

Results of Competition: SME Support to Evaluate Innovative Medical Technologies: Round 3

Competition Code: 1811_FS_OLS_SMEIMT_R3

Total available funding is £1,500,000

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
INSTANT ACCESS MEDICAL LIMITED	MyVytalCare - Enabling Patients to Effectively Manage Their Long Term Conditions	£211,647	£105,824

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

MyVytalCare is a comprehensive, multilingual, personal care record, hosted on HSCN, that empowers patients to take greater control over their treatment and monitoring of their long term conditions. It is available as a resident app on patients' mobiles, with automatic daily extracts from healthcare provider IT systems

MyVytalCare automatically analyses the incoming data and initialises our relevant NICE evidence-based personal care pathways, specific and unique to each patient, driven by the authoritative data from provider systems. The personal care pathways drive interactive alerts and follow-up on the mobile for all the actions each patient needs to take to get their best health outcomes, including interactive advice to promote well-being and prevention.

MyVytalCare significantly reduces the call and recall burden on general practices for long term conditions, health checks and immunisations saving time and resources and increases patient safety.

MyVytalCare puts the patient at the centre through their personal, multilingual app on PCs, iPhone and Android mobile devices to enable their best care outcomes, reduce inequalities and premature mortality, and improve independence and quality of life.

This study will demonstrate the significant improvements in quality of life and efficiency savings MyVytalCare can provide for patients and health care professionals dealing with long term conditions.

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PERSPECTUM DIAGNOSTICS LTD	Quantitative Magnetic Resonance Imaging in Biliary Disease: Health Economics Study	£238,435	£119,218

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Project description - provided by applicants

Biliary diseases are hard to diagnose and monitor, resulting in patient anxiety. There is an increasing incidence of biliary diseases, due in part to increasing levels of obesity, leading to increasing incidence of mortality. To date, there are no biomarkers for BD. We aim to redress this situation via a novel quantitative imaging technology, _MRCP_+.

Chronic inflammation of the biliary ducts leads to hardening, obstruction, and eventual destruction, particularly in primary sclerosing cholangitis (PSC), a chronic, immune-mediated biliary disease. Currently, liver transplantation is the only proven life-extending intervention. PSC is designated an "orphan" disease (low incidence), however drug development has proved unsuccessful to date due to a lack of a reliable clinical endpoint. Post-transplant biliary complications remain a major cause of morbidity and mortality for all liver transplantations (approximately 14,000 per year in US/Europe).

Currently, an invasive endoscopic procedure, ERCP, is a recommended modality for assessment of biliary disease, though ERCP is invasive and associated with significant risks of morbidity. This has encouraged take-up of MRI-based MRCP, which is non-invasive. Unfortunately, the advantages of MRCP are frustrated by its current limitations, a situation that this project aims to transform.

A position statement from the International PSC Study Group outlines areas of unmet need for imaging techniques in PSC, including (1) early detection of disease, (2) the determination of disease stage, activity and prognosis, (3) a clinically meaningful definition of dominant bile duct stenosis, and (4) the early detection of cholangiocarcinoma. A recent survey by PSC Support highlighted that patients experience significant anxiety due to the uncertainties surrounding the prognostics limitations. Thus, there is a clear need for effective, non-invasive staging and monitoring of disease progression in PSC and related biliary diseases.

Perspectum Diagnostics was spun out of the University of Oxford with the express aim to develop and commercialise technology for liver disease applications and its flagship product, Liver_MultiScan_, has been successfully adopted worldwide. Its new product, _MRCP_+, is the only image processing software to enhance and quantify MRCP images. We aim to gather substantial clinical evidence in support of _MRCP_+ to enable it to be deployed clinically throughout the world.

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HEALTHY. IO (UK) LTD	Home based digital urinalysis in antenatal pathway	£205,700	£102,850

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Project description - provided by applicants

Healthy.io will be testing smartphone-based home urine testing for antenatal care in 100 women in the Royal United Hospitals Bath NHS Foundation Trust. We aim to assess how smartphone-enabled home urinalysis, combined with home blood pressure measurement, improves patient safety through proteinuria earlier detection, reducing demand on health services by avoiding face-to-face visits and improving patient experience in a cost-effective and scalable way.

