

Innovate UK

Results of Competition: Biomedical Catalyst 2018 Round 1 Feasibility Studies

Competition Code: 1803_BMC_R1_FS

Total available funding is £2,000,000

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
IHG PHARMACO LIMITED	Feasibility of Manufacturing a Reproductive Biomarker Test and Scoping for NHS Adoption in Primary Care	£200,000	£140,000

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

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Funders Panel Date: 06/09/2018

Project description - provided by applicants

The project comprises determining the feasibility of making a manufactured form of a diagnostic test that can utilise capillary electrophoresis to detect an important gene associated with human health.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
S-BAHN MEDICAL LTD	Bioreactor and Thiel Cadaver-based Feasibility Evaluations of a Novel Magnesium Wireform Bioresorbable Vascular Scaffold	£192,222	£134,555
Golden Jubilee National Hospital		£4,920	£4,920

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Project description - provided by applicants

S-Bahn Medical is a medical device company based in Glasgow, Scotland who are developing a Bioresorbable Vascular Scaffold (BVS) or resorbable stent for the treatment of atherosclerosis. Atherosclerosis occurs due to the accumulation of plaque in an artery causing it to narrow and reduce blood flow to and from the heart. This condition is commonly referred to as Cardiovascular Disease (CVD).

Since the 1980's such narrowing of vessel lumen has been treatable by minimally invasive, catheter based medical device technologies that expand the narrowed vessel lumen to its native diameter. Over time these methods have developed significantly in their effectiveness to treat arteriosclerosis through new stent developments. S-Bahn Medical's current BVS is the next step in improving these treatments. Unlike conventional stents, bioresorbable vascular scaffolds (BVS) will dissolve in the body after initially providing the needed mechanical support to the expanded vessel. Conventional stents cannot resorb, and over time can become detrimental to patient health. In recent years there has been some success and development in this emerging technology. However, some key issues in these BVS designs have limited their effectiveness to treat patients compared to conventional non-resorbable stents. S-Bahn Medical's concept BVS, address these design limitations to improve overall treatment of Cardiovascular Disease in the UK and across the world.

With the Innovate UK funding, S-Bahn Medical will carry out their first in vitro and cadaver studies of their device in collaboration with the Golden Jubilee National Hospital.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
ACTIVE NEEDLE TECHNOLOGY LTD	A 'bridge to cure' for stratified cancer patients, using a novel, precision radiotherapy system.	£115,780	£81,046
XERION HEALTHCARE LIMITED		£72,440	£50,708

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Project description - provided by applicants

Application defined by a partnership: the lead applicant has an advanced ultrasound "driven" needle that greatly improves the accuracy of delivering medicines to deep tissues (improved tissue penetration and highly visible on ultrasound scanners); the partner has a nanotechnology based agent that generates highly localised free radicals to enhance the effectiveness of cancer radiotherapy. This project enables these two companies to bring these two highly complementary technologies together and explore the possibility of a more accurate system of targeting radiotherapy that is less traumatic, more effective and that may offer a route to a cure.

Uniting these two technologies opens up a considerable commercial potential for both parties. The vision is to propel both parties forward by developing a combination system that can drastically enhance the accuracy of treating challenging tumours in the head, neck and pancreas. To bring these two innovations together the feasibility of this approach must be explored. The applicants wish to understand how the combined system would be used to target a pancreatic tumour. The enclosed project will explore:

- * Configuration of advanced "Active Needle" that is suitable for the targeting of pancreatic tumours;
- * Use the above needle to validate biodistribution of the nanoparticulate radiotherapy enhancement agent in a mouse pancreatic cancer model;
- * Develop a future pre-clinical study protocol for the combined system validation;
- * Examine the relevant intellectual property landscape for this innovation and secure IP.

