

## Results of Competition: SME Support to Evaluate Innovative Medical Technologies Round 5

Competition Code: 1909\_FS\_OLS\_SMEIMT\_R5

Total available funding is £1.2 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
FIRSTKIND WOUNDCARE LTD	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.

To 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 geko(TM) and 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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Participant organisation names	Project title	Proposed project costs	Proposed project grant
BRAINOMIX LIMITED	Evaluation of the impact of the e-Stroke Suite across the NHS	£498,869	£249,434

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## Project description - provided by applicants

**Stroke is a life-threatening emergency** most commonly caused by a blockage to a blood vessel supplying the brain. Early treatment to unblock the affected blood vessel maximises the chance of a good recovery. The blockage to the blood vessel can be treated with either "clot-busting" drugs (thrombolysis) or removal under X-ray guidance up through the groin (mechanical thrombectomy). For every minute that goes by before a major blockage is treated two million nerve cells die. Both thrombolysis and mechanical thrombectomy are associated with potentially life-threatening side-effects and so **accurate and timely patient selection is crucial for good quality stroke care**. However, most patients arrive at non-specialist hospitals where there is not always the expertise available to support quick and accurate decision-making. This means that stroke treatment is often inconsistent and underused across the UK.

The **e-Stroke Suite** is a software solution built by **Brainomix**, a UK-based company and spin-out from the **University of Oxford**. The e-Stroke Suite uses **artificial intelligence** methods to interpret stroke brain scans and help doctors make the right choices about treatment and the need for specialist transfer of patients with confidence. It also provides a platform for doctors to share images between hospitals avoiding the delays to sharing scans that often occurs. The e-Stroke Suite has been shown to **improve patient treatment rates** in individual hospitals across mainland Europe. The aim of this project is to show the impact on patient care across a network of hospitals in a variety of different NHS settings. The impact on patient care will be measured using existing hospital performance quality frameworks and the change in treatment rates after introduction will be used to inform health economic models.

The results of this work will be used to inform future tenders for artificial intelligence stroke solutions in the NHS and abroad. There is a clear signal in the **NHS Long Term Plan** that artificial intelligence stroke imaging support should be widely adopted, and this project will position Brainomix to fulfil this vision. It will also help inform evaluations undertaken by guideline bodies such as NICE, the National Institute for Health and Care Excellence.

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BOLD HEALTH LIMITED	Personalised digital therapy and self-management programme for the management of Irritable Bowel Syndrome	£99,611	£49,806

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## Project description - provided by applicants

Bupa and the NHS estimate that 15-20% of the UK population is affected by Irritable Bowel Syndrome (IBS). IBS is a long-term condition with unexplained symptoms that can severely impact daily life. The objective of this project is to provide an at-hand, personalised, and set of behavioural-change and stress-reduction tools to support self-treatment for IBS sufferers.

A treatment mobile app Zemedy has been invented by Bold Health, based on the highly effective gold standard intervention of CBT for IBS, which is included in the NICE guidelines and currently offered offline by therapists. Zemedy will guide users in their treatment such that it can be delivered fully digitally, conveniently at both scale and cost. The main aim of this project is to gain real-world clinical evidence, user-feedback and understanding how Zemedy could be prescribed and accessed within the NHS setting. In parallel, the clinical trial required to gain clinical evidence of the benefits of Zemedy adoption will also be designed and a research protocol developed.

In line with the NHS long-term plan, Zemedy will assist with the Digital transformation of the NHS providing digitally enabled and remote care, empowering people to control their therapy options, with a solution that allows patients to undertake treatment at a time and place that is convenient for them. Zemedy will enable patient-centred management of IBS helping treatment compliance and reinforcing the treatment benefits.

The project, led by Bold, will utilise its partnerships with clinical centres within University College London Hospital and Manchester University to undertake a small user-trials within the NHS setting to generate real-world data. These will provide essential data and information regarding the integration of Zemedy within the current NHS Clinical pathway, establish usability and acceptability to patients and clinicians. The Health Economic evaluation of Zemedy will also be completed by our sub-contractor CHEATA.

Crucially, the output of the project will provide the stepping-stones required to undertake the necessary clinical-trial of Zemedy to enable evidence to be created enabling adoption of Zemedy across the NHS.

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DELIRION LIMITED	DeliriOn - Digital Assessment Tools	£194,834	£97,417

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Project description - provided by applicants

DeliriOn - Online toolkit to diagnose and prevent Delirium

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
INSIGNIA MEDICAL SYSTEMS LIMITED	ACT-FAST. ACcurate diagnosis for Triage and treatment and AI enabled STroke care Networks	£113,371	£56,686

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## Project description - provided by applicants

Stroke strikes every five minutes in the UK. It can happen to anyone, of any age, at any time and are a medical emergency where urgent treatment is essential. The sooner a person receives treatment for a stroke, the less damage is likely to happen.

Stroke is a common and devastating condition which is most commonly caused by a blockage of an artery or bleeding from an artery in the brain.

Of patients that have a stroke currently, a third die, a third are disabled and a third survive to live a normal life. Despite advances in recent preventative stroke care there are still around 100,000 strokes in the UK per year.

The diagnosis of stroke remains a clinical one and is only confirmed with medical imaging, typically a CT scan. Accurate diagnosis also relies upon the scans being read in a timely manner, correctly and then sharing images with specialist centres where treatments can be planned and delivered.

