pathway for your solution - positive or negative. Proof of market studies usually take 1-6 months and require around £5-10k of funding.

Introduction to health economics for the medical practitioner in the BMJ Postgraduate Medical Journal gives a clear and concise overview of health economics: Introduction to health economics for the medical practitioner.

With around 60 economists, the Centre for Health Economics (CHE) at the University of York is a world-renowned institute that produces policy relevant research and innovative methods that advance the use of health economics to improve population health: Centre for Health Economics (CHE)

Mtech Access offer a wide range of support and services to market access and HEOR teams from global to local level, including: evidence and market access strategy development, the generation and assimilation of evidence, and implementation and communication to payers and other stakeholders: Mtech Access.

NIHR offer a good introduction to health economics and economic evaluation: Introduction to health economics and economic evaluation.

YHEC give a definition of health economics: Definition of Health Economics.

Further resources – University of Leeds

The Innovation and Business Development team supports academics to engage in innovation activities, ranging from initial research translation projects through to larger-scale, multiple-partner collaborations. An impact officer from the team can carry out market analysis searches to support early-stage research with potential for translation: Innovation and Business Development Team.

POC and POM funding is available through impact accelerator account schemes – these must be developed in conjunction with the Commercialisation Team.

The University of Leeds library has compiled a resource guide to health statistics: Statistics and data sources.

You can search for clinical trials and systematic reviews using databases and websites, this is useful to understand technologies in clinical development. The University of Leeds library has compiled a resource guide: Clinical trials and systematic reviews.

Health Economists in the Faculty of Medicine and Health at the University of Leeds use a variety of economic and econometrics methods to address cost-effectiveness, efficiency and inequalities in health care provision: Health economics - A research topic within the School of Medicine.

9) Working with industry partners

This chapter covers:

- The importance of working with industry collaborators
- How co-development partners can support projects
- The importance of commercial partners in funding proposals
- Steps to develop your business case
- Further resources

Ensure you have prepared a confidential disclosure agreement before talking about your technology, or that you have adequately protected your IP.

Close working with industry partners is critical for successful innovation, translation and commercialisation of technologies. This is particularly true in the medical technologies sector, where there is increasing regulation to be navigated.

Commercial partners bring critically important regulatory and market insights that go beyond standard proof of market studies. These are vital to enable a project to reach and go beyond TRL5.

Industry can be brought on board to co-develop ideas, as a research collaborator, a commercial or investment partner, through a start-up or spin-out company or a licensing agreement.

Co-development partners can support projects through:

- In-kind support such as materials, facilities, processing, scientist or technician support.
- Time to attend meetings and review research or project outcomes.
- Financial support.
- Advice and guidance.
- Their access to clinicians, particularly key opinion leaders – potentially worldwide.

And they can help you to understand:

- Commercial value proposition.
- What existing products or procedures the technology would replace.
- Where they feel the real market opportunity lies for the technology.
- How the technology would fit with their current technology portfolio.
- How the technology impacts on their commercial competitiveness.
- The roadmap of major technical activities that would be required post-PoC project to bring the technology to market:
    - Regulatory compliance activities
    - Pre-clinical and clinical investigations
    - Manufacturing scale up activities including sterility assurance
    - Opportunities for further collaborative projects

The importance of commercial partners in funding proposals

The following Q&A looks at when commercial partners become important in a proposal.

Watch a video in which Ian Revie from Invibio Biomaterials Ltd explains how industry can support development of a new technology

Edward Draper of Richard Cornell Ltd explains how industry can support development of a new technology.

Watch a video in which Edward Draper from Richard Cornell Ltd explains how industry can support development of a new technology

Develop your business case

As you continue building your business case, think about the following areas:

- Is there a need for an external support for business engagement (consultancy work)? Who, and why are they the best fit? What questions will they address?
- What is the value of in-kind/match funding provided by project partners?
- Are there any conflicts of interest (financial or non-financial), whether real or perceived? What is your plan for how these will be managed?

It can be worthwhile to engage with industry-facing events with the KTN, NIHR Medtech and In vitro diagnostics Co-operatives (MICs): Medtech and In vitro diagnostics Co-operatives (MICs).

Further resources

UK Wide

UKRI have published a useful guide to engaging with business and industry: UKRI Stakeholder engagement guidance.

Medilink UK comprises five regional partners across England and Wales. Medilink UK is a national health technology business support network: Medilink.

NIHR work in partnership with medical device, digital technology and diagnostic companies (collectively known as MedTech) to help them successfully translate innovative ideas into the clinical setting. How NIHR supports industry.

UK government provides example non-disclosure agreements to help keep your technology or invention confidential when talking to others.

University of Leeds

A Non-Disclosure Agreement (NDA) or Confidential Disclosure Agreement (CDA) should be put in place prior to sharing any valuable or private information, knowledge or research results with a third party (for example, unpublished research data, details about new intellectual property, or non-public costs and prices). This will ensure that the other party keeps such information secret and will allow the parties to hold open discussions, without the fear of the disclosed information being misused or shared with anyone else by the other party. More about the University of Leeds' contracting process and the relevant template Non-Disclosure Agreements.

The Research and Innovation Development Managers (based in Research and Innovation Service) can identify potential commercial parties and support interaction, or can commission an external party to identify and introduce to you potential partners, supported by funding.

The NIHR MICs based in Leeds could help find and identify industry partners: Leeds In Vitro Diagnostics Co-operative, Surgical MedTech Co-operative.

Nexus is a vibrant community for innovators and entrepreneurs based at the University of Leeds.

10) Novelty and intellectual property

This chapter covers:

- The importance of Intellectual Property Rights
- What is intellectual property?
- What is a patent, prior art, freedom to operate, and IP landscaping
- A quick guide to preliminary freedom to operate analysis, prior art, novelty and IP landscaping
- What is your IP strategy?

- Protecting your idea and developing a business plan
- Protection with agreements and contracts
- Timescales for protection
- Steps to develop your business case
- Further resources

The importance of Intellectual Property Rights

Intellectual Property Rights (IPR) allow people to own their creativity and innovations in the same way that they can own physical property. IPR enables individuals and organisation to be rewarded for the time and investment in developing their technologies. Without IPR, such as patents, others would be able to copy and benefit from the research and development carried out by others and thus stifle innovation and technological progress.

Universities traditionally do not have the capabilities to commercialise and take a technology to the market, especially in the complex and highly regulated medical devices sector. Normally universities will progress technologies towards the setting up of a new commercial vehicle (a 'spin-out') or licence the technology to an existing company.

To enable this, you will need to protect the intellectual property (IP) or 'know-how' to exploit it.

It is critical to understand - and to protect - the novelty of your idea or technology in order to attract further investment and successfully commercialise a medical technology.

What is intellectual property?

The UK Government definition of intellectual property as something that you create using your mind – for example, a story, an invention, an artistic work or a symbol.

You own intellectual property if you:

- created it (and it meets the requirements for copyright, a patent or a design)
- bought intellectual property rights from the creator or a previous owner
- have a brand that could be a trademark, for example, a well-known product name.

Intellectual property can:

- have more than one owner
- belong to people or businesses
- be sold or transferred.

Intellectual property rights allow you to make money from the intellectual property you own.

IP Terminology

What is a patent?

The type of protection you can get depends on what you've created. A patent is the type of protection used for inventions and products. For further information on types of protection, please refer to the section below **'What is your IP strategy?'**

What is prior art?

Prior art is any evidence that your invention is already known.

Prior art does not need to exist physically or be commercially available. It is enough that someone, somewhere, sometime previously has described or shown or made something that contains a use of technology that is very similar to your invention.

See more on prior art from: European Patent Office.

What is freedom to operate?

Freedom to operate means the ability to commercialise a product or process without infringing another party's intellectual property rights - usually patents.

A preliminary freedom to operate analysis, prior art, novelty and IP landscaping report in the early stages of developing your innovation will be highly beneficial.

What is IP landscaping?

An intellectual property landscape is a systematic review of current patents in your technology's space – a map of everything competing and the relationships between them.

IP landscaping provides a thorough competitor analysis, and through this activity you may:

- Uncover unfulfilled opportunities
- Discover weaknesses of competitors
- Validate your technology's advantages.
- Reveal major players you are unable to challenge.

Preliminary freedom to operate analysis, prior art, novelty and IP landscaping for patentable technologies – quick guide

This quick guide:

- Offers an approach to check if your technology can be commercialised without infringing the Intellectual Property rights of others as early as possible.
- Provides an approach to check whether your technology is novel and can be protected. If in any doubt, seek professional advice from a patent attorney.

Identify any similar technologies you are aware of and research groups or companies working in similar areas. Start with a broad search using a search engine to find potential similar products, relevant articles and other competitors on the market.

If you have access to user-friendly software that searches patent databases, these can provide further insight and results can be grouped and filtered.

Use patent search tools, provided by national and regional patent offices, such as Espacenet from the European Patent Office and the United States Patent and Trademark Office, to access global dossiers of paperwork and better understand your freedom to operate.

Your findings may uncover competitors operating in your market - at this point you may need to adjust your development strategy, such as alter the geographical markets your technology might launch in, or the scope of the technology application.

Assess whether to pay a patent attorney to complete a professional freedom to operate search.

Prepare a report on the IP landscape. The report will influence the technology development, provide confidence in the technology opportunity, and highlight potential collaborators, licenses, and competitors that might try to stop the development of the technology.

Using patent search tools, prepare a list on intelligence you have uncovered. If you find a potential infringement, you are obliged to notify your patent attorney.

Further reading

For further information see: Preliminary freedom to operate analysis, prior art, novelty and IP landscaping for patentable technologies – quick guide.

What is your IP strategy?

Ensuring that you have a strategy to protect your idea is worth considering early on. In the UK, potential patent rights will be compromised by publication, public announcement, or non-confidential disclosure of the idea before filing a patent application. Publication is interpreted broadly, covering anything made publicly available orally; in writing; by use or demonstration; or any other way before protection is sought.

