Innovate UK

Results of Competition: SME Support to Evaluate Innovative Medical Technologies: Round 4

Competition Code: 1904_FS_SMEIMT_R4

Total available funding is £1.5 million

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
NEXA MEDICAL LIMITED	Evaluation of a novel wound healing device	£199,873	£99,936

Note: you can see all Innovate UK-funded projects here: https://www.gov.uk/government/publications/innovate-uk-funded-projects
Use the Competition Code given above to search for this competition's results

Funders Panel Date: 05/09/2019

Project description - provided by applicants
This project is intended to collect clinical and cost effectiveness data on the NEXA NPWT (Negative Pressure Wound Therapy) System. Hard to heal wounds, such as Diabetic Foot Ulcers and wounds that get infected after surgery cost the NHS over £700 million a year as well as adversely affecting the wellbeing of the patient and their families. NEXA Medical have developed a novel wound healing device that stimulates the body's natural healing process and ensuring infected material is removed from the wound. It does this through the application of a low level negative pressure applied at the wound site, although this technique known as Negative Pressure Wound Therapy (NPWT) has been used in clinical practice for over 20 years, many of the machines that deliver NPWT are complex, noisy and expensive and not really suited for mobile patients or for use in their home. The NEXA Negative Pressure Wound Therapy (NPWT) System has been designed to be simple to use, allowing the patient to manage more of their care in their own home. This reduces the nursing time, aids patient compliance and potentially reduces hospital stays and readmission rates. The savings that the NEXA NPWT System can offer to the NHS are potentially significant and include initial purchase cost, reduced nursing time, reduced hospital stay and lower readmission rates. From a patient perspective the potential benefits include less time in hospital, greater ability to manage their care, increased independence and decreased time off work if applicable. The purpose of the planned evaluation is to compare the NEXA device against standard treatment protocols for hard to heal wounds that are initially treated in the hospital and are sent home. Total costs will be measured as well as patient satisfaction and wound outcomes.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
SKY MEDICAL TECHNOLOGY LIMITED	Evaluation of Neuromuscular Electrical Stimulation as a New Method for Preventing VTE in Acute Stroke Patients	£241,364	£120,682

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Project description - provided by applicants

This project will look at the possibility of creating a new way to treat Acute strokes.

Acute stroke is a condition where the blood supply to the brain is disrupted, resulting in damage to the brain and impairment of body function.

It is most frequently caused by a clot in a blood vessel supplying blood to the brain. Or , it can also be caused by a burst blood vessel causing a leak into the brain.

Stroke can cause permanent damage, including partial paralysis and impairment in speech, comprehension and memory.

15 million people worldwide suffer a stroke each year and 5.8 million people die as a result of it. In the UK approximately 100,000 people a year will suffer a stroke.

Acute stroke patients are often bed-bound meaning that they are at risk from Venous thromboembolism (VTE). This a blood clot that starts in a blood vessel in the leg; this clot then breaks free causing a blockage elsewhere in the body.

Tor prevent this Intermittent Pneumatic Compression (IPC) is used this inflates cuffs on the lower leg moving blood around and preventing clots from forming. But, because of other conditions the patient may suffer IPC cannot be used. This means that about 30% of patients have no way of preventing VTE available to them.

The applicants have developed a patented new method -- the geko(TM) - for preventing VTE. This is a small, battery-powered device that sticks to the back of the knee, where it gently stimulates a nerve causing the muscles in the lower leg to contract and pump blood around the body. It is very comfortable to wear and can be used when IPC cannot.

The company has conducted tests on 1,000 patients that has shown that the geko(TM) is as effective or better than IPC and is far more comfortable than IPC. It can also be used in the majority of patients where IPC cannot. Of the 1,000 patients, 463 were treated with IPC and 11 suffered VTE; 203 were treated with gekoTMand none suffered VTE.

However, to prove this beyond doubt we need to test more patients to be able to legitimately make the claim that the geko(TM) is as good or better than IPC and can be used when IPC cannot.

We propose to study a further 2,500 patients across four Midlands hospitals to enable us to do this.