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VIDERA SERVICES LTD	Bioprocess for the manufacturing of affordable pharmaceuticals to prevent and treat cancers, obesity and age-related diseases	£158,006	£110,604
University of Bristol		£41,999	£41,999

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Project description - provided by applicants

The population over the age of 65 is predicted to double by 2070, increasing the incidence of age-related diseases and will put additional pressure on the medical and societal care infrastructure. Long term, cost-effective strategies are required to decrease the prevalence (and societal burden) of obesity and its associated co-morbidities, and to reduce the incidence and impact of age-related disorders and cancer on the quality of life of an ageing population.

Conjugated linoleic acid (CLA) refers to a mixture of various forms (isomers) of the omega-6 unsaturated fatty acid, linoleic acid. The safety and health benefits of CLA are documented in >4000 scientific publications, and >100 human studies have been published. It is an essential nutrient not produced by the body and not present in sufficient amounts in food, thus requiring dietary supplementation.

CLA is commercially produced by chemical conversion of linoleic acid or oils rich in linoleic acid (sunflower and saffron) as a mixture of four isomers that cannot be separated cost-effectively. The different isomers may exhibit additive, independent or antagonistic physiological effects. Pure isomers are not commercially available; thus, most studies on humans and animals were performed with isomer mixtures, which obscured the results and hinders elucidation of the mechanisms through which the individual isomers exert their health effects.

One of these CLA isomers has potent anti-obesity, anti-cancer, anti-osteoporosis and anti-atherosclerosis activity, while improving energy balance and maintaining lean muscle. However, its beneficial effects are reduced in the presence of the other isomers which may also have undesirable effects. Thus, for medical purposes, this desired isomer in pure form is urgently required as a low-cost preventative and curative treatment for a wide variety of metabolic disorders.

This project will investigate a novel route to produce these CLA isomers in pure form as a first step to provide cost-effective treatments for cancer, obesity and age-related disorders. VideraBio, a UK-based SMME, and BrisSynBio (a UK Synthetic Biology Centre) will collaborate to deliver this cutting-edge innovation.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
C4X DISCOVERY LIMITED	Harnessing the synergy between Conformetrix technology and crystallography to expedite identification of novel, selective a4b7 integrin inhibitors for the treatment of IBD	£199,950	£139,965

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Project description - provided by applicants

The objective for this project is to deliver an oral, small molecule anti-inflammatory agent for the treatment of mild-severe, inflammatory bowel disease (IBD). IBD is a collection of idiopathic diseases caused by a dysregulated immune response to host intestinal microflora. The most common sub-types are ulcerative colitis (a continuous band of inflammation throughout the colon) and Crohn's disease (transmural, "skip lesions" affecting any segment of the gastrointestinal tract). IBD patients are stratified as mild, moderate or severe. The current standard treatment for mild patients is aminosalicylate progressing to corticosteroids and then immunosuppressants as disease severity increases. Treatment for mild-moderate patients sees mixed response and is associated with significant side-effects. Moderate/severe patients that do not respond to immunosuppressants are progressed on to biological therapies which have revolutionised the treatment of moderate/severe disease. Unfortunately, a significant proportion of patients do not respond to biological therapies often due to the production of neutralising antibodies. Gastroenterologists have identified a clear need to develop non-biological agents that effectively maintain remission in moderate/severe patients. This need also extends to mild-moderate patients where cost effective, oral, non-biological, anti-inflammatory treatments with improved efficacy and side effects could prevent disease progression.

C4X Discovery will use its proprietary Conformetrix technology which has been previously been used to rapidly identify novel chemical scaffolds from known ligands, by elucidating their 3D shape(s) in solution. The technology will be used synergistically with protein crystallography to compare free and bound ligand 3D-shapes to pin-point the exact areas of the molecules that will need optimising leading to the identification of potent anti-inflammatory compounds.