Using computer vision and user-centric design, Healthy.io's is the first company to turn the smartphone camera into a clinical-grade medical device. Our urinalysis product (Dip.io) is the first CE accredited and FDA cleared smartphone-enabled automated urinalysis device. Built around the 10 parameter dipstick, a self-testing kit and a smartphone application, the device enables lay users to self-test for protein and other analytes in their urine, in the comfort of their home, with no quality compromise. Our proprietary algorithm and cloud-based service allow for interoperability and integration with any clinical system. Results are immediately available to clinicians for follow-up.

Blood pressure monitoring and urinalysis are part of routine antenatal care. Our 'maternity care box' combines our urinalysis test kit and a blood pressure monitor enabling women to self-test before and if needed, between visits and reliably share results with their midwife.

The study will last 12 months starting July 2019. A maternity care box will be offered to 70 women with uncomplicated pregnancies and 30 women with hypertensive pregnancies. They'll be instructed to conduct the urine test and BP measure before attending their antenatal appointment. Women with hypertensive pregnancies will receive additional Dip.io test kits to increase testing frequency between appointments. Shifting routine testing to the home has the potential to:

- * Improve women's experience and involvement in their health
- * Reduce appointment time spent on routine testing to enable midwives to focus on clinical and patient-facing activity.
- * Mitigate against risks in at-risk pregnancies through more frequent home testing to early detect complications (e.g. preeclampsia).
- * reduce up to 60% of Day Assessment Unit visits needed for at-risk pregnancies during the third trimester (if normal results).
- * Embed electronic results directly into clinical record.

This model has been implemented in non-NHS healthcare settings and has received positive feedback from both patients and clinicians. This study will evaluate the feasibility and acceptability of the model in an NHS setting, to generate evidence to help scale the innovation, make product improvements and test the Budget Impact Model designed by Kent Surrey & Sussex AHSN.

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SENSYNE HEALTH CO LIMITED	Evaluation of an enhanced version of GDM-Health including a physical activity intervention module	£240,996	£120,498
King's College London		£0	£0
University of Oxford		£0	£0

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Project description - provided by applicants

This project will evaluate a new way to improve the health and wellbeing of women with gestational diabetes (GDM) and their babies. It uses a digital health app called GDM-Health which helps mothers and their health care professionals manage blood glucose control, to deliver a life-style intervention targeted at improving physical activity levels.

GDM is a condition in which a woman develops high blood glucose levels during pregnancy, increasing the risk of complications for the mother and baby. Poor control of the condition increases the risk of babies that are too large, have low blood glucose and are jaundiced. Mothers are at increased risk of pre-eclampsia and caesarean section. Long term, mothers and children are at higher risk of being overweight and developing type 2 diabetes.

It is known that increasing physical activity in mothers is an effective way to bring blood glucose levels closer to normal. This has real benefits in reducing complications during pregnancy and problems during birth caused by larger-than-average babies. It also helps mothers to lose weight quickly after birth, and reduces the risk that they go on to develop type 2 diabetes. Unfortunately, mothers often feel isolated, tire easily, and lack the motivation to maintain levels of physical activity during pregnancy. It is therefore very important that mothers with gestational diabetes receive continuous support and encouragement. We have developed a programme; '_Stay Active_', for women with GDM that includes several behavioural change techniques such as motivational interviews and goal-setting, and provides follow-up contacts to help mothers improve or maintain their physical activity levels during pregnancy.

In this project we will test if an updated version of GDM-Health can effectively deliver the '_Stay Active_' programme to mothers with GDM. The resulting GDM-Health '_Stay Active_' system will reinforce behaviour change using goal setting, performance feedback, monitoring of activity levels and encouragement from the healthcare team. GDM-Health '_Stay Active_' will also provide an easily understood resource of NHS-approved information and videos on how to carry out simple exercises.

