Grow MedTech: Medtech Consultancy for progression of early-stage medical technology development 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 than 100 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 six projects that could benefit from additional expert/specialist input. We are seeking to identify potential supply partners who are well-positioned to provide this support from the Grow MedTech consultancy community. Non-confidential project summaries and requirements are provided below. You are invited to review these and to provide a quote for those which are aligned with your expertise and interests, and for which you have capacity to support within the time-frame 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, regulatory requirements and plan, market opportunity, clinical pathway alignment, commercialisation plan, health economic analysis or any further supporting information relevant to the project requirements.

Budget

The budget for this work is up to a **maximum of £10,000** including VAT per project, with an indicative expected budget of between £5-10K for each project.

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 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 supplier's framework or if you have worked with any of the Grow Medtech partner universities before (Bradford, Huddersfield, Leeds, Leeds Beckett, Sheffield Hallam or York).

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
000292	**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-house 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.	The aim is to identify potential safety issues and develop solutions to mitigate these. The safety issue may be intrinsic to the device or arise from usage. The former may result from manufacturing defect, mechanical or electrical failure or wear and tear. The application of best practice, standards, processes and guidelines will be employed to mitigate there. The main safety concern is risk of injury as a result of using the device. Injury that would not have occurred if performing physical therapy without. The key is understanding what design feature could minimise risk of injury and what instructions and guidance would help mitigate the risk of an accident occurring. The objectives are to: 1. Identify risks associated with performing physical therapy unaided (without device and without physiotherapist) 2. Understand what guidance is given by a human physiotherapist in relation to safety 3. Investigate what safety measures can be incorporated into the design of the device 4. Investigate what safety measures can be incorporated into device usage instructions (guidance) Expected outputs: Report detailing the potential safety issues and recommendations for mitigating these

000291	**Facial sensors for the detection of neurological conditions**	We are developing a device incorporating EMG sensors for the measurement of facial movement as a novel diagnostic for neurological disease, where patients show reduced facial expression.
		Depression is a clinically complicated spectrum of illnesses with variable responses to treatments, where patients show reduced facial expression and displays of emotion, termed flat affect (Depression in adults: recognition and management. NICE Clinical guideline 28 October 2009). There are no objective tests for diagnosis and monitoring of depression. Current diagnosis and treatment depend on subjective clinical assessment, supported by structured interviews such as The Hamilton Rating Scale for Depression.
		
		Parkinson's disease (PD) is a progressive nervous system disorder that affects movement, where patients show reduced facial expression, termed hypomimia. PD diagnosis is based on presence or absence of clinical features and experience of the neurologist. Early diagnosis of PD is very challenging resulting in misdiagnosis or delays in diagnosis for patients. There are no biomarker or clinical tests to confirm diagnosis.
		
		The development of EMG sensor measurement of facial movement will provide a cost effective, non-invasive, objective test for diagnosis of depression and early PD.
			We would like the work conducted to address the following questions:
			• What is the commercial opportunity for the facial sensor technology in each area (including the market drivers, overall market size and addressable market)?
			  ○ Is there a market for objective diagnosis of depression?
			  ○ Is there a market for objective diagnosis of Parkinson's disease?
			• What features and benefits would the technology need to have over current practice?
			• Are there any competing technologies or barriers to entry for each application?
			• Where and how could this technology be implemented within the NHS for each application?
			• What would be the advantages to the NHS of adopting the technology for each application (Impact and cost-benefit analysis)?
			Expected outputs:
			Market report, including a recommendation for which area to focus efforts on initially (PD or depression)