It might not be just patentable technology itself that is worth protecting - other types of IP build value as a package, for example design, data, and copyright. Sometimes non-patentable IP alone is sufficient to secure value. For example, you could:

- Register the name and logo as a trademark
- Protect a product's unique shape as a registered design
- Patent working parts
- Use copyright to protect drawings of the product.

Protecting your idea and developing a business plan

The following Translate MedTech film describes in further detail the different types of IP protection and the different IP strategy routes for academics.

Watch a video about protecting your idea and developing a business plan

Protection with agreements and contracts

Discussing your novel technology - confidential disclosure agreements

Discussing the technology with a potential collaborator is possible, but it must come alongside a clear statement that disclosure is on a privileged and confidential basis. It is recommended all parties sign a confidential disclosure of information agreement (CDA, also called confidentially agreement or non-disclosure agreement NDA) so that all partners can talk freely about the proposed ideas.
This type of agreement is usually short and straightforward and can be prepared with the support of your Research Support Service/Technology Transfer Office.

Working with external organisation and parties

If these discussions with potential collaborators develop further and you begin to work with any external parties, whether commercial, clinical or academic, then it is highly advisable for any work to be conducted under an agreement or contract of some sort. Your Research support service/TTO will be able to provide you with specific advice on the type of agreement. These agreements and contract will define IP ownership arising from the work, detail the work undertaken, milestones and deliverables, costs, payments and other formal and legal details to ensure the work runs smoothly.

Timescales for protection

For the types of protection you have to apply for (trademarks, registered designs and patents) you should allow time for their registration and processing.

From Gov.UK:

1 month

Registered designs – appearance of a product including, shape, packaging, patterns, colours, decoration.

4 months

Trade marks – Product names, logos, jingles.

5 years

Patents – Inventions and products, e.g. machines and machine parts, tools, medicines.

Develop your business case

As you continue building your business case, think about the following areas:

- What do you consider to be the closest relevant 'competitor' and why? Why is it similar and why is it different?
- Are there other academics/companies in the field of your idea? What do they do?
- Are there any important academic papers that could be considered prior art (note references)?
- Is your idea published or has it been submitted for publication? Are there plans in place to do this?
- Has your idea been disclosed to anyone external to the partner(s) leading/involved with the project?
- Are there any relevant patents in this area?
- Is your idea likely to produce new IP?
- Who will own the new IP and how it will be managed?
- Is there existing IP associated with the idea and what is the ownership of this?
- Do you need any contract or agreements in place to enable the development of your technology while protecting your IP position?

It can be a complicated matter deciding how best to protect IP rights. Registration processes, such as patenting are undertaken with the help and advice of a specialist, such as a patent attorney.

Further resources

UK Wide

Your Research Support Office/Technology Transfer Office can likely support prior art, novelty and IP landscaping for patentable technologies in-house. You should contact your Research support office/TTO before discussing your innovation concept or sharing information outside your organisation. They will be able to provide advice and guidance on contracts and agreements required to protect your intellectual property.

The US Patent Office has lots of good basic info about patents and the process to apply for a patent:

- Patent basics
- How to do a patents search Seven Step Strategy for conducting preliminary searches of U.S. patents and published applications
- US patent search resources.

UK Info

UK Intellectual Property Office

What is IP?

UK government provides example non-disclosure agreements to help keep your technology or invention confidential when talking to others.

Your Research Support Service/Technology Transfer Office should be able to support the early conversations around IP strategy.

UKRI EPSRC have a web-based guide to commercialising research, including intellectual property, patents, licensing, collaboration agreements and spin-out companies.

UKRI EPSRC have a web-based guide to protecting your intellectual property.

EU Info

European patent office

European patent search tools

Espacenet (search tool)

Classic Espacenet

We recommend to anyone planning to conduct patent searches to use the US and EU (Espacenet) search tool. Espacenet covers all European (including UK) patents and is more robust and comprehensive than the UK tool which is not comprehensive or easy to use.

University of Leeds

A Non-Disclosure Agreement (NDA) or Confidential Disclosure Agreement (CDA) should be put in place prior to sharing any valuable or private information, knowledge or research results with a third party (for example, unpublished research data, details about new

intellectual property, or non-public costs and prices). This will ensure that the other party keeps such information secret and will allow the parties to hold open discussions, without the fear of the disclosed information being misused or shared with anyone else by the other party. More about the University of Leeds' contracting process and the relevant template: Non-Disclosure Agreements.

The Innovation and Business Development team supports academics to engage in innovation activities, ranging from initial research translation projects through to larger-scale, multiple-partner collaborations. An impact officer from the team can carry out prior art searches to support early-stage research with potential for translation: Innovation and Business Development – Contacts.

The Commercialisation team works with several firms of patent agents and other external professionals.

If you need advice or assistance on IP that you think may have commercial applicability, contact the commercialisation team, find out more: Commercialising your research.

The University of Leeds Intellectual Property Rights (IPR) policy is a key document in the framework of policies on commercialisation activities. It sets out the University's policy regarding the ownership of IP, and the procedures in place for staff or students wishing to commercialise the results of research: What is IP?

11) Developing your technology: Proof of concept and prototyping

This chapter covers:

- Technical development and proof of concept stage
- Technical development and prototyping
- Proof of concept funding
- Activities that could be funded
- Steps to develop your business case
- Further resources

Technical development and proof of concept stage

A critical stage in the translation process for medtech innovation is the proof of concept stage. During the technical development process, the technology is developed and de-risked to produce a working prototype. This stage allows designs to be refined and iteratively tested if required. The leading functional prototype is then tested in clinically relevant, pre-clinical models. This proof of concept stage can involve in vitro testing, cadaver trials, and preclinical in vivo trials depending on the application and technology. Proof of concept studies investigate how the technology functions and further de-risks development towards clinical evaluation.

Technical development and prototyping

What is technical development?

This stage in the translation process often occurs alongside the development of the business case. In this phase initial technical concepts are developed, tested iterated and evaluated.

Simple bench testing is often utilised to rapidly narrow concepts. Proof of principle or feasibility is established and data is generated to enable the academic to apply for translational funding to take the technology to the next stage in development.

What about prototyping?

Prototyping allows for the rapid evaluation of different designs or concepts. Leading designs are then evaluated in more challenging tests or clinically relevant models, with the aim to narrow down quickly to reduce costs and timescales to enter into proof of concept studies.

The technical development of medical technologies is very dependent on the type of technology being developed. The development of a joint replacement is very different from a biological scaffold tissue replacement, which is unlike a digital or AI medical product.

What are the risks?

Each have their own risks and requirements that need to be addressed to ensure safe clinical use. The medical device classification (**see section 12 Regulatory considerations**) and risk profile of such products will drive the technical development and testing. However, common principles can be incorporated in the translation process:

- Understand the risks of your technology so that they can be evaluated, tested and mitigated during development
- Research on any standards (e.g. ISO 10993 for biological evaluation of medical devices), EU or US guidance documents, white papers and technical literature relevant to your technology.
- Learn from existing medical devices on the market or those in development.
- Engage with experts – this includes clinicians, industry, regulatory etc.

Develop a clear plan with timescales but be prepared to adjust and change the plan as you learn more.

Proof of concept

Proof of concept funding

Proof of concept funding enables clinicians and academic researchers, often with input from industry, to assess and demonstrate that their initial idea has both clinical application and economic potential.

Bridging the gap

Proof of concept projects aim to bridge the gap between fundamental research and commercialisation by moving projects on to higher technology readiness levels (TRLs), ensuring technologies are fit for purpose and ready for serious industrial investment.

What about grants?

Depending on the target device or technology, grants could be used to develop working prototypes, gather additional experimental data or carry out pre-clinical testing. Proof of concept grants are increasingly important for bringing technologies to a point where they

are market ready, able to generate commercial investment for product development or can attract other funding to move to clinical investigations.

Activities that could be funded

- Funding for academics and research institutions to undertake specific activities to accelerate the commercial opportunity.
- Support for legal and professional costs including commercial business plan development and assessment of market size and reach.
- Support for demonstration of 'proof of technical concept', preclinical safety and efficacy up to early clinical evaluation.
- Support for prototype development; early manufacturing, packaging and sterilisation development and other key aspects required as part of validating a commercial investment decision.
- Support to engage with additional commercial and investment partners that may have the capacity and potential to support taking the product to market.

Develop your business case

As you build your proof-of-concept phase and when you apply for POC funding, you will need to have considered your work plan and the work packages. For each work package include:

- Work package/activity title.
- Objective.
- Description of the work.
- Milestones.
- Deliverables.
- Timescales.

Further resources

UK-Wide

Proof of concept grants are available from a variety of funders including UKRI, charities and the NIHR Medtech and In vitro diagnostics Co-operatives (MICs), depending on the scope of the call and the technology being developed.

See more about translation and innovation funding in the **Funding for translational research and innovation** section, within **topic 15, Support from your Research Support Services.**

Proof of concept studies usually take 1-2 years and require around £100k of funding.

University of Leeds

A wide range of funding options are available to academics with an interest in innovation. These include translational funds to support academics to engage with external partners to explore the potential applications of their research.

The Innovation and Business Development team supports academics to engage in innovation and business activities, ranging from initial research translation projects through to larger-scale, multiple-partner collaborations.

Our team includes industry-facing Research and Innovation Development Managers and Innovation and Business Development Managers who work with academics at all career stages to raise awareness of available research, innovation, translational and business engagement funding and to maximise the opportunities for to progress innovation arising from their research.

Our Translational Research Portfolio team also provides dedicated, specialist support for the following impact accelerator and research translation schemes:

- Harmonised UKRI Impact Acceleration Accounts funded by BBSRC, EPSRC and MRC
- STFC Impact Acceleration Account (STFC IAA)
- Wellcome Trust Institutional Translational Partnership Award (iTPA).