The study will follow PA levels, control of blood glucose levels, and outcomes for mothers and babies together with patient satisfaction with care, app usage and overall costs of treatment. It will provide evidence on the clinical efficacy and healthcare costs of GDM-Health '_Stay Active_' in a group of patients for whom we know that physical activity is beneficial.

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INAVYA VENTURES LTD	AVATR CE Mark medical device:: study planning and preparation (Option 1)	£36,160	£18,080

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Project description - provided by applicants

The project supports the management of long-term conditions related to Cardiovascular Diseases (CVD), which are the leading cause of death globally, representing 31% of all global deaths. People with cardiovascular disease or who are at high cardiovascular risk (due to the presence of one or more risk factors such as **hypertension, diabetes, hyperlipidaemia** or already established disease) need early detection and management using counselling and medicines, as appropriate.

This proposal directly addresses the challenge by creating a service that helps improve methods and systems within a local health ecosystem based on the needs of the citizen at home and in the community, whereby pharmacist-led services in GP practices and community pharmacies are fully engaged as a key healthcare resource. The project aims to prevent CVD and improve clinical outcomes, helping to reduce costs and demand on NHS hospitals and GP practices. In doing so, the project will increase patient access to innovative technologies.

The project is led by **Inavya Ventures Ltd**, a UK-based SME that has created the CE marked medical device 'AVATR' to help patients with chronic diseases, with current deployment at the National Heart Centre in Singapore and Einstein Hospital in Sao Paulo. Deployed on a smartphone, AVATR provides management and remote monitoring of data from medical-grade wearables and also contextual information from other sources, such as diet, exercise, GPS location, local air quality. Take-up of AVATR requires testing the performance of AVATR in order to quantify clinical and operational improvements, and cost-saving to NHS.

The project is supported by **Firza Primary Care** (unfunded), which has access to over 600,000 NHS patients and delivers pharmacist-led clinical support services to 90 GP Practices throughout England; and **GreenLife Pharma** (unfunded), which provides technical, commercial and NHS clinical support services to 50 pharmacies to improve income growth and productivity while reducing expenditure. 42 of these pharmacies are owned by its parent company, Imaan Healthcare. During this four month project we aim to develop a detailed feasible plan to generate evidence directly from a local healthcare ecosystem of the clinical and cost-saving benefits of AVATR to the NHS. This evidence will enable AVATR to engage with the NHS and other markets, delivering commercial benefits to the partners, clinical improvements and cost saving to the NHS, and improved service to patients and citizens.

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VISIOPHARM UK LIMITED	Augmented Pathology using Artificial Intelligence	£249,580	£124,790

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Project description - provided by applicants

Medical science is openly discussing a future where cancer is a chronic disease, the vision being inspired by newly developed extremely specific and effective drugs. An example is Herceptin (trastuzumab) that prevents both cancer cell proliferation and stimulates the immune response. Cancer patients treated with Herceptin without actually being HER2 positive (false positive) risk serious side effects, while the drug is ineffective. Safe and resource-optimal use of the new drugs therefore requires increased precision in the diagnostic work. Prioritization of medical expenses will not suffice to finance the increased cost of cancer with the new efficient drugs, as cancer incidence is expected to increase by 50% by 2025. To make new treatments available for the many patients benefitting from them, rationalization and automation of time-consuming, and labour-intensive, workflows is required. While that future will be a tribute to the technological development, it will require tools to effectively address the practical and economic challenges that follow. Visiopharm's image analysis in digital pathology solution is one of the tools. The solution will help society get the greatest health and economic benefits from their investments in new and upcoming, highly effective but very expensive drugs.

Using image analysis Visiopharm has developed automated digital pathology for fast and accurate diagnosis of tissue samples. Trials have shown good concordance with pathologist and opportunity to reduce inconclusive cases. Overall, the solution fulfils three urgent needs in the cancer diagnosis.