00294	**Test Device and Method for Detecting Resistance to beta-Lactam Antibiotics**	Clinical Need: Antibiotic resistance is enormously challenging for healthcare providers, with current methods of detection requiring culturing of bacterial samples and taking days to produce results. There is an unmet need for a point-of-care test that allows the correct antibiotic to be given from the outset. Technology Solution: We are developing a lateral flow diagnostic (LFD) for the direct detection of resistance to beta-lactam drugs (such as penicillin) - thus identifying when beta-lactam drugs would be effective or when not to prescribe this class of drug. The test is designed to be fast and work directly from a patient's sample. Prototype strips have been successfully prepared - Novel, red-coloured gold nanoparticles labelled with a probe beta-lactam antibiotic are shown to bind selectively to the protein on the LFD test strips, indicated by a red test line. When exposed to a sample containing beta-lactamases (enzymes produced by resistant bacteria), the deactivated test nanoparticles no longer bind to the test line of the LFD, indicated by the absence of a red line. The method can successfully detect in human urine samples spiked with the beta-lactamases. The test nanoparticles are also being developed into a competition assay - the nanoparticles and the drug of interest compete for binding to the test line; therefore, the outcome can be used to determine if the competing drug was active or inactive. A patent application was filed in summer 2020 and a market report was commissioned, resulting in a number of recommendations to enhance the viability of such a device from a UK market perspective and these are currently being addressed in the on-going proof of feasibility project, the most pressing being increasing the shelf-life of the test device and confirming the LOD meets the clinical level.	Consultant expertise required: We wish to engage with a consultant with proven IVD development expertise, specifically with expertise in LFD development. Summary of proposed work: To conduct Commercial and Regulatory Planning and Technical Due Diligence, tailored to the specific requirements of our LFD. This will include strategies for optimisation of the immunoassay format, including maximising shelf-life. The work will include delivery of an outline IVD Development Plan, which will define the objectives and parameters for each stage of the project development, identification of key risks and recommended mitigations to progress the device to CE marking. We wish to understand the order in which each phase of the development should be undertaken and the requirements to be met before progression to the next phase. Also 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. Expected outcomes: Guidance on optimisation of assay format / Outline IVD Development Plan / Guidance on compiling the Technical File / Understanding (by the Project Team) of the requirements to take this technology to market.

000300	**myfood24 and diet optimisation**	Poor diet has a high impact on the NHS budget, ~£6 billion/year (BMA), greater than alcohol, smoking and physical inactivity. Yet, healthcare professionals do not have effective tools to support early intervention and prevention of diet-related disease. myfood24 is an online dietary assessment tool developed by the University of Leeds and now being commercialised by spin out company Dietary Assessment Ltd (DAL). Through funding from Grow MedTech, the University of Leeds is collaborating with DAL to develop an additional feature called the Diet Optimisation Engine (DOE), which uses input from myfood24 and provides suggestions for improving food choices to optimise nutrient intakes. myfood24 has been validated against independent biomarkers and is becoming a leader in the field in nutrition research in populations in the UK and Internationally. A new health app version for use between patients and healthcare professionals has been developed. In addition, a new module, the Diet Optimisation Engine (DOE) has been linked to the myfood24 health app. This combination of diet tracking and optimisation is being tested in gastroenterology surgery patients in Leeds and Tier 3 Weight Management patients in York.	We are seeking a consultant to scope requirements for regulatory and governance needs to take the myfood24/DOE solution to market and to obtain an external commercial opinion of the potential to utilise the technology in clinical and non-clinical healthcare settings. We propose to employ a medtech consultant to work with the team and provide expert advice on: 1. Scope requirements for regulatory and governance needs to take myfood24/DOE solution to market in the NHS and more broadly a. myfood24 currently would likely not be considered as a medical device. (MHRA Ref: E/2020/2339, correspondence 11 June 2020). However, introduction of the DOE into the system which provides guidance and suggestions for improving diet quality may change this grading. b. A review of requirements and documentation needed for Medical Device Regulation and CE Marking is required. 2. Obtain an external commercial opinion of the potential to utilise the technology in clinical and non-clinical healthcare settings a. Details of opinion from market leaders for the potential to use myfood24 and the DOE including stakeholder feedback, inputs from the NHS innovation landscape. This will consider primary and secondary care bodies, CCGs, Local Enterprise Partnerships. b. Engage with medical and nutrition trade bodies (e.g. BMA, BDA, AfN); NHS England; NICE. DAL project partners and find out how they could