More detail can be found on Research and Innovation service Innovation funding.

12) Regulatory considerations

This chapter covers:

- Adhering to the regulations
- Tips and pointers for researchers not familiar with the regulatory pathway
- What is a medical device? Regulatory definition
- How are medical devices regulated in the UK and the EU?
- Medical device product development lifecycle
- Key activities during early stage R&D
- Timescales
- Steps to develop your business case
- Technical work for regulatory submissions
- Packaging in medical device development
- Sterilisation development and validation
- Design control
- Manufacture and scale-up
- Steps to develop your business case
- Further resources

This chapter was developed in partnership with Medipex Healthcare Innovation Hub.

Adhering to the regulations

Medical technologies are tightly regulated in the UK and European Union. Before medical technologies can be placed on the market, manufacturers must comply with applicable legislation and have the device CE/ UKCA marked.

Adhering to regulation can be arduous and resource intensive, it usually requires specialist support to navigate this infamously complex pathway where mistakes are easy to make and costly to correct.

Academics developing new technologies must have a basic understanding of the legislation, an awareness of the technology's classification and what evidence and records should be kept during the technology's development. An early awareness can minimise the risk of timeline delays, duplication of work and avoidable costs, and may have implications on what materials you choose and what data you generate.

Tips and pointers for researchers not familiar with the regulatory pathway

The following Grow MedTech video of Michael Kipping from Innovate UK advises researchers on how much knowledge on regulation they might need to successfully develop a medical technology.

Watch video

Watch a video on tips for researchers not familiar with the regulatory pathway

Video transcript

Josephine Dixon-Hardy: Moving on I wanted to pick up on Michael's comment in his introduction, about regulatory and understanding the regulatory pathway. Now I think this is notoriously challenging, particularly at a time like this, with Brexit and the revision of regulatory guidelines. I wondered if you could give some advice to researchers on how to get to grips with this. If it's something they are not familiar with at this stage of their research. If you could give some tips and pointers.

Michael Kipping: We've talked about quite a breadth of areas and elements and tips to think about, but kind of early in the translation of space, early in the development of your product I would actually expect you to have a have a really strong view on the market opportunity. By the time you actually get to market in 2-3-4 years' time, whatever it is, you know the market will have changed, and your understanding of it will have changed as well. We would still expect you to have an understanding.

The same is true of regulation as well. I wouldn't expect you to have a detailed and regulatory plan at feasibility, but what I would expect you to do is to have an understanding that your product is an IVD, or it's a medical device, and knowledge that you would need a notified body down the line. You don't need to have a notified body, you just need to have an understanding of where your product sits, and what regulatory pathway broadly looks like at a high-level view. Obviously, the closer it gets to market the higher my expectations of you would be. If you came to us for late stage funding and you wanted to do a clinical evaluation, then I would expect you to have a really detailed plan. I'd expect you to have a notified body. I'd expect you to have an understanding when I say what 13485 was and have appropriate risk management measures. All that sort of stuff. I wouldn't expect you to have all that at feasibility! Sort of an incremental thing.

I put a link in the chat to talks with Global Guidance which is again, free, and it can you know it it'll give you a sense of what your product is. I think once you've done that feasibility, and

you've got a good sense that there is a clinical need and there is a potential market for it then I would suggest that you get some advice if you were to go for further funding if you were to go for sort of seed funding or angel or something like that. Spending a few thousand pounds with a regulatory consultant that can then help you develop a granular plan for your product that outlines you know the claims you want to make because, I'll use my glasses for this – it is the only trick I've got so bear with me. So with these glasses, if I say the glasses are here to protect my eyes from flying shards they're PPE, if I say they're really glasses then there are consumer product. If I say they have a prescription of 1.5 then there are medical device, only class one but still a medical device, so the same thing can follow different regulatory pathways depending on the claims you make. Working with a consultant to clarify those claims and then understand the evidence requirements that you need to address to put together your technical file to give to a notified body is well worth the money, because you got clear view on what you need the money for, you know those evidence requires he need the money for.

At first just get a high-level understanding of what it is you're developing, and then once you've got a you know a strong field that you've got you know the ideas got legs then spending a little bit of money with a consultant I would strongly suggest. To do that you can go to you know the likes Medilink and Patrick, there's also an organisation that I'm part of called TOPRA the Organisation for Professionals in Regulatory Affairs and they might be able to help you as well.

Lindsay Georgopoulos: Just building on that, this is aimed at the technology transfer professionals on the call here, the University of Sheffield, I don't know if you're aware, have recruited a regulatory expert in residence. It is a post, one day a week and it's to support all of their researchers who are developing medical technologies to give them that kind of introductory information on regulatory affairs. It's actually one of my colleagues, Claire Lankester, that's filling that role for the University of Sheffield for the next 12 months, so that's something that they're trying and it might just be worth something that other universities could consider, because for relatively low cost you've got somebody who can work across all the projects and at various different stages and give them the right kind of information to put into those funding proposals in particular but also to sort of upskill the academic researchers and kind of you know, enable them to share that knowledge with other people that they're working with.

Josephine Dixon-Hardy: A real sign of good practice that should maybe be shared across the HEI community I think there, thank you that's really helpful to know, we'll have a look at what's going on with Sheffield there as well.

What is a medical device? Regulatory definition

You need to decide if your product is a classed as a medical device before you begin thinking about compliance with the regulations.

According to the Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002), a medical device is described as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any

accessories, including the software intended by its manufacturer to be used specifically for diagnosis or therapeutic purposes or both and necessary for its proper application, which is intended by the manufacturer to be used for human beings for the purpose of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- Investigation, replacement or modification of the anatomy or of a physiological process, or
- Control of conception.

A medical device does not achieve its main intended action by pharmacological, immunological or metabolic means although it can be assisted by these.

A medical device includes devices intended to administer a medicinal product or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device.

How are medical devices regulated in the UK and the EU?

In vitro diagnostic (IVD) devices are usually a:

- Reagent
- Reagent product
- Calibrator
- Control material, kit, instrument, or apparatus.

Equipment or system intended for use in vitro to examine specimens including blood and tissue donations from the human body.

Further reading

Further high-level information on medical device regulations can be found on GOV.UK: Medical devices: how to comply with the legal requirements in Great Britain.

Guidance on what a software application medical device is and how to comply with the legal requirements: Medical devices: software applications (apps).

What is a medical device?

The following Translate MedTech video describes the definition of a medical device, and what sets them apart from more general consumer products or drugs.

Watch a video about what is a medical device

How are medical devices regulated in the UK and the EU?

Regulations vary in different territories. As a UK-based academic, it is sensible to have an understanding of the requirements in the UK and the EU.

In the following film, Clare Lankester from Medipex Ltd explains why regulatory processes were significantly upgraded in the EU in 2017, what the objectives of the regulations are and who the key players are in the process. How Brexit affects the regulation in the UK is also outlined.

Watch a video about how medical devices are regulated in the UK and the EU?

Medical device product development lifecycle

The Medical Devices Regulation (MDR) takes a whole lifecycle approach to regulation to ensure the manufacturer can demonstrate that they have control over every aspect of the product they are selling, particularly those that impact patient safety.
Every stage from initial design through to testing, manufacture and monitoring of devices sold into the market has its own requirements. The stages are:

1) Concept
2) Planning
3) Design
4) Validation
5) Launch
6) Post market

Key regulatory activities during research translation

To maximise the likelihood of future regulatory success, we recommend a number of key activities academics can complete. These activities could be included in grant applications to show the funders that the project team have a good understanding of the field.

Key activities during early stage R&D

In the following film, Clare Lankester from Medipex Ltd explains some of the key activities academics can complete:

Watch a video on key activities during early stage R&D

Timescales

The typical approval time for medical device CE marking depends on the device classification and the quality and completeness of the technical documentation and clinical data submitted.

The following information, taken from An Innovator's Guide to the NHS gives a guide:

- Class I (non-sterile, non-measuring) - 1 month
- Class I (sterile or measuring – 3 to 5 months
- Class IIa - 1 to 3 months
- Class IIb - 2 to 6 months
- Class III - 6 to 9 months

Develop your business case

As you continue building on your business case, and navigate the world of medical regulation, think about the following:

- Using the RegMetrics tool, what classification is your technology?
- What records will you keep as evidence for later?
- Is there a need for an external opinion (consultancy work)? Who, and why are they the best fit? What questions will they address?

Technical work for regulatory submissions

Formal risk analysis, technical documentation, design control, packaging validation and ISO accredited testing are all part of the regulatory stage and can be preparations required for clinical investigations and then market approval. Traditionally academics have not focussed on these stages in medtech development, often aiming that the technology would be licenced or spun out before these stages are required. However, in recent years there is evidence to indicate technologies require further de-risking before licence or spin out. This is in part due to the increased requirement for clinical evidence in the MDR and industry being more risk averse and invest in technologies at a later stage, thus driving academic development into clinical investigation stages and the required regulatory work.

For efficient translation and to minimise development timescales and costs it is advisable to begin to consider these processes as early as practicable. This will reduce the need to repeat studies at a later date.

Packaging in medical device development

Development and validation

Development and validation of the packaging for your medical device is an integral part of the development process and normally needs to be finalised and fully defined before entering into the clinical investigation stage.

It is useful to consider packaging requirements early in the process and incorporate packaging in the preclinical testing plan. For many medical devices, packaging is crucial for maintaining product sterility during transport and storage, and consideration on the products form, size and protection requirements should be taken into account, along with whether aseptic delivery is required and thus double packaging to enable the sterile device to be delivered to the sterile operating field.

Terminal sterilisation method

The method of terminal sterilisation (see the Sterilisation development and validation section below), such as gamma irradiation, ethylene oxide or autoclaving, is also important and will influence packaging materials

Packaging validation will require planned testing for shelf-life and aging studies. Seal strength and sterile barrier integrity will have to be tested. It is often advisable to contract

these tests to specialist-accredited laboratories that can carry out these tests to the appropriate ISO and ASTM standards and facilitate regulatory approval.