Increasing data and processing quality requirements as well as new cancer specific drugs have resulted in the need for standardized and more accurate quantification. The solution includes resources for standardization of workflows, and patented technology, reducing variability and accuracy.

The technology replaces a time-consuming manual work process. The solution is designed to optimize the use of pathology resources, allowing for workload redistribution where the technical aspects of image analysis can be taken by technicians.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
DIAGNOSTICS FOR THE REAL WORLD (EUROPE) LIMITED	Planning project for evaluation of SAMBA POC testing at HIV PrEP sites	£49,790	£24,895

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Project description - provided by applicants

DRW has developed a simple, point-of-care (POC) nucleic acid test (NAT) platform, called SAMBA, which allows complex, high-performance HIV tests to be carried out in doctor's offices, pharmacies and other primary and community health-care settings.

SAMBA was designed specifically for use in such settings, whereas currently-used complex nucleic acid technology is not designed for use outside of complex, centralised laboratories with highly skilled staff. DRW has two CE marked tests: one for early HIV detection and one to estimate HIV viral load for treatment monitoring. The tests are currently used in remote settings in Zimbabwe, Malawi and Uganda but are equally suited to point-of-care settings in the UK and other developed countries.

The proposed project will investigate how SAMBA can be integrated with NHS sites providing new preventative treatment for people at very high risk of contracting HIV. During this planning phase DRW will work with a clinical consultant in the NHS and a software engineer to identify and contact clinical sites offering this treatment. DRW together with the consultants will then plan how SAMBA results reporting can be integrated with Laboratory Information Management Systems in use and develop a protocol for evaluating SAMBA for HIV diagnosis at these sites.

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POLYPHOTONIX LIMITED	Real-world Evaluation of Noctura 400 sleep mask for Diabetic Retinopathy (RENDER)	£249,847	£124,924

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Project description - provided by applicants

The Noctura 400 Sleep Mask is a novel and innovative treatment for Diabetic Retinopathy and Diabetic Macular Oedema, which are the serious and sight threatening complications of Diabetes.

The mask offers a completely new approach to treatment of these conditions as it delivers a low level of light into the eye while the patient sleeps. It is non-invasive and offers a more pleasant experience to patients compared to the current treatments which involve injecting a high cost drug directly into the eyeball or using lasers to cauterise leaky blood vessels in the retina.

This device costs a fraction of the spend on the current standard treatments and its adoption by the NHS will save a large amount of money on the drugs bill, as well as increasing efficiencies, reducing waiting and recall times and will improve clinical outcomes and give patients a better experience.

As well as treating eye disease, Noctura 400 can be used at an earlier stage to prevent retinopathy from developing and this would benefit both patient's quality of life as well as save the NHS money by avoiding progression to the hospital setting and the cost of the expensive clinical treatments and procedures given to patients today.

Noctura 400 has completed clinical trials and has been approved for use as a medical device, however it has not been widely adopted in the NHS as clinicians and managers require more proof of its cost effectiveness in the real world.

The key objective for this project is to follow patients using the Noctura 400 Sleep Mask in the NHS setting, collect both clinical progress and financial impact data and analyse the outcomes in the form required by hospital and CCG managers, presenting a clear and unequivocal case for widespread adoption in the NHS.

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ELAROS 24/7 LIMITED	The Digital Bladder Diary: Reducing unnecessary referrals to secondary care and empowering GPs to make clinical decisions closer to the patient	£137,962	£68,981

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Project description - provided by applicants

At some point in their life, two out of three adults will have a bladder related problem.

Diagnosis involves keeping a 'bladder diary' where the patient records on paper, the time, urgency and volume of urination.

Elaros has developed with clinicians and patients a CE marked Digital Bladder Diary to speed up the diagnosis of patients with Lower Urinary Tract Symptoms (LUTS), in primary, community and secondary care which aims to replace the current, paper-based diary.