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VISION TECHNOLOGIES LTD	Protocol development for RCT evaluating wearable Low Vision Aid	£44,347	£22,174

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Project description - provided by applicants
One in nine people aged 65+ will be diagnosed with AMD (age-related macular degeneration). Low vision patients like these are unable to read or identify faces, leaving them unable to engage in most everyday activities. Untreatable sight loss conditions such as AMD cause loss of central vision, resulting in blurry and distorted vision not helped by spectacles. However, the vision which patients have left can be leveraged through sight aids. We have already demonstrated that our SightPlus device can return functional sight to Low Vision patients. Because devices like SightPlus are very new, they have not yet become the standard of care. In order to create patient access to new low vision aids similar to the availability of hearing aids for the hard of hearing, we need to provide evidence to the NHS that the device works and is cost effective. Through this project, we will therefore develop and test a plan to show exactly that. This requires a lot of background research and planning, since conventional ways of showing cost effectiveness rely on methods that are insensitive to issues arising from sight loss. This project focuses on: * Development of a robust methodology for the comprehensive evaluation of modern Low Vision Aids in context of requirements from NHS, NICE, clinicians and patients. * Closing evidence gaps and evaluating product performance in a way meaningful for NHS decision making. * Put all the foundations in place to demonstrate the performance of SightPlus compared to the current standard of care. Successful project delivery will result in a scientific study protocol that is ready to be deployed in a large-scale randomised controlled trial.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
CAMBRIDGE RESPIRATORY INNOVATIONS LIMITED	Clinical effectiveness of N-Tidal C in monitoring Chronic Obstructive Pulmonary Disease in the community (MONITOR)	£238,544	£119,272

Note: you can see all Innovate UK-funded projects here: https://www.gov.uk/government/publications/innovate-uk-funded-projects
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Project description - provided by applicants
About 835,000 people in the UK suffer from Chronic Obstructive Pulmonary Disease (COPD), a progressive respiratory condition. People with COPD experience flare-ups, called exacerbations, which are distressing and can cause permanent damage to their lungs. **Cambridge Respiratory Innovations Limited (CRiL), of Swavesey, Cambridgeshire**, has developed a respiratory monitor which measures CO2 in normal tidal breathing. It is easy for the patient to use and takes just 75 seconds to capture a record. N-Tidal has been designed to measure an established but under-used respiratory biomarker, tidal breathing CO2 waveform shape changes. Parameters captured by N-Tidal have been shown in clinical studies to change more than 48 hours in advance of a COPD exacerbation, whilst the person with COPD is still asymptomatic. **This advanced warning of deterioration will enable COPD patients to increase their medication earlier, avoiding the distress of an exacerbation, improving long-term outcomes, minimising avoidable hospitalisations and reducing healthcare costs.** **This MONITOR project is a clinical effectiveness assessment of N-Tidal C in monitoring COPD in the community.** N-Tidal C is a connected, low cost personal monitor which will measure lung function and communicate the information securely to the healthcare professionals in the Provide respiratory team. This will allow them to advise the N-Tidal C users when they are starting to deteriorate, which will reduce exacerbations. This six month clinical effectiveness assessment will be completed with four cohorts of 25 patients using Provide's COPD services: 1. standard care 2. tele-help 3. N-Tidal C 4. N-Tidal C with tele-help N-Tidal C is treatment agnostic and does not impact the standard medical care of the patient. CRiL has been advised by NICE during the development of N-Tidal C, both with the META tool and Light Scientific Advice. Eastern AHSN is acting as adviser and consultant on the structure of this assessment and Health Enterprise East will complete the clinical effectiveness assessment. SBRI Healthcare commissioned an independent health economic report on N-Tidal which concluded that the **NHS would save £67m per year on the treatment of moderate-to-severe COPD**, assuming that N-Tidal could identify 50% of COPD exacerbations at least 48 hours in advance. The N-Tidal clinical data from recent clinical study completed at Addenbrookes has been analysed by IQVIA Predictive Analytics. **Through machine learning, IQVIA determined parameters from N-Tidal which identified over 80% of COPD exacerbations at least 48 hours in advance.** This algorithm will be used in the clinical portal to provide advice to COPD patients.

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OXEHEALTH LIMITED	Impact of non-contact monitoring of mental health inpatients on safety and experience	£218,933	£109,466

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Project description - provided by applicants
Oxehealth's Digital Care Assistant (DCA) alerts staff to potentially high-risk behaviour and can take vital sign checks (pulse rate and breathing rate) contact-free in Mental Health hospitals. The Oxehealth platform is highly innovative; there is currently no contact free solution to digitally monitor and provide care to Mental Health inpatients. At night time, patients sleep in single occupancy bedrooms. Currently, nurses conduct "eyes on" observations of patients at intervals, such as every 15 minutes, to check that a patient is safe. But the nurses cannot be there to know this all the time. The checks also disturb the patients and are time-intensive for ward staff. The DCA has been well received by patients and staff in these settings, and we now aim to evidence the clinical and financial benefit of Oxehealth to improve patient safety and experience in Working Age Mental Health Hospitals. We will focus on quantifying the reduction in incidents (self-harm and behavioural) and improvement to patient experience.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
AMDEL MEDICAL LIMITED	Non-injectable Arterial Connector (NIC) - Extension	£248,862	£124,431