Guidance

Guidance documents such as ISO 11607 provide a list of methods that should be followed. Examples of such tests include dye penetration testing (ASTM F1929, ASTMF3039); Peel testing/seal strength (ASTM F88 / F88M, EN 868-5 Annex D) and Burst testing (ASTM F1140/F1140M, ASTM F2054/F2054M).

Costs and timescales

It is advisable to factor these costs and timescales into the development of your medical device as shelf life studies for packaging and the product itself may have to be carried out in real-time, depending on the requirements of the product.

Sterilisation development and validation

The purpose of sterilisation

It is advisable to understand early in the development process if your medical device will need to be provided sterile to the user and which method of sterilisation is most suited to your product.

The purpose of sterilisation is to ensure any microbiological contamination is inactivated and unable to cause harm to the user or recipient. However, production of a clean and sterile product is not only dependant on the final step in the manufacturing process – clean manufacturing processes and reducing bioburden and contamination during the manufacturing process is also critical to ensuring a safe and sterile product.

Choosing terminal sterilisation

The choice of terminal sterilisation method is often influenced by multiple factors, such as the compatibility of the medical device to the sterilisation method. The design, materials and size of the device and how these factors interact with sterilisation processes needs to be considered. Common methods of sterilisation are gamma irradiation, ethylene oxide gas, and high-pressure steam autoclaving. Choice of serialisation method is also influenced by manufacturing factors such a physical size, batch size and cost.

The sterilisation process

As with packaging, sterilisation processes must be fully controlled and validated. There are ISO standards and guidelines covering sterilisation (see link for the BSI white paper on Sterilisation – Regulatory requirements and supporting standards). Manufacturers and developers of sterile medical devices must be able to demonstrate microbiological safety. This will be required prior to first in human trials. Developers will have to control and measure bioburden and microbiological load, demonstrate a validated sterilisation process and ensure sterility of the product after manufacture and during its shelf life.

Engaging early

The main advice to translational academics wishing to take their developments into clinical investigation and commercialisation would be to engage early with experienced consultants or organisations that will be able to advise you on sterilisation processes, validation and the

guidance and standards required.

Design control

What is design control?

Design control is a US regulatory defined process, but it is also relevant to UK and EU processes. It is the process by which a developer/manufacturer documents and describes the process by which the medical device is being developed to demonstrate that all stages are managed to ensure that the device being developed is effective and safe for use. All but the simplest and lowest risk medical devices require design control. All class II and III medical devices need to be developed under design control. Design control can often scare away academics thinking about translating and commercialising their technologies. However, in its simplest form, design control can be considered as documenting the steps and decisions being made in the development of the device.

Understanding design control

Having an understanding of design control can be useful when working with industrial partners or trying to licence technologies to industry. Having robust documentation can make the difference in that licensing going ahead or stalling due to new risks or challenges that have not been addressed arising during the due diligence process.

Design control is often visualised as the waterfall diagram that shows the main stages in design review are:

User needs – The team should define the needs of the intended users and describe how the proposed device will meet those needs, including its intended use and indications. This stage can include patients and clinical feedback, questionnaires and focus groups etc.

Design inputs – The development team will describe the specification of the proposed medical device. These take into account the user needs.

Design and development plan – The team will develop a plan that describes the design and development activities. This will include roles and responsibilities and describe the process by which the stages and documents are managed and controlled, e.g creation, reviewing, updating and approval of protocols and reports.

Design outputs – this documents the technical work carried out by the development team and describes the design(s) developed, materials or components used and includes the technical information that is required to build the medical device, such as drawings and designs.

Design History File (AKA Technical File) - All documentation about design control should be compiled into a master file which is labelled the DHF.

Design review – this is the process by which designs are approved, often in medical device industry these may be called stage gates and include formal sign-off to enable progression to the next stage and release of funding required. These review points ensure that the development is on track.

Design verification – During this step the development team will test the medical device to ensure it functions as expected. This verified that the design outputs meet the design inputs ("did we design the device right?")

Design transfer – this stage transfers the development of the device to manufacturing so that the device is in production. This is when the design is frozen ready for manufacturing.

Design validation - Design validation ensures that the devices conform to defined user needs and intended uses ("did we design the right device?"). This stage can include user testing and/or pilot clinical investigations.

Manufacture and scale-up

Where would this happen?

Manufacture and scale up would generally happen in the company setting, but they can be important considerations earlier in the translation process to provide confidence for investors. Plus, the academic team may well be involved in the process as technical experts.

How will technology be manufactured?

Even at an early stage, academics should think about how their technology will be manufactured in the numbers required to be able to meet the markets needs and projected sales forecasts, as described in the business plan.

Understanding costs

Cost of manufacturing and goods need to be understood to ensure that the marketed products are cost effective and within health providers budgets. This is where understanding your competitors and existing products on the market is useful. Examining the cost of existing products, their clinical performance, pros and cons against your new technology, the potential cost and the clinical outcome benefit is useful.

The process

All these factors will inform the development team of the 'window of opportunity' for the product, in terms of the sweet spot where the cost/price and performance benefits are favourable compared to the competition. Design for manufacturing is a process by which products are developed from the initial design concepts for ease of manufacturing in order to develop a better product at a lower cost.

Develop your business case

As you continue building on your business case, think about the following:

- Have you considered the regulatory classification of your device?
- Is it a medical device or an in vitro diagnostic medical device?
- Does your product need to be sterile? How will it be sterilised and is your product compatible with the method?

- How will your product be packaged? Does your product need to be protected during transport? If your product is delivered into the sterile operating field during surgery, does it need to be double packaged?
- How will your product be stored? Does it have to be stored and transported under any special conditions, e.g. cold?
- What is the shelf life of your product and have you validated this in stability and shelf-life studies?
- How will your product be manufactured? Have you considered manufacturing costs? Who will manufacture it?

Further resources

External support will probably be necessary later on in the project, as part of a proof-of-concept study, but it is sensible to have an understanding of regulatory pathways in the early stages.

Regmetrics is digital tool to make it quicker and easier to understand how medical device regulations apply to your product in order to obtain a CE mark certificate.

Further high-level information on medical device regulations can be found on GOV.UK: Medical devices: how to comply with the legal requirements in Great Britain.

Guidance on what a software application medical device is and how to comply with the legal requirements

The BSI have produced an excellent white paper, which covers medical device sterilisation and the regulatory requirements, and supporting standards: Sterilization – Regulatory requirements and supporting standards.

13) Pre-clinical and clinical (in-human) investigations

This chapter covers:

- Clinical investigations and the role they play
- Preclinical investigations
- Clinical investigations
- Regulation of clinical investigations
- Steps to develop your business case
- Further resources

Clinical investigations and the role they play

Preclinical investigations and clinical investigations play an increasingly important role in the commercialisation of a medical technology. These studies are ultimately designed to gather data to meet regulatory approval requirements. Valid and credible clinical research will also provide invaluable help in the design of new technologies to improve health and patient care.

During the preclinical testing phase, the technology prototype will go through a cycle of

preclinical testing and redesigning until the technology is safe to be tested in humans. Preclinical studies may be required to test the device in animals to collect data and demonstrate its safety and sometimes efficacy.

Preclinical investigations

Preclinical investigations can involve:

- Bench testing - for the safety and performance of the device. These tests will contain the majority of design verification and validation testing.
- Technical testing - performed to test materials and electronic elements for accuracy and reliability.
- Animal testing - animal testing in medical research has been reduced in recent years both for ethical and cost reasons. However, commonly medical innovation will still involve some animal testing to de-risk and ensure patient safety when developing diverse and innovative technologies. Steps should always be taken to minimise the use of animals in medical research. Ethics applications require that the principles of 3Rs (Replacement, Reduction and Refinement) are incorporated into studies. With the advent of AI and computer simulation there is also a growing interest in in-silico simulations or trials, which should also be considered as part of the 3Rs and cost-effective medical technology development. New standards, such as ASME V V 40 provide guidance on assessing the credibility of computational models for these purposes.

Clinical investigations

If the preclinical trials are successful, you may need to carry out a clinical investigation. Clinical investigation involves testing the new product in human volunteers for safety and efficacy. They are often first-in-human trials for novel devices and treatments so need to be carefully controlled for risk to the participants. The EU MDR puts a higher requirement for clinical evidence and as such, there is an increased requirement for clinical investigations.

Medical device clinical investigations fall into three categories:

- Pilot studies - these are performed when additional information is needed on a product before a larger-scale clinical study is started. Pilot studies are usually single-centre trials using a limited number of subjects. They are often primarily focused on demonstration safety rather than efficacy.
- Pivotal trials of safety and effectiveness - for safety and effectiveness there are larger, controlled studies designed usually as hypothesis-testing studies to support the submission of a conformity assessment for CE mark registration.
- Post marketing studies - these can vary in size and design, depending on the research purpose. Aims of post-market research include comparative effectiveness claims, gathering information on a specific safety or performance issue, or failure analysis investigations.

Regulation of clinical investigations

Medicine and Health Regulatory Agency (MHRA) notification

Clinical investigations required as part of medical device development must be notified to the MHRA before the investigation is initiated. This is a formal process by which the MHRA will review documentation supplied by the developer to ensure trial participant safety. You must inform the MHRA if you are planning to do this at least 60 days before starting your investigation.

Primary function of the MHRA

The primary function of the MHRA is to make sure that all risks other than those being directly tested in the investigation have been addressed. This includes aspects such as manufacturing, packaging, sterilisation, shelf life and suppliers. This is a risk-based process, with the manufacturer being required to show that in all stages risk has been reduced to a level that is low as possible and all stages in the products lifecycle are fully controlled.

MHRA notification for clinical trial requires considerable work and documentation to be submitted for review.