The Elaros Bladder Diary is an innovative, digital, system where information is captured on a hand-held device. The device is discreet and convenient, and the information captured is 100% secure. The information gathered from the diary is uploaded remotely and automatically to the cloud which provides an immediate indicative clinical diagnosis and recommended clinical action. The system also produces lifestyle alerts, to help patients manage their own condition.

This project aims to further develop the bladder diary by enabling the collection and analysis of real-world data so as to fully evaluate the clinical and health economic impact of the product, whilst capturing usability data.

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APARITO LIMITED	Medication Optimisation using mHealth engagement	£47,311	£23,656

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Project description - provided by applicants

The purpose of this project is to assess the utility of Atom 5, a direct patient-facing technology provided by Aparito, to improve adherence and persistence with oral anticoagulation through increased engagement with a cohort of elderly patients with atrial fibrillation (AF), the commonest form of heart rhythm disturbance that is responsible for over 20% of all strokes.

Oral anticoagulants (OACs) are highly effective in stroke prevention in AF and their increased use is an NHS priority. Increased uptake of OACs, particularly of the newer non-vitamin K-antagonist OACs (NOACs), has recently been shown to significantly reduce the annual number of AF-related strokes in England. However, concerns remain about poor adherence and persistence with OACs resulting in suboptimal stroke prevention. We found that 15% of patients do not continue their NOAC in the community after their initial 2-month supply from Barts Health NHS Trust runs out. Other UK studies have reported a similar rate of early non-persistence, increasing to 25% by 12 months.

Data are as yet limited on the ability of technologies such as Atom 5 to improve healthcare, in this case through improved medication adherence and persistence, in an elderly population who may be less tech-savvy, yet it is precisely this population that potentially has most to gain from innovative approaches. This project will involve patient engagement to understand their needs and acceptability of such a solution, a clinical trial design developed in partnership with key opinion leaders and a NICE Scientific advice procedure to ensure a data generation strategy that is patient centric, feasible and able to demonstrate clinical and economical value

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
AMPERSAND HEALTH LIMITED	Ampersand Health Digital Therapeutics Platform	£183,550	£91,775

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Project description - provided by applicants

Ampersand Health is a social enterprise that's developing the first clinically validated digital therapeutic for people with long term inflammatory conditions. Our intervention helps patients take greater control of their own care by providing them with actionable information therapy via a mobile application; and allows clinical teams to monitor their condition and intervene when necessary via a SAAS platform.

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270 VISION LTD	BPMpathway Remote Patient Reporting	£38,360	£19,180

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Project description - provided by applicants

BPMpathway is a cost-effective remote patient assessment platform that supports orthopaedic patients through their preparation for surgery, during the acute hospital phase and, crucially, supports them throughout their rehabilitation, whilst providing clinicians with the information they need to remotely assess their recovery and prioritise resources accordingly. Using medical-grade technology, patients can be released early from hospital with personalised post-operative programmes by clinicians who have confidence that they will have sufficient, accurate information about their patients' recovery to assess remotely their on-going progress. Outpatient support can consequently be prioritised to those who need it most rather than the current standard package offered to all.

Patients leave hospital with the reassurance that they are being overseen by their surgical team and have clear guidance as to what to expect during their recovery programme. As a result, patients are typically more engaged with their rehabilitation and motivated to achieve their targets, thereby improving PROMs.

****GATHERING EVIDENCE TO PROVE THE FOLLOWING CLAIMS WILL FORM THE FOCUS OF THE PROJECT:****

* ****Early supported patient discharge****, potentially on the same day as surgery, thereby reducing in-stay time and cost and improving patient flow.

* ****Efficiently-targeted care across the critical weeks post-surgery**** by prioritising resources to those patients needing them the most within an expanded group of recipients.

* ****Decreased readmission rates**** through the early identification of developing complications.

* ****Enhanced patient recovery programmes**** by harnessing technology and innovation to create personalised post-operative support.

* ****Improved patient motivation and engagement**** with feedback, reassurance and encouragement playing an important role in improving patient outcomes and PROMS scores.

