Grow MedTech: Medtech development expertise and mentoring for progression of early stage medical technology opportunities

Request for Quotes

Background

Grow MedTech is a UK programme providing specialist support for innovation in medical technologies, involving a consortium of six universities across the Leeds and Sheffield City Regions.

We are a collaboration between the Universities of Bradford, Huddersfield, Leeds Beckett, Sheffield Hallam and York, led by the University of Leeds and funded through the Research England Connecting Capability Fund.

By combining the different strengths of six Yorkshire universities in medical and related digital technologies, innovation and commercialisation, we are providing capacity and capability in medtech that far exceeds that offered by a single institution. Additionally we link into the wider network of healthcare innovation support organisations across the regions, to create added value.

Our approach is to bring both product development and market viewpoints, alongside patient views into the early-stage technology development process, to 'de-risk' technologies into defined value propositions ready for translation and commercialisation. This is supported by our programme of translation project funding and sector-specialist innovation management, helping projects to navigate the broadening translation gap, building confidence for investment into opportunities to support new product development and commercialisation, and enabling them to progress to full clinical evaluation, regulatory approval and market entry.

Further information: https://growmed.tech/

Brief and Requirements

Since the start of Grow MedTech in 2018 we have experienced a substantial number of earlier stage technology opportunities (>250) and are working to validate and advance these. We have directly funded more than100 technology development projects, providing specific and directed translational support to bridge the gap between fundamental research and industry investment. As we enter the final 6 months of the current programme, we are focussing on progressing these downstream, strengthening their commercialisation roadmaps and strategy in order to build confidence for further investment.

Our Executive and Innovation Management groups have recently identified five projects that could benefit from additional expert/specialist input and have allocated a budget to be used to fund industry mentoring time to critically evaluate and provide support for project in terms of commercialisation strategy/next steps. This activity should be used to compliment skills and expertise in the technology management team and additionally, should look to build long term relationships between the project team and industry mentor.

We are seeking to engage people with the appropriate expertise to support these projects from our regional medtech consultancy community, Advisory Board and other key partners who are well positioned to provide this support. Non-confidential project summaries and expertise required are provided below. You are invited to

review these and to provide a quote for those aligned with your expertise and interests and which you have the capacity to support within the timeframe below. We expect competitive rates to be negotiated for distinct packages of work.

Timescale

A final version of the agreed outputs will be required by **21st May 2021**. Outputs may include but are not limited to technology roadmaps, commercialisation plan, report on further work packages and questions that need to be addressed in order to progress the technology forward and any supporting information relevant to the project requirements.

Budget

The budget for this work is up to a **maximum of £10,000** including VAT.

Quotations and Proposals

All quotations should outline the following:

1. The project you are providing a quote for.
2. Your track record and relevant expertise in conducting similar work
3. The proposed approach to complete the work and to and address the key requirements described in the table below. (Please note - we would expect there to be a project kick-off meeting with the academic project team and Grow MedTech Technology Innovation Manager, an interim update and final report as a minimum).
4. How the work will be presented (details of the information and report that will be supplied)
5. A detailed breakdown of costs and timescales
6. Detail on whether you are currently on the University of Leeds suppliers framework or if you have worked with any of the Grow Medtech partner universities before (University of Leeds Bradford, York, Huddersfield, Sheffield Hallam or Leeds Beckett)

Please note that if you are providing a quote for more than one project we require a separate and distinct proposal for each project you are quoting for, and points 2-5 listed above should be tailored to each.

All quotations should be emailed to the address below by **12pm Friday 5th February.**

Contact

If you have any questions or require further information, please contact: Danielle Miles, Grow MedTech Programme lead, d.e.miles@leeds.ac.uk, 07711484475.