Technical documentation

Technical documents will be required to show that all risks, expect those being tested in the investigation have been adequately controlled. Documentation on risk management, product design control, manufacture, packaging and safety testing will be required. This includes formal risk analysis, technical documentation, packaging validation, sterility testing and validation and material and biocompatibility testing completed.

Test articles for clinical investigation should be produced and packaged as the final commercial device with all risks, other than the risks being tested in the clinical investigation, fully controlled and mitigated.

Human Research Authority (HRA) and Research Ethics Approval

The HRA is an organisation with the core purpose to protect and promote the interests of patients and the public in health and social care research in England. Its role is to:

- make sure that research is ethically reviewed and approved
- promote transparency in research
- oversee a range of committees and services
- coordinate and standardise research regulatory practice and
- provide independent recommendations on the processing of identifiable patient information where it is not always practical to obtain consent, for research and non-research projects.

HRA approval is also required for clinical research and investigations and incorporates ethical review processes. The HRA brings together the HRA's assessment of governance and legal compliance with the independent ethical opinion by a Research Ethics Committee

(REC). HRA Approval is for all project based research involving the NHS and Health and Social Care (HSC) that is being led from England.

Clinical trials documentation

Development of clinical trials documentation and ethics application through the HRA online system IRAS (Integrated Research Application System) will also be required prior to approval and commencement of the clinical trial. Working with clinicians/clinical teams experienced in planning and conducting clinical investigations is critical to ensure smooth and efficient commencement of clinical studies. Working with a clinical trials research unit would also be advised.

Develop your business case

As you continue building on your business case, think about the following:

- Is there a need for support from a Contract Research Organisation (CRO)? Who, and why are they the best fit? What questions will they address?
- Think about how you will take your technology to commercial realisation, including the phases we have covered so far. You may want to consider: regulatory compliance activities, pre-clinical and clinical investigations, manufacturing scale up activities including sterility assurance

Further resources

How clinical research in the UK is organised from the NIHR covers key organisations involved in clinical research in the UK including administration, organisation, funding, regulation, local support services:

Notify the MHRA about a clinical investigation for a medical device is described on the MHRA pages of the gov.uk website. It is advised to work with a regulatory consultant:

NAMSA is a medical research organization specialising in the support of medical device development for medtech, diagnostic and regenerative medicine companies. They are among the world leaders in clinical research efforts.

National Centre for Replacement, Refinement and Reduction of Animals in Research are UK-based scientific organisation dedicated to helping the research community worldwide to identify, develop and use 3Rs technologies and approaches.

The Institute of Medical and Biological Engineering (iMBE) develops preclinical testing methods for musculoskeletal and cardiovascular interventions, which have gone on to become international standards adopted across the sector. The IMBE houses the world's largest academic facility for the experimental simulation of artificial joint replacements, and has expertise in both in vitro and computational modelling of tissues, devices and interventions.

InSilicoUK is an open network representing all the stakeholders in the field of In-Silico Clinical Trials, including academics, industry, government, regulators, standards developing organisations, facilitated by Innovate UK KTN, and already has over 650 members. Membership is free and open to everyone. It is led by University of Leeds' Professor Alejandro Frangi, Diamond Jubilee Chair in Computational Medicine.

A framework for establishing the credibility of computational models for medical device applications is provided by ASTM V V 40, 2018 – Assessing credibility of computational modelling. The HRA provides excellent guidance and advice on its website:

- About the HRA
- What approvals do you need
- Research Ethics Committee review.

The Integrated Research Application System(IRAS) is a single system for applying for the permissions and approvals for health and social care/community care research in the UK.

14) Working with patients and the public

This chapter covers:

- Patient and public needs
- Public and patient involvement versus engagement
- Finding relevant patient groups
- What makes a good funding proposal in the eyes of a patient reviewer?
- A patient representative's advice to research groups struggling to find a relevant patient involvement group
- Steps to develop your business case
- Further resources

Ensure you have prepared a confidential disclosure agreement before talking about your technology, or that you have adequately protected your IP.

Patient and public needs

Patients bring new insights to the table; they help ensure that what you create is relevant and practical. By keeping patient needs at the forefront of your mind as you work on your technology, you can ensure that research and development is focused where it is needed,

and the work progresses on the right path. Engaging and involving patients at an early stage can bring benefits later on, for example by improving recruitment to clinical evaluations or creating patient champions to support routes to adoption.

Medical technologies aim to tackle real-life problems – and will only be successful in the market if they do so. We can only understand what those problems are by involving the stakeholders who are impacted by them. Patients and those with long-term conditions are rarely the only stakeholders of a new technology. But even medtech innovations that will only be used by clinicians – that patients will never see – still need to be designed to ensure patients benefit, and so they should have a role in their development.

Public and patient involvement versus engagement

Many funders believe Public and Patient Involvement (PPI) is too often focused only on engagement – bringing users in at the end of the process. They want to see users involved from the outset and expect this to form part of all the projects funded.
Meaningful engagement or involvement of patients and public could include activities such as:

- Identifying and prioritising the research question.
- Helping design study protocols and patient information.
- Inputting into the application and/or ethics approval.
- Helping carry out elements of the study, rather than simply participating as a subject.
- Evaluating the research findings.
- Dissemination and implementation of outputs and outcomes.

Finding relevant patient groups

It can be difficult to know how and when you can involve people in your research.

Make sure your involvement of lay people starts as early as possible when planning your idea.

Think about different avenues you can use to approach public and patients to engage, such as clinics, Research Design Service, your own network, your university public engagement and user involvement teams, support groups, forums etc.

A proof of market type award may be beneficial using a partner organisation or charity to run workshops on patient needs Proof of market studies usually take 1-6 months and require around £5-10k of funding.

What makes a good funding proposal in the eyes of a patient reviewer?

The following film looks at what makes a good funding proposal in the eyes of a lay audience or public/patient reviewer.

Watch video

Watch a video on what makes a good funding proposal in the eyes of a patient reviewer

Transcript

Josephine Dixon-Hardy: I'm going to ask Sue to talk further about the elements you're involved with. Sue, in terms of the patient and public involvement, what makes a good funding proposal in that sense?

Sue Watson: Yes. For me, it's the PPI section: in very plain English, no jargon or as very little as possible, and it's also very important to have meaningful PPI rather than tokenistic. So that means that you have to look at the funding for any PPI that you need throughout the course of the funding project and get PPI in as soon as possible. There are loads of resources you can go to: NHIR everybody knows about, I'm sure, which is an excellent source of help and lots and lots of PPI groups around the country would be able to help.

And it's worth noting that, you know, these are impartial people, PPI members, they're not there to criticise out of any malice, but they are there to make your funding bid more successful, and it's just worth noting that, sort of, to get in as soon as you can with them and they'll be a tremendous help to you.

Josephine Dixon-Hardy: I mean, can I just pick up, Sue, that one of the earlier points was made around communication? Because I think the lay summary is often a very important part of a proposal. If you have a patient involvement group reviewing it, they may well not have specialist technical expertise in the area. Some of them may, but not all of them will. So, have you any thoughts on providing the lay summary?

Sue Watson: It's really just, I think, thinking about your target PPI members that are going to be reading it. It needs to be without too much technical knowledge or information, if you can make it so. I mean, obviously, you're going to have to have some medical information, I'm sure. But it's really just looking at it and thinking, would my seven-year-old, be able to understand that? and if not, then you've probably got too much jargon in it. So, it's really plain English, no acronyms, and you're well on your way there.

Josephine Dixon-Hardy: That's really helpful as a really helpful way of expressing it, Sue, to say, imagine a child reading it and that's probably a very good baseline. I think we sometimes forget because we're immersed in high tech language all the time, it's sometimes easy to forget that not everyone will follow it. Thank you. Danielle, is there anything you'd like to elaborate on or bring in addition to what's been said?

Danielle Miles: Yeah, I 100 per cent agree what everyone's already said. And I think a lot of the points that were made were things I would have liked to have made as well.

But I think one of the things I'd like to say is that when you're applying for innovation and translation funding you need to be aware, particularly if you're from an academic setting, that those proposals are different to research proposals. You should be thinking about them as a way of starting to develop your business case, starting to think about how the funding proposal itself becomes a bit of an asset to you. And that's part of the project itself, how you articulate the things that have already been commented on: your need, your solution, your market opportunity, your competitors.

So actually, putting the time and effort into these funding proposals, it shouldn't just be about getting the money. It's also about building that evidence case and thinking about how you communicate that information.

One thing I've got a bit of experience over the last couple of years, I mean, I'm not sure I want to tell people how to suck eggs here. But one of the things I've been pleasantly surprised by is a lot of the funders are now putting out some really good guidance. And Innovate UK always have extensive guidance around their calls, frequently asked questions, tips, and advice on how to answer it. And it still surprises me how many people haven't read those before they start drafting their first application. And actually, then what happens is that people aren't answering the exam questions. So actually really sort of taking the time to read through the guidance, read through the extra information, read through the frequently asked questions, can be really useful and help you think about how you communicate your idea, how you answer the questions that are being asked in the in the funding proposal. And I think importantly, that then goes on sort of thinking about the difference between research proposals and innovation proposals. As we've already said, it's really about the solution and the need.

So one of my bugbears is actually, and Sue sort of touched upon this with the jargon and some of the others have as well, that you really need to think carefully about the scientific and technical information that you put in there. And is it appropriate? Think about who the reviewers are. They're not probably going to be your peers in your academic setting. They're going to be innovation and commercialisation professionals, potentially other companies. Some of them might have specialist knowledge in your particular technology, but they weren't in the same way that your academic review panels will do. So, I think making sure that you sort of put information in that's relevant, how you answer the questions rather than just putting data in there or graphs or technical jargon for the sake of it is really important. So, sort of thinking about the specific proposal and the questions you're asking. Then just finish off and build upon this is as well as thinking about the questions that are being asked in the proposal.