An effective, safe, oral small molecule therapy for IBD could meet the healthcare need across IBD patient severities and help reduce the significant economic burden caused by the disease. There are currently over 300,000 patients in the UK with IBD and prevalence increasing. The NHS economic cost of IBD was £720 million in 2006. An effective oral anti-inflammatory agent will lower the healthcare burden by reduced hospitalisation of patients, lower Cost of Goods compared to biologics, and no necessity for hospital visits for administration, thereby increasing patient access to a life-changing therapy. The positive impact at a patient and community level would be a pain free, convenient, discreet medication reducing social stigma.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
CADSCAN LIMITED	Low-cost in-shoe pressure measurement	£103,332	£72,332
Staffordshire University		£91,798	£91,798

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Project description - provided by applicants

The successful completion of this feasibility project will generate a novel measurement system for assessing the loading that is applied on the foot-at-risk of developing a foot ulcer during activities of daily living. It therefore would have significant potential for disease prevention and proactive management of health and chronic conditions.

This novel system will be simple and easy to use and it will cost only a fraction of the cost of existing electronic in-shoe pressure sensors. This will enable its use in wide cohorts of people with diabetes to enhance prevention of ulcers through better risk assessment and evidence-based interventions. More specifically, the proposed system will open the way for new screening protocols to identify people that overload critical areas of their feet and therefore are at risk of developing an ulcer. Moreover, it will also enable healthcare professionals working on diabetic feet to identify the areas of the foot that are subjected to critically high loading and to design effective interventions to offload them. Overall the proposed system will empower clinicians to intervene early and effectively to prevent ulcerations and most importantly to prevent the first ulceration.

The management of diabetes and its complications is one of the most critical societal challenges of our age. In the UK alone, there are 3.6 million people already living with diabetes and it is estimated that approximately 15% of them will at some stage develop diabetic foot ulceration that could lead to amputation. Indeed, in the UK up to 135 people/week have a limb amputated as a result of diabetes with a huge impact on the patients' quality of life and mortality rate. The successful completion of the proposed project will significantly help address this key societal challenge.

A reduction in ulceration rates will also result in massive savings for the NHS and economic benefits for the UK. The clinical care of diabetic foot complications cost more than the five most costly forms of cancer put together. In the UK the annual direct cost of amputations and ulcer management is estimated to be between £0.97-1.13 billion/ year. Indeed, it is calculated that a modest 1% reduction in ulceration rates will translate in annual savings for NHS of £1.2 - 4.8 million in direct treatment cost.

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ALTAIR MEDICAL LTD	Toxicity Alert Biosensor (TAB)	£179,235	£125,464

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Project description - provided by applicants

Opioids are a class of drug prescribed for pain relief or used illicitly for their euphoric effect. In 2016, 23 million prescriptions were issued for opioids in the UK. In that same year, 2,893 people died from accidental opioid overdose. In the USA, there were more than 42,000 deaths. Opioid overdose is now the largest cause of accidental death in most developed countries- far greater than road traffic accidents. Nearly all of these deaths are preventable, either through safer use of opioids or early detection of overdose and administration of a life-saving antidote.

Harm from overdose isn't restricted to deaths. For every fatal overdose, there are 20-30 non-fatal overdoses resulting in ambulance call outs, hospital admissions, hospital treatment, loss of productivity and temporary or permanent disability. The estimated annual costs in the UK are in the region of £3.5bn. In the US, the estimated cost is in excess of \$500bn.

Closely linked to the extent of harm from opioids is the potential for misuse. Opioid users quickly develop tolerance and doses have to be increased rapidly to gain beneficial effects. As the population ages, and with rising health problems, many more patients require the need for pain relief. This has created unprecedented demand for long-term use and an explosion in rates of opioid misuse.

Altair Medical Ltd is a health technology start-up company spun out of successful healthcare and IT companies based in Scotland. Our innovative technology continuously monitors patients taking opioids using a small, wireless wearable sensor paired to a smartphone. Data collected by the sensor is analysed by artificial intelligence which monitors drug usage and advises on safe timing of doses, tailored to each individual patient, to reduce the risk of overdose. Should this fail, it detects overdose and alerts first responders to administer naloxone, the powerful opioid antidote.

By continuously monitoring high risk opioid users, our technology can also:

- * identify signs of opioid misuse and facilitate treatment
- * improve pain control and reduce the risk of side effects
- * reduce the risk of opioid interactions with other types of medication
- * send reports to the prescribing doctor to assist in clinical decision making
- * assist in determining safety for driving.

