

## Results of Competition: SME Support to Evaluate Innovative Medical Technologies: Round 2

Competition Code: 1807\_FS\_OLS\_SMEIMT\_R2

Total available funding is £1.5m

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
ASEPTIKA LIMITED	Asthma +me (CE-marked, Class 1 Medical Device): RCT for digital alternative care pathway to unblock paediatric asthma outpatient clinics.	£232,500	£116,250

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

Asthma is the most common chronic medical condition among children and young people in the UK and an NHS priority (NHS England). 932,000 children in England receive treatment for asthma. It is the most frequent reason for emergency admission and the UK has the third highest risk of death from childhood asthma in OECD nations (Asthma UK).

The current care management programme is based on primary care visits and referral to specialist clinics as required. Asthma UK's recent report "Slipping through the net" identifies the need for referral to specialist paediatric centres for children and young people with difficult or severe asthma as they are at greatest risk without expert care.

Our CE-Marked Asthma+me care solution for children and young people with stable but difficult or severe asthma and will be used to support them and their families keep well at home.

It combines:

- \* self-care technology
- \* education
- \* training
- \* support
- \* data sharing with primary, secondary and tertiary care, to support existing out-patient care

Asthma+me is a solution that helps NHS paediatric centres meet NICE guidelines for self-care and addresses the needs identified by Asthma UK in their "Slipping through the net" report (July 2018).

<https://www.asthma.org.uk/globalassets/get-involved/external-affairs-campaigns/publications/severe-asthma-report/auk-severe-asthma-gh-final.pdf>

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LIGHTPOINT MEDICAL LTD	Evaluation of the LightPath Imaging System in head and neck cancer surgery	£114,938	£57,469

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## Project description - provided by applicants

There has been a 31% increase in the prevalence of head and neck cancer (HNC) in the UK over the past three decades, a trend which is set to accelerate over the next 20 years. Currently, 12,000 people are diagnosed with the disease each year and HNC is responsible for 4,000 deaths annually. By 2035, the incidence rate is predicted to soar by 33% with a 38% increase anticipated in mortality rates.

Surgery is one of the primary treatments for HNC. The complete surgical removal of the cancer, indicated by a clear margin of healthy tissue around the excised tumour, is closely associated with an improved prognosis for patients. However, surgeons are very limited in their ability to ensure that a clear margin is achieved. Reliant on the crude methods of visual inspection and palpation to identify the full extent of the tumour, surgeons frequently leave cancer behind. As a result, patients require additional treatments, including repeat operations, radiotherapy and chemotherapy, which can severely impact quality of life and add a substantial financial burden to the NHS. Therefore, the accurate identification and removal of cancer during surgery is critical to improve patient outcomes and health system efficiencies.

Intra-operative frozen section analysis (FSA) has been used for decades in the NHS to help oncology surgeons try to achieve clear margins, yet its performance limitations are widely acknowledged. It is also time-consuming and labour intensive, adding substantial cost to the NHS. The proposed study will compare the performance and cost effectiveness of a novel intra-operative imaging device, the LightPath Imaging System, against gold-standard histopathology and FSA to assess whether LightPath could offer HNC patients better outcomes at a lower cost to the NHS.

Proven in breast and prostate cancer surgery, the LightPath Imaging System is a CE-marked diagnostic device. The proposed study, which will be the first use of LightPath in HNC surgery, will be run at the world-renowned cancer centre, The Royal Marsden Hospital in London, by the eminent HNC surgeon, Professor Vinidh Paleri. The device promises the potential to significantly improve HNC patient outcomes at the same time as substantially reducing NHS costs. The study will therefore aim to provide initial data to substantiate performance and health economic claims in HNC surgery to aid the rapid translation of the technology into the NHS.