Whilst there have been major advances in stroke care, there are still significant delays in the diagnosis as it is often difficult to detect on the initial scans and current technology does not readily support scans being shared in a timely manner with specialised centres. This can lead to delays in treatment for stroke victims and also the unnecessary transfer of non-stroke patients to specialist centres.

The ACT FAST project aims to overcome these problems by evaluating the use of technology that enables sharing imaging rapidly across hospitals and also using the platform to begin to test advanced Artificial Intelligence (AI) tools that will aid the clinicians in reading the scan to diagnose stroke.

Such tools are already deployed in other countries with tangible benefits and efficiencies in stroke care. As well as assessing the performance of how such a sharing platform could augment delivery of stroke care in the NHS, we will also use an already established stroke research data set and create a repository on which clinical decision support AI based tools can be first tested and second delivered.

Speeding up access to stroke imaging in a regional network and providing access to advanced decision support tools will reduce the time to make more accurate diagnosis. The sooner a person receives treatment for a stroke, the less damage is likely to happen and the more likely they will be to recover and lead a normal life afterwards.

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RINICARE LIMITED	SAFE Evidence Generation Project	£181,038	£90,519

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## Project description - provided by applicants

In-patient falls at hospitals are a massive concern for both the NHS and for patients. It is estimated that a typical 800-bed acute hospital experiences approximately 1,500 in-patient fall events annually. Rinicare has developed the SAFE system, which uses a non-invasive thermal sensor and a proprietary AI algorithm to automatically and almost instantaneously identify the position of a patient in and around a hospital bed. It allows patient activity to be monitored discretely and remotely, and it provides early warning to a caregiver when the patient enters a position of potential risk to the patient.

In this project, Rinicare will deliver a comprehensive trial collecting evidence of the impact the SAFE system has in a hospital ward; from preventing patients falls to reducing the number of days a patient has to stay in hospital due to fall accidents. The analyses will also include cost-benefits and other measures to show how the SAFE system can help the NHS deliver even better service and quality of care to at-risk patients.

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MICRIMA LIMITED	Using MARIA® alongside Magnetic Resonance Imaging (MRI) in women; a prospective, data-collection study to assist in characterising and improving MARIA® lesion identification.	£154,377	£77,188

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## Project description - provided by applicants

Breast MRI is an imaging modality used frequently in the surveillance screening of younger women who are unable to have a mammogram. It is also used within diagnostic clinics for younger patients or those who have challenging cases that are not confirmed by other imaging. Breast MRI is the 'gold standard' imaging modality, capable of imaging even small irregularities within the breast volume. However, breast MRI is an expensive and lengthy process, with a typical MRI taking around 60 minutes. Patient experience is also an important consideration with MRI, as is the use of a contrast agent.

This study intends to explore the possibility of using radio-wave imaging in place of MRI. This idea is in its infancy, but this research would enable a valuable dataset to be constructed, containing data on the imaging of approximately 25 patients who have undergone a breast MRI scan alongside the trial imaging procedure, known as a MARIA(r) scan.

MARIA(r) is a CE-marked device specifically designed for the imaging of female breasts. It consists of a patient bed with a scanning unit housed underneath an aperture in the patient bed. The patient lies face down on the bed with their breast through the aperture and the scanning unit rises to meet the breast. The scanning unit contains a hemispherical antenna array that is customised to fit the patient with a range of removable ceramic inserts, ensuring a close fit that is non-compressing. Including fitting, a MARIA(r) scan takes around 20 minutes and research to date has shown the modality to have a high-level of patient comfort. Patients who will be having a breast MRI will be invited to also have a MARIA(r) scan performed and it is anticipated that recruitment will comprise of patients who are having their screening MRIs due to risk as well as patients having MRI as part of other diagnostic imaging due to symptoms of the breast. The data obtained from this research project will be used to further develop the MARIA(r) system for this patient population, building on previous research that has demonstrated an ability to locate cancer, particularly in dense tissue.

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ODI MEDICAL LTD	The value of monitoring micro-circulation status in the management of trauma	£53,060	£26,530

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## Project description - provided by applicants

The cells and tissues in the human body rely on the circulatory system getting oxygen to them to enable them to function and survive. This is termed microcirculation and can be impacted by a variety of diseases and trauma, including shock, sepsis and cardiovascular events. However current clinical practise focuses on managing the macrocirculation of the patient. The assumption is that macrocirculation and microcirculation are aligned (coherent) and working in parallel . This may not be the case, and loss of coherence may explain the observed failure of interventions (resuscitation: treatments and therapies) aimed at normalising global oxygen delivery, where tissue circulation may become de-coupled from the systemic circulation by local disease processes. Leading clinicians agree that resuscitation should be targeting the true end point: delivery of oxygen to the cells, and have proposed that microcirculation needs to be monitored so that early stage hypoxia and tissue damage can be detected earlier, enabling adjustment of the intervention therapies to improve tissue and organ function and outcomes.

ODI Medical has developed a non-invasive microcirculation monitoring system (recently CE marked). The system has been shown to assist in the management of acute heart failure patients on heart and lung machines and assists in the management of premature babies.

The Company now plans to carry out clinical studies with the Intensive Care Units at a major NHS hospital, Leeds Teaching Hospital Trust, to establish how microcirculation status can assist the clinical team in the management of patients with shock and severe trauma.

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