Project Summaries and requirements

Project Number	Project Title	Project Summary	Requirements
000296	**Portable, high-sensitivity and multiplexed immunosensor**	Technology Summary: A high-sensitivity immunosensor technology that uses a light beam from an LED to illuminate a sensor chip and extract sensing information by taking an image with a simple camera; the sensor chip can be made by silicon mass-manufacturing methods and the design of the chip is IP protected. The performance of the technology is now as good as or better than the laboratory standard ELISA and can reach a sensitivity of 1pg/ml. We have demonstrated this performance in urine and are currently developing the capability to measure in serum and in blood. The on-going technical development includes further improvement of the technology and quantification of sensing performance on a handheld instrument. As a platform technology, it could be used to measure biomarkers relevant to a number of clinical conditions and so a number of market scoping consultancy reports have already been commissioned, and the technology has been discussed with patient public involvement (PPI) groups. The physical science work is supported by EPSRC with further applications currently in the pipeline. A previous POF successfully demonstrated the multiplexing capability and the operation with urine as a matrix. The initial work on detection in blood was supported by UoY IAA funds and is on-going. Clinical Applications: A number of use cases have identified, including acute kidney disease, heart disease and the monitoring of immunosuppressed patients, in particular rheumatoid arthritis patients. We also envisage a COVID-19 antibody test as a further possible application. We see the USP of the technology as the ability to provide a rapid, high-quality readout at the point of care, in the community or at home. The test outperforms lateral flow devices, such as pregnancy tests, which are far less sensitive but very low cost; at the other end of the market are the ELISA and LAMP tests that are very sensitive but require blood tests at the clinic or the transport of sample to a laboratory, with the corresponding overhead in terms of cost and delay.	Consultant expertise required: We wish to engage with a consultant with proven IVD development expertise (10+ years' experience in the in vitro diagnostics industry). Summary of proposed work: To act as a project consultant and advise the project team on our User Needs and Design and Regulatory Strategy Development, tailored to the specific requirements of our optical sensor. This will include delivery of an outline IVD Development Plan, which will define the objectives and parameters for each stage of the project development, with estimated timelines, costs and risks (e.g. identification of the key scientific and engineering challenges). To define the processes for project delivery with the aim of a better understanding of User Needs, Design Development, Risk Management and Document Control, particularly how we should define, track and log every part of the design and development process to create a Technical File that will be fit for purpose and withstand scrutiny for regulatory submission. To understand our regulatory obligations under the In Vitro Diagnostic Medical Devices Regulations (IVDR) and the FDA Regulations for IVD Products. To define the processes that we would need to adhere to for CE marking. This will include advice on the Classification of our IVD in different territories and an outline Clinical Strategy to help us understand how we should develop our technology to meet user needs and clinical requirements. Expected outcomes: Outline IVD Development Plan / Guidance on compiling the Technical File / Outline Regulatory and Clinical Strategy / Understanding (by the Project Team) of the requirements to take this technology to market