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MD INTERNATIONAL LTD	Docly – a Digital First application for patient centred primary care	£194,688	£97,344

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## Project description - provided by applicants

Docly is a Digital First technology. It was designed by doctors who wanted to make healthcare more accessible to everyone and change the way it was delivered forever - to the benefit of patients, doctors and society. The service is available via an app or website and allows NHS patients to consult a clinician without attending a GP surgery. Once they log in, patients are presented with a list of conditions included in the online service, for which they can seek help. Upon making their selection, patients are guided through an online questionnaire that has been carefully created by doctors using clinical best practice to gather all the information needed to help with that condition. This information is then put forward to a clinician. Patients will receive a notification as soon as their case has been assessed (typically within minutes). They will be given advice, and may have been prescribed medication, or asked to have some tests. If further information is required, the patient will be sent a secure message. If desired clinicians can request a telephone or video call.

Docly has a number of benefits over current digital health services:

\\*Docly is designed to be part of normal general practice and commissioned on a geographical basis. Patients stay registered with their current GP - Docly is an alternative channel for routine care, not a replacement.

\\*The system is linked to the existing electronic health record. This enables safer, more informed decision making and better continuity of care.

\\*Clinicians working within the Docly service are recruited from participating practices, thus increasing "buy in", and bringing with them expert knowledge about how services are structured locally. In addition, patients might then be able to "see" their own doctor online.

\\*It is anticipated that the vast majority of patients will be fully managed online, without needing to revert back to standard care. If face to face follow up is required, Docly aims to have in place a management plan and initiated any investigations.

\\*Docly is an algorithmically driven medical service. This enables us to efficiently utilise our clinicians, thus increasing the number of patients one doctor can safely treat.

\\*The Docly system is designed to deploy high quality medical algorithms supporting best medical practice at scale

\\*Algorithmic healthcare has empowered pharmacists and nurses to take on roles more traditionally filled by doctors

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PERSPECTUM DIAGNOSTICS LTD	LiverMultiScan for clinical decision making in Autoimmune Hepatitis	£242,017	£121,008

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## Project description - provided by applicants

This project aims to improve the standard care of patients with Autoimmune Hepatitis (AIH). AIH is a chronic inflammatory disease of the liver of unknown cause that, if untreated, can lead to liver failure, and death. Whilst there is an effective treatment with steroids and medicines that suppress the immune system, these are not perfect, with many patients experiencing relapses and undesired side effects (such as weight gain, sleep disturbance, osteoporosis, eye problems). Efforts are therefore made to reduce doses where possible. As a result AIH patients require lifelong treatment and monitoring.

Liver biopsy is the gold standard for evaluating the health of the liver but is risky, imprecise, expensive and painful, and therefore not a favoured option for treatment monitoring. Blood tests can identify when the liver is inflamed, but are not sensitive enough to small changes that might indicate a patient's condition is likely to worsen. Better treatment monitoring in AIH has the potential to reduce the negative consequences of a relapse or 'flare', to reduce the chances of progression to cirrhosis from undetected long-term inflammation and to inform treatment more effectively, potentially reducing side effects. It also has the potential to reduce the need to invasive painful and risky biopsies.

Perspectum Diagnostics spun out of the University of Oxford to commercialise MRI technology for diagnosing liver disease. Its flagship product, LiverMultiScan, is a non-invasive procedure that can quantify the health of liver in a simple 15-minute scan. LMS has been successfully adopted worldwide for clinical trials investigating non-alcoholic fatty liver disease. In this project, Perspectum will join with the internationally-recognised experts in the field of AIH in the department of hepatology at Kings College Hospital NHS trust, to address the utility of MRI to quantify liver fibrosis and inflammation in AIH patients, aiming to improve patient care and reduce healthcare costs.

The main aim of the project is to demonstrate how adding a LiverMultiScan into the standard care pathway for patients with AIH may allow better treatment and accurate dosing of steroids thus preventing liver failure and associated NHS costs.