* ****Cost -effective deployment**** -- the initial outlay being outweighed by the potential cost savings

****THE INNOVATION COMES FROM THE PATENTED TECHNOLOGY**** that has resulted in a disposable sensor model delivering a low per patient cost. BPMpathway requires little upfront investment other than the cost of providing each patient with a single sensor, who then run the software on their own tablet.. The opportunity afforded by BPMpathway to reduce in-stay times, costs and readmission rates suggests that the potential ROI could be substantial.

No other remote patient assessment system has the same credentials as BPMpathway, which uniquely offers cost-effective, reliable and patented award-winning technology in support of remote patient assessment undertaken by clinicians.

In 2018, 270 Vision won the prestigious ****Outstanding Achievement Award**** at the National Medilink UK Healthcare Business Awards and BPMpathway was named ****Best Digital Health Platform**** in the 2018 Juniper Research Future Digital Awards.

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WALK WITH PATH LIMITED	Path Finder: A Health Economics Evaluation of Visual Cues as a means to Reduce Falls in Parkinson's	£33,189	£16,594

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Project description - provided by applicants

Every year the NHS spends around £2.3 billion on falls. Falls are due to a variety of reasons including neurological conditions such as Parkinson's disease. A symptom of Parkinson's called 'freezing' causes sufferers to suddenly feel as if glued to the floor and unable to move. This often happens mid walk and is a major cause for instability and falls, leading to up to 70% of falls in Parkinson's. Falls can lead to serious injuries such as hip fractures, or in some cases they may even cause death. Path Finder reduces the time spent freezing as well as how often a person freezes, by projecting visual cues. The device hooks over the users shoes and projects a green

laser line in front of each opposing foot. This triggers walking and helps the user to walk more fluidly and independently.

Our proposed project will begin to assess the clinical cost effectiveness of the device in the NHS. We will commence with a small scale study in a NHS hospital to start gathering data to support the cost effectiveness of the device. We will then work with NICE to critically analyse our evidence to date. This will be used to help plan our route to sell into the NHS. Path Finder has been on the market throughout the European Economic Area (EEA) since June 2017\.

We sell mainly directly to customers and through some distributors. Selling into healthcare systems such as the NHS, however, will be our biggest source of revenue.

Currently, healthcare systems such as the NHS do not have a single good solution to falls and freezing in Parkinson's disease. Walking canes and frames are used for support, but they can be bulky, making them hard to maneuver when freezing and when in the home (where freezing most often occurs). Physiotherapy is also used, and although it can be effective, it carries a 70% non-compliance rate, meaning that people do not do their exercises. As such, it becomes an expensive and ineffective solution.

Path Finder offers a new method to alleviate a specific symptom in Parkinson's disease, which has been demonstrated to cause the majority of falls for this population. As such, Path Finder holds great promise in reducing falls and the human and economic costs that follow.

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

Results of Competition: SME Support to Evaluate Innovative Medical Technologies: Round 3

Competition Code: 1811_FS_OLS_SMEIMT_R3

Total available funding is £1,500,000

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
EXROID TECHNOLOGY LIMITED	eXroid Electrotherapy for Haemorrhoids NHS Value Research	£49,311	£24,656

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

Project description - provided by applicants

eXroid is a healthcare company bringing an established medical treatment for Haemorrhoids to the UK following significant advances in technology. The Electrotherapy treatment has a track record of over 155,000 successful treatments worldwide and over 2,800 in the UK. NICE have evaluated and published constructive guidance regarding the electrotherapy treatment, which is delivered by Consultant Surgeons.

There is no need for sedation or anaesthetic, and there is no recovery time, so patients can usually get back to normal activities straightaway. This is a significant health benefit to patients in comparison with other surgical solutions and many patients feel instant relief from the moment they leave the clinic. This has the potential to provide significant resource and cost savings for the NHS.

Note: you can see all Innovate UK-funded projects here: <https://www.gov.uk/government/publications/innovate-uk-funded-projects>

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