000295	**A Raman spectroscopy test for detection of prostate cancer at point-of-care**	Clinical Need: Prostate cancer is the second-leading cause of death in men. 40,000 new cases are diagnosed, with the number of prostate cancer deaths increasing per annum. The PSA-test is not accurate enough to be beneficial as it fails to detect cancer in one-man-in-six, with two-thirds being told they have the disease when they do not. Subsequent costs arise from unnecessary testing and inability to easily and accurately monitor disease-progression, or determine if the cancer is aggressive or not. Thus, treatments may not be targeted or even necessary. Across all measures, the PSA-test misses cancer in 17% of cases. Hence, there is a significant human cost associated with inaccurate PSA-testing, as well as health-system costs from complex diagnoses and overtreatments. Technology Summary: We are developing a Raman-based diagnostic for early-stage detection of prostate cancer. Raman spectroscopy, which involves light-interaction with matter, is a promising method that can elicit molecular-scale fingerprinting of disease at the single-cell-level. We are working on a POF project to validate this technology on normal and disease samples. Our lab has developed label-free, Raman (light-assisted) fingerprinting, which delivers molecular-testing at the single-cell-level with greater accuracy for prostate cancer detection (up to 94%-sensitivity; 93%-specificity). We have developed biomarking software that facilitates rapid disease identification. A health economics assessment by YHEC shows even a very modest gain in overall accuracy over the PSA-test would lead to positive cost-saving per patient for the NHS. Funding to build a portable Raman was obtained and the equipment has been assembled and tested at Guy's Hospital. Collection of both healthy donor (York) and disease samples (Guy's) is underway and is continuing even with the current lockdown restrictions. Analysis of samples to date demonstrates the sensitivity of the test platform.	Consultant expertise required: We wish to engage with a consultant with proven translational diagnostic expertise (ideally 10+ years' experience in the in vitro diagnostics industry). Summary of proposed work: To advise the project team on the commercial development of the technology, with particular consideration to the specific requirements of our Raman-based diagnostic device - the attributes of Raman allow extremely detailed molecular information to be obtained from a patient blood tissue sample for high accuracy cancer diagnostics. We wish to understand the most commercially attractive/clinically-acceptable routes for interfacing the output from the instrument with our in-house analytical software for rapid cell-type and biomarker identification and (ultimately) diagnosis of disease-state. It is expected that this will be encompassed in an outline IVD Development Plan, where the objectives and parameters for each stage of the project development will be stipulated. We aim to develop an understanding of User Needs, Design Development, Risk Management and Document Control, particularly how we should define, track and log every part of the design and development process to create a Technical File that will be fit for purpose and withstand scrutiny for regulatory submission. Expected outcomes: Strategies for interfacing instrument with analytical software / Outline IVD Development Plan / Guidance on Technical File / Enhanced understanding of the product development process among the project team through mentoring.

000275	**Feasibility of a novel ‘Gut Glue’ to improve healing of bowel tissue**	Surgery on the gastrointestinal tract (also known as the digestive tract) is required to treat many different bowel diseases with approximately 50,000 operations each year in the UK alone. Following removal of diseased bowel, it is essential to suture or staple the normal bowel back together. However, the join between 2 pieces of bowel is inherently weak and failure of this surgical join occurs in up to 19% of patients. This is a potentially catastrophic event for the patient and is a major source of morbidity, mortality, reoperation and prolongation of in-hospital stay, with patients often consigned to a permanent stoma bag. Surgical join failure provides a significant financial burden for the NHS of ~£162 million per year. We have developed an injectable gel (hydrogel) which supports the cells of the digestive tract, where they can attach, grow and recapitulate the natural structures of the digestive tract. This application is one of a platform of potential applications for our platform hydrogel technology with hydrogel systems in development as treatments for lower back pain as well as this application for ‘gut glue’. The migration of cells into a surgical join and support normal cell function and structure are essential for successful repair following surgery. This therefore provides an opportunity to utilize this novel hydrogel (‘gut glue’) at the time of surgery. This holds the possibility of increasing the strength of the join, improving healing and potentially preventing anastomotic failure.	The current programme of technology development work is determining the ability of 'Gut Glue' to infiltrate within sutured tissue, improve immediate strength of the tissue and support cellular ingress of cells, supporting improved healing and restoration of mechanical and biological function of the tissue. We are seeking to engage with a medtech specialist that has expertise in regulatory affairs within the clinical setting to take a holistic view of the project and providing advice on regulatory stages needed to progress to clinic and a more complete market analysis to provide insight into the pathway to commercialisation Expected outputs: Report outlining the pathway to clinic, the regulatory steps to clinic and current market analysis.