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MYCOGNITION LIMITED	Assessment of cognitive health in a large heterogenous primary care long-term conditions patient population with chronic pain	£62,426	£31,213
Cambridgeshire and Peterborough CCG		£0	£0

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## Project description - provided by applicants

MyCognition was recently launched 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 our 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.

Chronic pain is a widespread condition affecting between 33% and 50% of the UK population, having the additive effect of causing considerable distress and adversely affecting mental and physical health. Some long-term conditions (LTCs) such as fibromyalgia and rheumatoid arthritis have data linking cognition and chronic pain but not so in other LTCs. Healthcare professionals are unable to recommend effective cognitive intervention based on a patient's cognitive profile because there is no simple validated test available. And to date no study has profiled cognitive function across more than one or two domains in LTC patients. Current NICE guidance is to use a combination of physical exercise, painkillers to relieve pain and psychological therapies, such as cognitive behavioural therapy (CBT). Current effectiveness evidence of CBT is mixed with limited data on evidence-based approaches. Therefore, not surprisingly, most healthcare professionals find it difficult to make treatment decisions/modifications to improve patient outcomes. Meanwhile, patients continue to present frequently to general practice and secondary care unable to cope with their pain.

The current consensus is that the NHS needs to do more to meet the needs of people with chronic pain, preventing mental illness presentation and decline and enable patients better manage their physical health. By meeting these needs the NHS will deliver national and local healthcare benefits and savings as well as improving safety and reducing harm.

This funding will help MyCognition develop a study designed to address the above clinical evidence gaps using MyCQ assessment tool and test the impact of the cognitive intervention, AquaSnap. And also help MyCognition assess its technology's clinical performance and cost-effectiveness when used to improve cognitive resilience of chronic pain patients and their mental and physical health.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
NGPOD GLOBAL LIMITED	NGPod	£247,897	£113,075

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## Project description - provided by applicants

Never Events are defined as Serious Incidents that are wholly preventable because guidance or safety recommendations provide strong systemic protective barriers which are available at a national level and should have been implemented by all healthcare providers.

Administering feed or medication via a misplaced nasogastric tube is a never event: a patient should never suffer due to a nasogastric feeding tube being misplaced into the lung. Despite a multitude of safety alerts since 2011, 26 never events still occur between 04/17 and 03/18 - with no real change in incident rate since 2010\.

Moreover, the current state-of-the-art for confirmation of position of nasogastric requires pH testing of fluids from an aspiration of the patient. In a 2014 study, in approximately 50% of cases (Cardiff and Vale University Health Board 2014), fluids can not be aspirated and tube placement is confirmed by x-ray. This can in a multitude of chest x-rays for the patient, delays, and high cost to the NHS.

NGPod (NGPod Global Ltd) is a device that confirms if a nasogastric feeding tube has been positioned correctly, without need to aspirate the patient. This project performs large clinical trials to assess and quantify the positive impact adoption of this technology will have on patient outcomes and the provision of healthcare in the UK.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
RESCON LTD	Improving Me Maternity - Phase 2	£248,997	£124,498

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## Project description - provided by applicants

Improving Me Maternity (IMM) is a clinical and health economic assessment project of Rescon's CE marked Lincus software as a service connected Personal Health Record (PHR) management system for its application in the maternity, and postnatal marketplace. Rescon was commissioned by the NHS Women and Children's Improving Me Vanguard to develop Lincus Maternity as a digital maternity PHR that expectant mums could enter information into.

The Improving Me Vanguard has been merged into the Cheshire and Merseyside Sustainable Transformation Partnership (STP) and supports over 30,000 births every year.

The funding for the development of Lincus Maternity was justified to address poor maternity outcomes in the region along with the mismatch between tariffs and spend. Until the development of Lincus Maternity there was no tool available that would provide expectant mums with a CE marked and digitally held record that could be used to track and manage their health and wellbeing for better pregnancy and postnatal outcomes. Lincus Maternity developments and features are outlined below.

\* Lincus Maternity was co-developed utilising best practice guidelines, research and stakeholder engagement for tracking prenatal and postnatal signs, symptoms and events.