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All of which have the potential to dramatically lower the risk of harm from opioid use.

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COHESION MEDICAL LTD.	Cancer Early Detection And Risk (CEDAR) System	£199,632	£139,742

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Project description - provided by applicants

Cancer can be debilitating for patients and families resulting in wide physical, psychological and social impact.

COHESION Medical Ltd will build on existing award-winning Digital Health technology to develop an innovative Cancer Early Detection And Risk (CEDAR) system using Big Data and Artificial Intelligence (AI) to provide a digital "early-warning" system for cancer diagnosis and cancer treatment toxicity. This innovative system will enable the generation of individualised cancer risk profiles, suggestions for changes to patient behaviour and the prediction of adverse toxicity reactions for individual patients. The system will have economic, social and personal impact through earlier cancer diagnosis, more targeted cancer treatments and earlier adoption of new cancer medicines.

The project is supported by MASScot, NHS Greater Glasgow & Clyde, University of Strathclyde and Stratified Medicine Scotland Innovation Centre.

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BILITECH LTD	Generation of human-sized bioengineered bile ducts	£124,000	£86,800
CAMBRIDGE ENTERPRISE LIMITED		£0	£0
CELL THERAPY CATAPULT LIMITED		£75,179	£75,179

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Project description - provided by applicants

Advances in biological research has the potential to enable scientists to build artificial or bioengineered organs by combining human cells with biologically- or chemically-derived scaffolds. Bilitech, a SME based in Cambridge, has developed a technology to manufacture bioengineered bile ducts in the laboratory and aims to translate it to the clinic for use in patients.

Bile ducts form a network of tubes that transfer toxic bile from the liver to the gut. Damage to bile ducts through injury or disease leads to overflow of bile in the liver causing, severe liver damage and failure. Currently, due to the lack of healthy bile ducts that could be used to repair or replace the damaged ducts, the only treatment for the management of bile duct disorders is liver transplantation or a complex operation in which the small intestine is used to drain the bile from the liver. However, liver transplantation is limited by the lack of available organs, while both operations are associated with significant complications, multiple hospital admissions and increased cost for the NHS.

To address this challenge Bilitech has developed a technology for the generation of artificial bile ducts in the laboratory. This technology has been successful in generating miniature bile ducts which were used to successfully replace the bile duct of mice. Bilitech's overall aim is to advance this product from its current miniature form to a viable clinical therapy for humans. The company is uniquely placed to deliver this impact through its links with the University of Cambridge and the NHS which, allow access to expertise, resources, patients and infrastructure. Bilitech will additionally collaborate with experts from the Cell and Gene Therapy Catapult to identify the best manufacturing process for human-sized bioengineered bile ducts, and to perform health-economic analysis identify the best strategy for bringing the technology to the market.

The aim of this project is to test the feasibility of the technology to generate human sized bioengineered bile ducts and asses the market potential and cost of developing this therapy. The generation of bioengineered bile ducts will provide the first alternative therapy to liver transplantation for the management of bile duct disorders, reducing pressure and cost for the NHS and significantly improve patients' health and quality of life.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
SUREPULSE MEDICAL LIMITED	Surepulse - Monitoring The Newborn	£198,515	£138,960

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Project description - provided by applicants

Amazingly, 10% of babies need assistance with their breathing at birth ~14M/year worldwide. Reasons for this include being born too early or partial umbilical cord strangulation. Those who receive the necessary aid quickly/efficiently will generally go on to lead normal lives, however those for which this is not the case are at risk of harm including damage to their brain or blindness for example.

Doctors have several ways they can help but need a way of assessing how well their treatment is working. They do this by measuring the heart rate (HR) and Oxygen Saturation (SpO₂), the amount of oxygen in the baby's blood. HR becomes much lower than it should be if the baby is poorly. An increase in HR means that treatment is working.

However, unfortunately there is no good way of measuring HR reliably straight after birth. A stethoscope is the common method, but the baby's heart beat can be weak making the heart's sounds difficult to hear and errors can occur in calculating the HR.