One of the things I always try and get my team to do up front is actually not think about the proposal itself, think about the project, take a step back. What are you trying to address? What questions need answering? What are your current biggest technical risks? Why do you need to do this bit of this project and get this money in the first place? Then while you're doing that as well, not only thinking about what you need to immediately address, but what will you still need to address at the end of this project? Because that starts how you formulate your next steps, follow-on plan, and makes it sound more realistic rather than kind of tokenistic, because actually you can really be honest in your appraisal of where you're at, what you're going to do in this bit of project and what you're going to do next, and I think that's really important. You know, no grant funding is going to get you from idea to the market, realistically, especially not in the medical technology space so knowing where you're at, what you're going to do in the project and what you're doing next is really important.

Josephine Dixon-Hardy: And I think that's a really important point there actually, Danielle, because this is actually about reality and reviewers knowing that you recognise what the key questions and challenges are and you thought about how you're going to navigate them. So, it's really important, I think. Thank you for that.

A patient representative's advice to research groups struggling to find a relevant patient involvement group

The following Q&A with a public and patient representative gives advice to research groups struggling to find a relevant patient involvement group.

Watch video

Watch a video on a patient representative's advice to research groups struggling to find a relevant patient involvement group

Transcript

Josephine Dixon-Hardy: There was a question coming through the chat, which I think I'll direct to Sue in the first instance, which says we've struggled tremendously to find any PPI group active or meaningful to our technology, even via our clinical collaborators, what would be your advice?

So, someone here's looking to find a relevant patient involvement group for what they're trying to develop? I think Danielle might have some insight into the actual technology here as well. So maybe Danielle, do you want to say a little bit about the angle of this to help Sue to think about it?

Danielle Miles: Maybe actually, Sue, if you don't mind if I if I start this and then maybe you can come in with how you can make it meaningful but I think one way that we've seen was already mentioned. They've sort of tried to go about it through their clinical collaborators which is one route but not having much success as of yet, another way that we've had quite a bit of success through numerous projects on our programme is actually looking at medical research charities so there's the Association of Medical Research Charities, they've got a website, they've got all of their members listed on there. Quite often the research charities will have PPI groups associated with them or be able to connect you into that. That's one route.

There are more generic patient and public involvement groups at pretty much all hospitals, and some GP surgeries will as well, and sometimes you can connect with and also sort of local and national ones as well sort of more broader, so I think it depends on the kind of questions you're asking and how you wanting to get people involved. I think, just keeping the highlight here on me a little bit, but I think you need to think about what you're trying to do with them and what and what you need to help with and actually going back to what makes a good funding proposal. I'm a really big advocate of getting patients involved at the kind of draft development stage. They can really help you with your lay summaries, with are you articulating all the points and then they can become champions and advocates for your

project as you as you move forward. Sue, I don't know if you've got any other thoughts about how people can engage with patients in a meaningful way or get access to patients?

Sue Watson: I think you've answered most of it, Danielle. Charities is a good place as well to go to for any relevant medical need and things like that. Because I don't understand too much about the fungal infection, but whether or not dermatology would be involved in that. Dermatology at Chapel Allerton has a great group which may be an avenue to go down or it might be worth just contacting some of the PPI groups and they may have contacts at other places, and not necessarily just look at your own area but especially now we have zoom you can look through other areas as well and other hospitals to see if they have any PPI groups so it's casting the net as wide as possible. I know that we get at the BRC in Leeds requests that don't come under the musculoskeletal and we're sometimes able to push them across to other relevant PPI groups. So even if it's not a relevant one you may want to just try a PPI group that you know is successful – and I'll plug ours because it's very good – and they may be able to pass you on to someone who is more relevant to you.

Josephine Dixon-Hardy: That's really helpful. I hope that helps Yoselin, and if not do get back in touch with us and we'll see if we can help some more.

Develop your business case

As you continue building on your business case think about the following:

- How have you involved patients in developing this idea so far?
- What do you want from the people involved and how will it influence your research?
- How many people would you like to be involved?
- How will you find people to be involved?
- How will patients be involved in steering and implementing the project in the future of its development?
- If you're using a broad organisational PPI infrastructure, how is that infrastructure being engaged or accessed?

Further resources

UK-Wide

UKRI have published a useful guide to engaging patients and the public: UKRI Stakeholder engagement guidance.

The NIHR have developed guidance is for researchers new to public involvement in research and just starting to consider how best to involve members of the public in their work: Briefing notes for researchers - public involvement in NHS, health and social care research.

A useful collection of resources on patient and public engagement are available on the NIHR website: PPI (Patient and Public Involvement) resources for applicants to NIHR research programmes

NIHR Research Design Service Yorkshire and Humber can offer advice and support you to plan public involvement in your research and they also offer funding too, like the Universities Research development fund.

Versus Arthritis have some excellent involvement resources for researchers: Involvement resources for researchers.

Alongside researchers and people with arthritis, Versus Arthritis have co-developed Involving people with arthritis: A researchers' guide which aims to support researchers to integrate PPI into their work so that it enhances their research.

Involve are the UK's public participation charity, on a mission to put people at the heart of decision-making.

The Association of Medical Research Charities (AMRC) is committed to embedding public involvement in health and care research and provides more information and guidance on patient and public involvement.

University of Leeds

Leeds BRC has extensive expertise in PPI activities: Patients, public and carers - How to get involved.

Leeds Teaching Hospitals Trust have a Patient, Carer & Public Involvement (PCPI) Team that work in collaboration with staff, patients and the public to develop and shape services, improving care by using patient feedback: LTHT Patient, carer & public involvement.

The Engaged Research Microsoft Team is a place to bring together everyone who is involved in or interested in engagement with research: Public Engagement - People development.

The Research Development Fund invites staff to apply for up to £600 to fund the involvement of members of the public (e.g. public, patients, carers, service users and other stakeholders) in shaping or developing research ideas, i.e. at the research development stage prior to submitting a research proposal: Funding for public engagement.

15) Support from your Research Support Services or Technology Transfer Offices

This chapter covers:

- What are Research Support Offices?
- What are Research and Innovation Support Services?
- Opening a conversation with your RSO or RISS
- Funding for translational research and innovation
- What makes a great innovation funding proposal?
- Steps to develop your business case
- Further resources

What are Research Support Offices?

Research Support Office is a generic and widely used term. The terminology and naming used within specific organisations may differ.

Their remit is usually to implement strategies and policies to increase a university's research funding income and to respond to the changing research landscape and requirements of funders. Their support may also extend to managing awards and monitoring outputs, outcomes, and impact.

Most research support offices will be able to offer support in sourcing and applying for funding for research translation, developing confidentiality agreements, material transfer agreements and collaboration agreements.

What are Research and Innovation Support Services?

Research and Innovation Support Services (also known as Technology Transfer Office/TTO) is a generic and widely used term. The terminology and naming used within specific organisations may differ.

A note compiled by some of the UK's leading university technology transfer professionals outlined the remit of the RISS/TTO as follows. You can see more here [UK University Technology Transfer: behind the headlines.]

What is a Research and Innovation Support Service (RISS)?

The RISS is the part of a university that is responsible for protecting and commercialising intellectual property developed at the University for social and economic benefit around the world.

Remit of the RISS

The primary remit is to identify, protect and transfer knowledge created in the university out to business where it can be developed into products and services that benefit society and generate economic benefit for partners, universities, staff and students. RISSs seek a fair and equitable share of the financial benefits of success for the university to reinvest in university research, teaching and future commercialisation activity. Most universities set financial objectives for their RISS over varying timescales; with varying emphases on generating income, making a profit, and promoting research impact.

The TTO and Research Support Office

The Research Support Office of a university will also be involved in intellectual property and negotiating arrangements for research funding involving industry, as well as charities, EU and government. In some universities, the Research Support Office establishes ownership of university intellectual property, which is then passed on to the RISS for commercialisation. Each university will develop its own organisational structures for managing research funding, consulting, equipment services, material transfers and sales, and technology commercialisation. RISSs can be part of university administration, a wholly owned subsidiary company or rarely a contracted-out service.

Who is the RISS representing?

The RISS is representing the interests of all those involved in transferring technology: the central university, department, academic (who may or may not still be at the university), student inventors (many of whom are no longer students) and funders who have contributed to the research. Ultimately, the RISS is responsible to the senior governing body of the university it represents; but many of the beneficiaries it is representing are not. This is what makes the activity remarkably complex.

Opening a conversation with your RSO or RISS

You will undoubtedly need the support of your RISS or RSO if you are planning to translate your research into a product. The sooner you engage with these services, the more efficient your journey will be.

To prepare for your meeting, take along a current version of your business case so far, having worked through the business case development tasks in this guide.

Funding for translational research and innovation

Where to find funding for translational research and innovation

The landscape for funding the development of new medical technologies is ever changing. We recommend starting your search for appropriate funding with:

In-house funding database

Various specialist research funding databases for the research community are available. By using your institution's preferred database, you will have access to the most up to date opportunities.

UKRI

UKRI is a non-departmental public body sponsored by the Department for Business, Energy and Industrial Strategy (BEIS). The organisation brings together the seven research councils, Research England, which is responsible for supporting research and knowledge exchange at higher education institutions in England, and the UK's innovation agency, Innovate UK.
UKRI provide funding to:

- researchers
- businesses
- universities, NHS bodies, charities, non-governmental organisations (NGOs) and other institutions.

Funding is provided for every stage of research, from fundamental research to applied and translational research that develops new products and services.

Search UKRI funding opportunities

UKRI EPSRC

Costs may be requested for Proof of Concept (PoC) studies, that is, where initial data from a small number of tests is being gathered to validate and inform the continual development of

the technology developed as part of the project: Costs you can apply for - Proof of concept studies in healthcare.