\* Lincus Maternity developments for expectant mums have included signposting to educational content, nutrition and activity management, transition of care tools (health passport), and video consultation.

\* Lincus Maternity allows clinical access to the woman's PHR as a unified collation of all pregnancy related information. It has alert functionality which was an especially important feature for midwives in the co-development sessions.

\* Lincus Maternity allows administration access so management can review clinical activities and outcomes using IMM's data aggregation and analysis tool that is already native to the Lincus platform.

Though Lincus Maternity is now officially live having completed information and clinical governance requirements, iterative technical development continues with planned full release in April 2019.

We have completed early discussions with senior clinical teams and NICE about the best way to assess Lincus Maternity however are lacking the resources to prepare for and complete a full health economic assessment that would provide the evidence to have Lincus Maternity commissioned across the UK and beyond.

IMM will provide Rescon with the resources they need to build in women, family, commissioner, clinician, NHS, NICE and Royal College informed evaluation tools and conduct a controlled trial with the Wirral Clinical Commissioning Group. This will allow the team to gather the evidence that will support future commissioning and sustainability of Lincus Maternity.

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MIRADA MEDICAL LIMITED	Determining the value proposition for DLCExpert in NHS radiotherapy planning	£49,448	£24,724

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## Project description - provided by applicants

For approximately 50% patients diagnosed with cancer, radiotherapy can be offered as a treatment instead of (or sometimes in combination with) surgery or chemotherapy. Radiotherapy directs beams of radiation to specific regions of the body to kill the cancer cells.

Contouring is a critical part of radiotherapy treatment planning which defines where the radiation will be applied and which areas must be avoided. Deep Learning Contouring is a method for auto-contouring organs-at-risk (OAR) and other standard anatomical structures using deep learning. The system is trained to imitate human contouring performance based on hundreds of training cases, and has been found to generate contours with greater clinical acceptance than previous auto-contouring methods.

This project is a collaboration between Mirada Medical, Oxford University NHS Foundation Trust and the Oxford Academic Science Health Network which will develop a study to be carried out with the National Institute of for Care and Health Excellence that clearly demonstrates the health economic benefits of this technology which can simplify the contouring process and mean that these radiation therapies can be offered to more patients in the NHS.

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WILLINGSFORD LIMITED	RCT protocol development to evaluate MPPT in venous leg ulcers	£49,994	£24,997

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## Project description - provided by applicants

The main reason wounds and ulcers have difficulty or fail to heal is infection. For the past decade, it has been standard medical practice to use antimicrobials to treat wound infections, but several clinical studies have shown that they have minimal effects and NICE and the FDA no longer encourage their use. Furthermore, both antibiotics and antiseptics strongly contribute to the creation of antimicrobial resistance, a global health problem.

Micropore particle technology (MPPT) is a novel approach which acts as a passive immunotherapy for wound infection and healing. MPPT disrupts the weaponry bacteria and fungi use against the immune system with the result that the immune system regains control of the wound and the wound healing process. In a comparative clinical study MPPT removed wound infections and initiated healing 60% quicker than an antibiotic and an antiseptic and it reduced the number of hospitalisation days by 31%. Annually in the UK alone, 2.2 mill wounds require treatment causing direct costs to the NHS of £5.3 bn. Estimates indicate that MPPT can reduce the costs of wound care by 21% and can assist many patients who are strongly affected by wounds. MPPT is patented and expected to meet a global unmet clinical need. MPPT is not antimicrobial and will not contribute to the creation of resistance.

A key factor in supporting the introduction of a new healthcare technology is to obtain an appraisal from NICE, which evaluates all data and offers an opinion on the health benefits of the approach. The purpose of this project is to prepare the first phase towards receiving such an appraisal. Once achieved, this will be used to support the introduction of the technology in the UK as well as to support export efforts as NICE recommendations are closely studied in most countries worldwide.

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