SurePulse was set up to solve this dilemma. The HR monitor that we have developed uses a small and safe optical sensor mounted in a soft cap placed on the baby's head. This sensor detects small pulsatile changes in blood supply to the forehead to calculate a HR. The SurePulse monitor has been successfully tested at the Nottingham University Hospitals.

The second important indicator for a newborn baby at birth is the amount of oxygen in the blood. This is measured in a totally safe manner by shining two LED colours at the skin (red and Infrared) and measuring the amount of each colour that returns. The ratio of the light power from these two colours indicates the amount of oxygen in the blood. We also have a patent that that allows us to detect the signature in these colours and we will be using this.

Overall this means that we will be exploring another hugely important factor so that we can provide paediatricians with an ability to measure the SpO₂ in even the smallest of babies where the signals are weak. This proposed Innovate UK project has a highly experienced team of engineers, clinicians, scientists, parents and the general public to ensure a successful outcome which will benefit newborns in the years to come.

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HOTHOUSE MEDICAL LIMITED	Synthetic Vascular Graft	£146,843	£99,290

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Project description - provided by applicants

Vascular grafts (prostheses) have been used successfully during open surgical treatment of abdominal and thoracic vascular disease for many years and are predominantly constructed from woven or knitted polyester fabric and pre-sealed with bovine collagen, albumin or gelatin. Over recent years however, there has been increasing scrutiny by medical device regulators on the use of animal derived materials within implantable devices, particularly regarding assurity of supply and the potential transmission of bovine spongiform encephalitis (BSE). Hothouse Medical Ltd (HHM) is a Scottish based micro SME operating as a device development and consultancy company in the implantable cardiovascular field and through this project, seeks to develop a fully synthetic vascular graft that would facilitate simplified regulatory approval and easier adoption into complex cardiovascular devices, whilst maintaining suitable performance characteristics.

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CARTHAGE ORTHOBIOLOGICS LIMITED	Corthotec: Feasibility Study	£149,650	£104,755

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Project description - provided by applicants

A UK-based project to develop novel technology to improve the healing of broken bones.

Although not well publicised, in the UK as many as 85,000 people a year have problems with broken (fractured) bones healing and instead of healing in the normal six weeks, do not heal for months or years. The pain and disability associated with the fractured bone persists much longer than normal, which impacts not only on the patient, but their dependents and society as a whole.

Traditionally these persistent fractures have required complex, expensive surgery, however even this can fail. This is where certain classes of treatment termed 'orthobiologics' come in. Orthobiologics encourage bone healing and when used in conjunction with surgery can increase the chances of a positive outcome for the patient.

Currently there are limited options for patients and surgeons. By focusing on preventing the failure of healing in at risk groups such as the elderly, or patients with chronic diseases such as diabetes, the proposed approach has the potential to significantly reduce the current need for costly and complicated surgery alleviating the resulting disability and poor quality of life in those affected.

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CHAIN BIOTECHNOLOGY LIMITED	Mucosal delivery of Clostridium spores encoding recombinant overlapping peptides of HPV antigen as therapeutic vaccines for cervical cancer	£100,000	£70,000
University of Oxford		£80,000	£80,000

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

HPV is the most commonly sexually transmitted infection with over two-thirds of the population infected at some stage during life. Most infections are cleared without symptoms within a few months; however, infections with high risk types of HPV can lead to development of cancer in for example the cervix. Vaccination against these high-risk types is now available and these vaccines are being used in most high income countries and China to protect girls and women at risk of infection. While such interventions are recommended and have led to a decrease in cervical cancer incidence, the approach also has disadvantages. Stability of the vaccines is poor and the way in which the vaccines are given (by injection into muscle) does not give good protection at the sites where the virus normally enters the body. Critically, the high cost of these vaccines greatly limits their use in low income countries, where HPV infection is most prevalent.