000276	**Shapemaster**	In the UK there are 1.2 million People with Stroke (PwS) with approximately 25% experiencing a second stroke within five years. The benefits of exercise following stroke are widely known to improve fitness, strength and ability to perform tasks of daily living as well as reduce the likelihood of further strokes. Access to exercise equipment is a challenge for PwS as conventional exercise machines usually require the ability to take steps independently and initiate movement and additional support within the gym setting is necessary. The use of power assisted exercise (PAE) machines offers a sustainable solution to improve physical fitness and reduce the likelihood of further strokes for PwS. Shapemaster Global Limited (Shapemaster) develop and manufacture PAE machines that are accessible for people with complex impairment following stroke. Shapemaster equipment, however, does not incorporate clinical training principles for PwS and is unable to differentiate between active muscular effort and equipment induced passive movement. Both requirements are necessary if the benefits of PAE are to be realised. Sheffield Hallam University (SHU) have published a clinical feasibility study which evidenced the accessibility and acceptability of PAE machines for people with neurological impairment and developed bespoke software, co-designed with PwS and clinicians that will allow the differentiation of active and passive movement and enable bespoke training schedules. SHU, in collaboration with Shapemaster, have identified significant potential to advance the commercial proposition of this technology and fill an unmet need for PwS by developing the training software that will improve the effectiveness of PAE for PwS. The PAE equipment is controlled from a touchscreen console and the bespoke software would be integrated with the console and machine settings.	Shapemaster manufacture 16 pieces of power assisted exercise equipment. Through GMT funding three machines are undergoing advancement through digitalisation and development of an effort detection programme. The digitalised machines have the potential for rapid commercialisation across the leisure and rehabilitation sectors. Key workstream phases include digitalisation of additional machines suitable for leisure and rehabilitation end users, usability testing and marketing of the upgraded equipment. The development work on user interfaces of the software is complete and participant usability testing is progressing well. Development of the software added to cycle cross machines is also well underway in preparation for pilot testing with planning to use the Advanced Wellbeing Research Centre (AWRC) at Sheffield Hallam University as a pilot site. We are now seeking support of a specialist with expertise in medical technology development including knowledge of regulatory routes regulatory affairs possibly within the area of stroke rehab to help in clinical implementation and marketing of new rehabilitation/exercise products would accelerate and strategize the commercialisation plan. Expected outputs: Report outlining the regulatory pathway to market and clinic/rehab in gym settings

000293	**Virtual Physiotherapist**	Every two seconds, someone in the world will have a stroke. It is the fourth biggest killer in England and Wales, and the third in Scotland and Northern Ireland. There are over 1.2 million stroke survivors in the UK. They suffer a variety of cognitive and physical problems including weakness, paralysis, spasticity, balance problems, pain, numbness or burning sensations, and speech problems. Post-stroke Rehabilitation focuses on stroke survivors who suffer movement or mobility difficulties. It mostly takes place with the help of a physiotherapist, and sometimes an occupational therapist too. Rehabilitation continues till the person regains function. However, previous research and recent reports show that there continues to be a shortage of NHS Physiotherapists in particular to cover ongoing home visits to optimise patient compliance. Public-private partnerships are emerging as a model of service provision to fill the gap. One such example of private sector provision is Virgin Care and Care UK. Hence, there is an opportunity for the use of technology in rehabilitation to provide in-home treatment without the cost of funding private sector organisations, but instead in collaborations with CCG's. To help achieve that, we have developed a Virtual Physiotherapist, which is an intelligent system to support upper-limb rehabilitation at home. The system has the potential to provide real-time feedback to both patient and a clinician at different locations and provides an 'objective measure' of progress. The prototype has been demonstrated to neurologists, physiotherapists, and occupational therapists. A series of patient consultations have taken place and will continue. These activities provided much needed insight and led to a list of design modifications and improvements necessary prior to conducting a study. The virtual physiotherapist system uses video analytics, to support upper limb rehabilitation within the patient's home. It monitors the exercise and has several potential benefits: • More frequent virtual physiotherapy sessions • Improved clinical assessment of progress • Cost effective management of a long-term condition.	We require input from a medtech specialist with expertise in digital heath-tech – in particular the combination of hardware and software for use in a patient's home. Areas the academic team would like guidance on include: developing a technology roadmap and identification/prioritisation of next steps, regulatory considerations, and advice regarding safety/risk assessment and management for both the hardware and software. Expected outputs: Shared knowledge and improved understanding of the critical steps required to get the technology to market, including a draft technology roadmap.

For commercial sensitivity and confidentiality reasons, the information supplied above is relatively limited. However, after award of the contract a confidentiality agreement will be completed and further detailed information will be supplied for the purposes of undertaking the work. The consultant/organisation undertaking the work will also be able to speak to the academic project team to obtain further technical details.