NIHR

NIHR Medtech and In vitro diagnostics Co-operatives (MICs) can help you to develop new medical technologies including access to proof of concept funding for projects

BRCs also fund early experimental translational research: Invention for Innovation programme (i4i) supports.

i4i FAST is a translational funding scheme which advances healthcare technologies and interventions for increased patient benefit in areas of existing or emerging healthcare need.

Charities

Charities with an aim to develop breakthrough interventions in the clinical target area of your technology may have funding available for innovation – for example Versus Arthritis have offered translational proof of concept awards in the past. See the AMRC (Association of Medical Research Charities) membership database.

British Heart Foundation offer Translational Awards aim to progress the development of novel, innovative technologies towards benefits to human cardiovascular health.

University's Research Support Office

Your university's research support service may have internal funds available – for example Impact Acceleration Account funding. Impact Acceleration Accounts (IAA) are strategic awards provided to institutions to support knowledge exchange (KE) and impact from their UKRI funded research. IAAs allow Research Organisations to respond to opportunities in flexible, responsive and creative ways, aligned to their institutional strategies and opportunities.

What makes a great innovation funding proposal?

Funding applications can be daunting, whether it is for large or small sums of money. And they can make or break a project. The Grow MedTech Opportunity Management Panel (funding review panel) answers questions on what takes an innovation funding proposal from good to great.

These are bite-sized, digestible chapters, taken as live recordings from the annual conference, 'Collaborating for a competitive future' held on 28-29 April 2021. Find the full selection of videos here: From good to great: What makes a great innovation funding proposal.

What stands out as a strong funding proposal?

The following film offers tips from the Grow MedTech Opportunity Management Panel on what stands out as a strong funding proposal.

Watch video

Watch a video about what stands out as a strong funding proposal

Transcript

Jo Dixon-Hardy: I'm going to start with a question which I'm going to pose in two ways to the panel, depending on which they find the easiest way to answer, which is either from your perspective, what stands out for you in a really good funding proposal? Or you may want to view it from the angle of, what would make a proposal look, particularly as if it had got a lot of gaps. You can take that from either way you want to, I'll maybe start with Michael on this one in terms of what makes you think 'Wow that's really got it' or 'wow that's really missing something,' are there any things you can flag to the audience?

Michael Kipping: In the context of developing products for patients and healthcare professionals, so Sue and other patients, and health care professionals would be my primary interest area. So, what's the current gold standard of care and what are the potential benefits of whatever product you're considering developing? Because, you know, that's the fundamental basis for it. If you don't have a strong view on what the gold standard is and how your innovation might benefit patients and users, then you're not going to get anywhere basically.

And moving on from that, Innovate UK broadly asks ten questions. We look at the need, we've talked about the clinical need already. What's innovative about your approach, and having an understanding of, firstly the gold standard, but other companies, organisations approaches within that space – it's really important.

But at an early stage, you don't need to worry too much, but having an understanding of what your product is. By that I mean, is it a medical device or is it a consumer product or what is it? And there is a is a really good free tool that you can use called Oxford Global Guidance. If you tap into to Google, it's free tool, and it's basically it's a decision tree. It'll ask you questions about your product. They'll tell you whether you're a medical device or not and what sort of class of medical device you are. And that's really quite helpful in understanding the sort of evidence you'll need together down the line for your products.

Also having an understanding of your freedom to operate. Okay, you've looked at the clinical need and the gold standard and the benefit to patients and users. And you've looked at the market, but do you have freedom to do what you want to do or has another company or organisation already sort of snaffled the IP in that space?

Those are the key areas. The area I see commonly which is the weakest is the understanding of the regulatory pathway, and for me, if you don't understand that, then you don't understand the evidence requirements needed for your product.

Josephine Dixon-Hardy: That's a really helpful point and some really useful links there for people as well. I'm going to ask other members of the panel if they want to elaborate on or add any elements. Lindsay?

Lindsay Georgopoulos: Yeah, I everything that Michael just said is completely spot on.

I think for me as well, one of my biggest things is making sure that it's really clear throughout what the need is what you're targeting, that the description of it is really, really clear. If I had to Google something that's in a lay summary, that sort of instantly makes me

worry that I'm not going to be able to understand the rest of the application, so I think it's really important. Some reviewers will be specialists in your area, they will be deliberately chosen because they know about your area, but there will be some generalists as well who, yes, have scientific knowledge or medical knowledge, but won't be experts in your niche. So, making sure that you really clearly describing what it is you're trying to do and the problem that you're solving, I think is really important.

And kind of building on what Michael was saying about your freedom to operate in competitors. Don't be afraid to actively encourage people to acknowledge competitors that are in the space because, number one, it's not always a bad thing that there are competitors trying to solve the same problem, as it kind of validates the fact that it's a real problem, so it can demonstrate that there's a real activity in this area, but also articulating it in a way that "these are all out there, but actually ours is this better because of this," because what the reviewers often do is do a quick Google of this problem, they'll find 10 solutions that say they solve that problem. They might not necessarily look into the detail of it and come back and say "well, this what you're doing, there's loads of stuff already out there." So, if in your application you can tackle that head-on and say "we are aware of these other things, but actually they don't meet the clinical need because of X, Y and Z, and ours does," that really helps kind of head-off any negativity at the pass, I think, about the novelty and the need for your idea.

Josephine Dixon-Hardy: So you're really focused there, Lindsay on communication, what they're about, thinking about the audience, thinking about the language you use, how you say things and making it accessible was really coming through. Thank you for that. Patrick, do you have further things you'd like to elaborate on?

Patrick Trotter: Yeah. I fully endorse what both Michael and Lindsay said. And I guess when you talk about the need, another way of looking at the need is what what's the problem that you're trying to solve and what is your solution, and why does it add value that the other solutions don't have.

One, I guess, a bit of a bugbear that some of the organisations I work with, they'll consider competitors only as those organisations with the technology quite similar to them. And they're not really thinking about all the different solutions. For example, you might have an in-vitro diagnostic device, but some of the solutions can be imaging devices, which are answering the same problem, so try and think a bit more holistically about other disruptive technologies that might address that problem and address it from that perspective.
I guess one thing that's not been mentioned so far is outline that roadmap to commercialisation and look at the skills that you'll need to do it, and make sure you've got an appropriate skill set. And if you haven't got that skill set, find people who have got those skills to bring them into the team. Because, again, if you haven't got the team or the skills to develop the project and make it a commercial success, there are reviewers who are going to kind of question mark that and you don't want to get marked down on one question that your team's weaker than it should be.

Michael can probably comment on the Innovate UK ten questions, but if you're not scoring eights, eight and a half, nines and over nine on those questions, if you score poorly in one question, you're probably not going to get it funded.

Josephine Dixon-Hardy: And that's a really important point you make, Patrick, because we often think from an academic perspective about what are the gaps in academic expertise that we need to fill. So, we might collaborate with other universities on addressing those, but actually thinking about the gaps in the skills and knowledge to actually take that technology forward down that innovation pathway are actually just as important.

Patrick Trotter: Yeah, and I think it's those commercialisation skills, the regulatory skills that are critically important.

I guess the other comment that I would like to address is that a lot of our organisations get products CE marked and then they'll start using a lot of bad language about the NHS, why they can't get it adopted. But that's because as part of that project, they have not identified reimbursement as an issue that they need to address. It's really important to get that business case for adoption, not just for the NHS, but for those international markets that you're addressing, and make sure that your evidence plan, that your clinical trial design, builds up that business case for adoption and knowing what your clinical investigation is going to look like, the number of patients, etc, can help you frame those milestones and justify how much cash that you're actually asking for.

Josephine Dixon-Hardy: That's great, Patrick, and I think that probably provides a nice segue into Sean, who may have some further views on that end of the pipeline.

Sean Clarkson: Yes. Thanks, Jo. Again, echo everything that everybody said already. Actually, I was going to focus on the communication point Lindsay made earlier, actually. And just talk a little bit more about a couple of things that you mentioned, Lindsay.

So I think putting it right back to basics, the two key things that every funding proposal has to have in it for me is: what is the challenge and opportunity you are trying to address, and what is your solution or project or product?

And it sounds like a really daft basic answer to the question, but you will be amazed at the amount of funding applications that I read on a weekly, daily basis that don't have those two key bits of information in there.
And putting yourself in the position of a reviewer who's got a stack of these applications to review. If they can't quickly identify the challenge you're trying to address and what your solution is, it makes it so hard to try and read the rest of the application and kind of assess the application and me myself sitting on these review panels is really helped hone my skills in that area.

So, I kind of implore everybody to try and put themselves in the position of a reviewer, think like a reviewer. And if you do get any opportunities to be a reviewer and kind of learn in that way, then I would definitely do it. And just building on that point around communicating what kind of project or product is, I think intellectual property is often seen as a bit of a

barrier to be able to apply for funding and to be able to communicate actually what your product or project is.

I remember sitting on a Dragons Den style funding panel, and it was after, I think, a six month intensive accelerator programme where all the companies on this accelerator had been through training on product adoption, regulatory, intellectual property and so on. There we all sat and heard their elevator pitches for their products. And it was a fantastic product pitched as part of this. And the impact that they were demonstrating was incredible around how they were looking to transform cancer patients, address waiting times and all sorts and the impact on the NHS, the impact on patients, would have been phenomenal based on what they were saying. However, the panel found it absolutely impossible to get out of them what the actual product was that they developed. And it was so frustrating for the panel that not being able to actually fund this project, which sounds like it had massive potential for impact, yet we couldn't identify what they're actually doing and they were following what they believe was IP advice around not disclosing what the product was and as important as IP is and all of us on this panel today will testify to that.

I think taking a very pragmatic approach to it is so important that from the stage, you've got to give the reviewer enough information to be able to make a pragmatic and judgmental decision about whether this product could be invested in what the business value is there.

Josephine Dixon-Hardy: Well, I mean, we're getting some really, really good practical pointers here, which is absolutely what we were looking for. So, thank you very much so far.