			support our initial route to market. This work will build on the market research and early adopters identified for the myfood24 health app (including hospital teams and general practice). c. Identify potential commercialisation partners and routes and key business requirements needed by the clinical team and patients to effectively track nutritional intake and identify changes for clinical and healthy eating support. 3. An external IP review of the DOE Expected outputs: Requirements scoping brief Market plan report Report on IP review
000229	**Development of High intensity Ultrasound for treatment of head and neck cancer**	Grow Medtech is funding a proof of concept project aiming to develop a functional prototype ultrasound guided high intensity ultrasound (UsGHIFU) device that can be used to precisely ablate tumour cells with minimal damage to surrounding tissue. Currently most HIFU is guided via MRI and has resulted in low uptake due to cost, the team's proposal would be significantly cheaper than the current competitors. Currently the project is focussed on combining the guidance and HIFU system into a single portable device.	Initial market assessment and regulatory advice has been carried out and has highlighted the complexity and long timeframes for commercialisation around such a device therefore further advice around the commercialisation pathway is sought to aide further development. We are now seeking to engage a medtech specialist with an understanding of the HIFU market and/or experience of taking large/complex medical devices to the market. We require input on the commercial roadmap, including key milestones for getting to clinical trial, basic health economics and assistance in identifying and connecting with industry contacts. Expected outputs: Report outlining commercial strategy.

000297	**Microwave Medical Imaging of Burns**	Clinical Need: Over 13,000 people in the UK are referred to specialist burn units each year; 50% of which are admitted for ongoing treatment. Burns are complex in nature as their severity depends on both area and depth, which can vary across the wound, and can increase over the first 72 hours after injury. Accurately, rapidly and repeatedly assessing the depth of a burn is therefore critical in determining the treatment received and achieving optimal patient outcomes. Laser Doppler Imaging (LDI) is the current best practice, but only provides accurate assessment 48 hours after injury and the burn has stabilised. As no technology capable of producing a 3D image of a burn is currently available, and LDI is cumbersome and expensive, assessment is most commonly by visual appraisal and clinician experience. Technology solution: A device that produces a 3D image of temperatures up to 2cm below the skin surface. This technology will be highly portable, rapid to use, and require minimal training. It will be particularly useful in assessing children, as imaging will only require them to remain still for seconds, and the device can be brought to them. This device works by measuring microwaves naturally emitted by the body, the strength of which depends on the temperature of the tissue. It combines recent critical advances in the design of phased-array antennas and ultra-fast data acquisition to make microwave medical imaging both technically and commercially viable. To date, the work has focused on laboratory-based technology development, testing and optimisation to meet the specifications required for burn imaging. The hardware components of the system required to make measurements have been tested and characterised up to a 4-antenna system. These data informed relative positioning of the antenna to reduce noise in the measurements. The visualisation software was successfully developed to the point of full visualisation of the data that can be obtained by the current system. The measurement system can successfully communicate data to a PC, and the software is then able to accurately analyse the data and plot it in a graphical user interface (GUI). YHEC completed a preliminary Health Economics Study and PPI is underway.	Consultant expertise required: We wish to engage with a medical device consulting company/consultant with proven industry expertise in the commercialisation of medical devices, preferably to include experience with imaging devices. Summary of proposed work: To provide expertise and input into the project, specifically to work with the project team to generate a Strategy for Market Access for our portable, non-contact imaging device. Although COGs are not finalised, it is anticipated to be in the region of £10K, and at this price point there will be challenges to adoption. We wish to understand market access routes, along with the documentation needed, to benefit all parties in the healthcare system (e.g. clinicians/providers, payers and patients). This would be expected to include, but not limited to, a better understanding of our pricing strategy in the UK and main international markets, with reference to the corresponding reimbursement systems and specialist requirements such as Health Economics, local hospital value dossiers (in the US) etc. Expected outcomes: Market Access Strategy / Understanding (by the Project Team) of the requirements to take this technology at this price point to market

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.