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Project description - provided by applicants
The NIC is an needle-free non injectable arterial connector which when attached to the three way sampling port prevents accidental injection into the arterial line, blood spillage, colonisation of the arterial hub, onward transmission of bacterial to patients while allowing for standard gas sampling methods. The NIC is an innovative device, patents granted in the EU and USA, with a patent pending in China. It is CE marked and has been commercially available to the NHS for 4 years. The East of England ASHN conducted a clinical evaluation of the NIC across the east of England involving 16 NHS trusts and 10,000 patients. The positive findings resulted in the NIC being made generally available across the NHS. The NIC has additionally been awarded patient safety wards, been subject to clinical papers in the journal Anaesthesia and in 2017 was selected by Health England to be one of the first medical devices to be invited to be part of the inaugural Heath England Accelerator Program. This program led to the NIC becoming part of the first Health England Innovation and Technology Tariff (ITT). The ITT is designed to diffuse the adoption and long term use of products that are innovative and improve patient safety by providing the product on a free of charge basis to NHS Trusts. A further piece of clinical evaluation has been carried out recently which involves attaching an additional NIC to the transducer port attached the arterial line. This small study has shown that by using two NICs - one on the arterial port and another on the transducer port, a closed circuit is created which further reduces bacterial contamination and extents the time that sets can be used on patients. This work has been shared with Health England and it has been agreed that further work in this area needs to be carried out. To allow for the adoption of this further protection for patients a more significant multi centre study needs to be undertaken. We will carry out a study which includes a rigorous protocol, bacterial analysis and health economics to generate the data that demonstrates that through this innovation, there will be decreased risk of wrong route injection of medication, further protection from bacterial contamination and extended use of expensive arterial and transducer sets which will provide very significant savings for the NHS.

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FAT FISH GAMES LIMITED	Evaluation of the clinical and cost effectiveness of MyCognition to support patients with type 2 diabetes	£249,958	£124,979

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Project description - provided by applicants
Fat Fish Games with MyCognition recently launched its App to help healthcare professionals profile a patient's cognitive health in 15 minutes via its MyCQ assessment App, then treat cognitive dysfunction with a personalised intervention called AquaSnap. Five years of research in clinics and real-world environments such as business, residential care homes, schools and colleges show the validity of the App assessment and intervention on users' cognition, mental health, performance and quality of life. Cognitive health, and its decline, are tightly linked with mental and physical health. Research confirms cognitive deficits are significant predictors and major risk factors for depression, anxiety and stress. Alternatively, robust cognitive health contributes to building good psychological resilience, self-management and control, which are major protective factors for good mental and physical health. Cognitive impairment in Type2 diabetes is widely reported. Zheng et al, Diabetalogia 2017, observed significant longitudinal association between HbA1c and long-term cognitive decline. 50% of people with Type2 diabetes have cognitive impairment that affects how they look after themselves and their health. Resulting in poor glycaemic control, raised risk of developing depression and increased cost to the general practice. By addressing cognition people have the opportunity to build mental resilience, better self-manage and change the trajectory of their disease. Pourabbasi et al, BMJ 2016, observed the correlation between poor glycaemic control and cognitive impairment noting the lack of community based validated tools to assess cognition and provide restorative cognitive intervention. In general practice if healthcare professionals wish to assess they refer patients to health psychologists who are only able to profile cognitive function across one or two cognitive domains. These paper based tests are subjective, difficult to scale and adopt, and by the nature of being non-digital are unable to be powered by accurate algorithms to predict and report statistically accurate results. The new long term plan builds on the 5 year forward view that the NHS needs to do more to meet the needs of people with diabetes, building better resilience, improve self-care and prevent and reducing mental illness presentation. By addressing these needs the NHS will deliver national and local healthcare benefits and savings as well as improving safety and reducing harm. This funding will plug the evidence gap of the incidence of diabetes related cognitive impairment in general practice using MyCQ assessment tool and secondly assess the clinical performance and cost-effectiveness the cognitive intervention, AquaSnap, to improve physical and mental health.