Further resources

UK-Wide

We recommend following the steps above to find suitable funding to progress your technology. Funding available at the time of developing this course – this is not an exhaustive list:

Medical Research Council (MRC) offer a Developmental pathway funding scheme - an ongoing scheme with a budget of approximately £30 million a year

The NIHR Invention for Innovation (i4i) Programme supports the preclinical and clinical development of medical technologies in areas of existing or emerging patient need. They fund projects that have demonstrated proof-of-concept and have a clear pathway towards adoption and commercialisation.

University of Leeds

The University of Leeds has access to a range of funds to support the translation of research into real-world products, services and solutions.

These funds exist to help academics deliver impact from their research by working in partnership with businesses, government bodies and other organisations.

Internal funding is available for a range of translational activities including:

- exploring the potential for commercial products or services to be developed based on research at the university of Leeds
- developing relationships with external partners and facilitating the adoption of new research
- improving the flow of knowledge and skills in both directions between the university and external partners
- developing academic awareness and understanding of translational research.

Translational funds are awarded to the University from a range of funders.

To secure institutional translational funding, academics must apply through an internal competitive process.

To find out more visit the Research and Innovation Service Institutional Translational Funding webpage.

Our Translational Research Portfolio team also provides dedicated, specialist support for the following impact accelerator and research translation schemes:

- Harmonised UKRI Impact Acceleration Accounts funded by BBSRC, EPSRC and MRC
- STFC Impact Acceleration Account (STFC IAA)
- Welcome Trust Institutional Translational Partnership Award (iTPA).

More detail can be found on the Research and Innovation Service innovation funding webpages.

Develop your business case

To prepare for your meeting, take along a current version of your business case so far, having worked through the business case development tasks in this guide.

16) The Medical Technologies IKC

This chapter covers:

- A successful approach to medtech innovation
- Case studies
- Further reading

A successful approach to medtech innovation

The following film describes the IKC's sector specific innovation translation system, featuring Prof John Fisher CBE, Academic Director of the IKC, and Dr Josephine Dixon-Hardy, Director of Medical Technology Innovation.

Watch a video on a successful approach to medtech innovation

About the Medical Technologies Innovation and Knowledge Centre

Since 2009, the University of Leeds has been working with UK HEIs to accelerate technologies closer to market through the Medical Technologies Innovation and Knowledge

Centre (IKC), funded by the Engineering and Physical Sciences Research Council. Over the years, we have developed a unique innovation infrastructure, a team of experienced professional innovation and IP managers, and successful innovation and evaluation methods to advance medical technologies and remove uncertainty and risk.

Our achievements

Our approach has enabled us to deliver a large portfolio of proof of concept projects. By de-risking technologies at an early stage, we've opened the door to over £200m private sector investment to progress technologies towards commercialisation. Most of this investment, £148 million, has supported seven start-up companies established to take the technologies forward, while the remainder has supported work by established industry partners. This investment has enabled new products to be developed and manufacturing facilities to be established in the UK, the European Union, Switzerland and the USA.

Other organisations, including the medical charity Versus Arthritis, have also partnered with us, to apply our approach to their research funding programmes.
Since 2009, we have:

- Created and supported seven spinout and start-up companies
- Enabled £200m downstream investment into the private sector
- Supported 267 proof-of-concept, technology development and demonstration projects; 84 have progressed beyond TRL level 4
- Delivered 50+ products and services that are reaching the market

In 2018, the team won funding from Research England's Connecting Capability Fund to replicate our approach to innovation as part of a consortium of six universities in the Leeds and Sheffield City Region, called Grow MedTech. The consortium comprised the universities of Bradford, Huddersfield, Leeds, Leeds Beckett, Sheffield Hallam and York.

In 2015, we won an award through Office for Students for Translate MedTech, to enhance and embed medical technology innovation know-how across the Leeds and Sheffield City Regions.

The Translate MedTech programme led a targeted innovation development programme to enhance innovation awareness, understanding and capacity. From 2018 to 2021, the programme was funded by the partner universities themselves to run alongside and enhance the support Grow MedTech was offering.

Case studies

Innovative technology that led to a global company

Since the inception of the UKRI EPSRC Medical Technologies IKC, it has supported and advanced technologies in regenerative medicine that have been commercialised through University of Leeds spin-out Tissue Regenix, one of the most successful medical technology companies from any UK university.

In the late 1990s, Professor Eileen Ingham's team in the Institute for Medical & Biological Engineering at the University of Leeds, along with her colleague, medical engineering

Professor John Fisher, developed a ‘deceullarisation’ process – removing cellular and DNA material from donated human or animal tissue, but leaving a tissue frame or ‘scaffold’ behind. The scaffold could be used as an implant to replace or restore diseased or injured tissue and support the growth of new tissue, using the patients’ own cells. As well as reducing the chances of rejection, this innovation – later trade marked as ‘dCELL®’ – proved to be clinically effective with relatively short development times and costs compared to cell and molecular-level therapies.

Medical Technologies IKC supported Tissue Regenix following its spin out from the University of Leeds in 2006. Since 2009, Tissue Regenix and the IKC have worked together on proof of concept and co-development projects. A co-development project with IKC funding, matched by the industry partner, was run in the University of Leeds which developed industry standard test methodologies for dCELL® porcine meniscus. Proof of concept studies were conducted on decellularised porcine tendon and porcine pulmonary heart valves. Other funding from UKRI EPSRC and BBSRC has supported the advancement of the underpinning dCELL® technology and the extensive patent portfolio.

The UKRI EPSRC IKC was also instrumental in supporting the development of the tissue scaffold decellularisation technology with the National Health Service’s Blood and Transplant Tissue & Eye Services, which is developing human tissue derived dCELL® scaffolds for use in the NHS. Decellularised dermis repair technology is currently being used in NHS hospitals to treat chronic leg and foot ulcers.

And this led to…

Tissue Regenix, a University of Leeds spinout, was listed on the London Stock Exchange’s Alternative Investment Market in 2010. It now has a portfolio of 12 commercial products on the market, involving different tissue types and for a range of patient conditions, and has also moved into natural bone regeneration. It employs 77 people across three global manufacturing facilities, annual revenue of £13 million and has over the last decade had a Market capital value estimated at between £30 million and £140 million.

Funding to de-risk ‘joint’ innovation

As people live longer and remain active into their later years, even following joint replacements, they are demanding more and more from their new hips and knees.

New and innovative designs are needed to meet these demands, and reliable testing of designs at an early stage is crucial to de-risk the innovation process. Taking forward designs that later fail in clinical trials is extremely costly.

IKC Proof of Concept funding has supported co-development projects between the University of Leeds and simulator manufacturer, Simulation Solutions, to help de-risk innovation in total joint replacements.

Professor Louise Jennings leads the University’s world-leading joint simulation facility and is a member of the core IKC team. As such, she is both the lead academic and the TIM for her proof of concept projects, while gaining translational development support and training

through her IKC involvement. The IKC also enabled her to tap into a wider network, notably through presenting her research at the IKC's annual conference.

She describes the work with Simulations Solutions as a 'loop', which benefits the company, the wider orthopaedic industry and, most importantly due to the better joint replacements designed as a result, patients as well.

Professor Jennings and her team take information from clinical retrievals – the joints that need replacing again following failure – to see what's gone wrong and where there is uneven wear. They then specify a simulator able to replicate loading and motion patterns that can reproduce these clinical failure mechanisms, which the company then design and build. Professor Jennings' team validates the new simulator and develops a research test method and standard operating procedures for it, making it a marketable product for the company. The knowledge they gain then feeds into the specification for the next simulator, to begin the process again.

And this led to …

The new standard operating procedures have become part of the international standards, enabling Simulation Solutions to market their machines across the world and providing a reliable basis on which orthopaedic companies can design and test new joints.

The proof of concept funding from the IKC has also been the catalyst for other industry collaborations to develop new simulation methods and procedures.

From virtual to clinical trial

Funding from Versus Arthritis, provided in partnership with the IKC, enabled the first ever 'virtual' trial of an orthopaedic device. The funding, and IKC support, has helped the technology gain MHRA approval and progress to clinical trials.

TOKA aims to improve outcomes for high tibial osteotomy (HTO) operations. These are used in younger osteoarthritis patients, to realign the knee and take pressure off damaged areas of the knee joint. Correct alignment during surgery is vital, but often difficult to obtain, particularly using standardised metal plates to hold the tibia in place.

The new technology uses the patient's CT scans to print a 3D personalised surgery guide for each patient and create a bespoke 3D printed titanium plate. TOKA was developed by Professor Richie Gill and Dr Alisdair Macleod from the University of Bath, knee surgeons from the Royal Devon & Exeter Hospital and Alberto Casonato from 3D Metal Printing Ltd.

Unlike most orthopaedic devices, each TOKA implant is unique, which makes the regulatory process more complex. The team used the Proof of Concept funding to create computer models of different tibias based on CT scans from osteoarthritis patients. They used these models to assess how a standard HTO and a TOKA plate would behave if implanted into the same tibia – a 'virtual' or 'in-silico' trial. The results were analysed alongside mechanical stress testing on the titanium material used in the 3D printed TOKA plates, proving that fatigue and wear in the standard HTO and the TOKA plates were very similar. This helped the team gain MHRA approval and was a critical component of their bids for clinical trial

funding. The IKC supported the team to further develop and patent the technology and helped in their applications for further funding.

And this led to …

3D Metal Printing, the SME partner that developed the product for market, won UK government small business funding to run the first clinical trial that tested the technology in 25 patients in Italy. Initial findings were very positive.

Further funding from Versus Arthritis is supporting a larger randomised controlled trial in 88 patients, due to start in 2022, which will compare the outcomes of TOKA to standard HTO.

Further reading

Read more case studies on our successful approach to innovation.

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The University of Leeds
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Versus Arthritis

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