In this project, CHAIN Biotechnology Ltd, a microbiome company with expertise in developing _Clostridium_-based therapeutics, is collaborating with experienced immunological researchers from the University of Oxford to overcome limitations of currently available vaccines. The aim is to develop an oral vaccination approach to prevent HPV infection and also to treat people already affected by the virus. Delivery of vaccine directly to the mucosal surfaces of the gastrointestinal tract (GIT) via ingestion of harmless bacteria, overcomes the low pH and enzyme-enriched environment in the stomach that would destroy other oral vaccines. If successful, the approach provides a substantial improvement over the current vaccination strategies. It is non-invasive and would allow mass vaccination without the risk of spreading blood-borne infection by needle injuries, and administration could be performed by non-medical personnel. If the approach is successful, the project will give rise to the possibility of extending this technology to develop vaccines against other viral and bacterial infections that present challenges to global health such as for example HIV, Ebola or cholera. There is also the possibility to develop therapeutic vaccines that target the destruction of cancer cells.

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ADVANCED EXPERT SYSTEMS LIMITED	Automating faecal immunochemical test result interpretation using artificial intelligence and machine learning	£199,738	£139,817

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: 06/09/2018

Project description - provided by applicants

Bowel cancer screening services invite asymptomatic persons aged >60 years to conduct guaiac-based Faecal Occult Blood testing (gFOBt) every two years. From Autumn 2018, NHS England's Bowel Cancer Screening Programme (BCSP; commissioned by Public Health England; PHE) will roll-out Faecal Immunochemical Test (FIT) to replace gFOBt. FIT is simpler, more sensitive, and improves neoplasia detection. However, FIT is less specific than gFOBt, increasing the number of 'false positive' patients being referred for colonoscopy.

FIT results will be interpreted manually by a Bowel Cancer Specialist Screening Practitioner. To improve the overall efficiency of the BCSP, and to optimise the interpretation of the FIT result, Advanced Expert Systems Ltd (AES), experts in Artificial Intelligence (AI) and Machine Learning (ML) software, propose a feasibility assessment of a new system (using similar principles to an AI-based system they have developed for the MoD) that

1. Automates the interpretation of FIT-results, considering them within a framework of other data variables within the electronic patient record;
2. Automates the wider BCSP as much as possible, from invitation of patients to delivery of results and onward forwarding of patients, where required.

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Innovate UK

Results of Competition: Biomedical Catalyst 2018 Round 1 Feasibility Studies

Competition Code: 1803_BMC_R1_FS

Total available funding is £2,000,000

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
APPLIED NANODETECTORS LIMITED	POC-ASTHMA: Point of care exhaled breath test for asthma diagnosis	£168,340	£117,838

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: 06/09/2018

Project description - provided by applicants

We propose to investigate the feasibility of a point of care (POC) exhaled breath test for the diagnosis of asthma for use in primary care setting. The rapid and accurate diagnosis of asthma and identification of patients would be essential to ensure that adequate treatment, including hospitalisation when necessary, is implemented as early as possible. This type of diagnostic techniques would lead to more efficacious treatments and help to reduce the burden of disease.

Asthma is mainly diagnosed principally on the basis of a careful clinical history take taken by a clinician. However, studies of adults diagnosed with asthma suggest that up to 30% do not have clear evidence of asthma. There is a critical need for objective testing using fractional exhaled nitric oxide (FeNO) and detection of volatile organic compounds (VOCs) that would offer a significant improvement to current practise.

We will work on innovatively integrating these two new sensor elements into a handheld device for use by healthcare professionals. A low-cost gas sensor fabricated using active nanomaterial metal oxide (MOx) gas sensor array and flexible polymer substrates for the detection FeNO and VOC biomarkers in exhaled breath associated with the diagnosis and management of asthma. A new flow sensor fabricated using new nanomaterial formulations that can detect and measure gas flow that could be used to make lung function measurements.

Nanomaterial formulations will be carefully formulated and deposited onto plastic substrates and subsequently modified to selectively detect FeNO and VOC biomarkers. The printed FeNO gas sensor will be then excited using Applied Nanodetectors new patented innovative excitation technique and then exposed to test gases mixtures to optimize the sensor performance. The target is to provide breakthrough technology in diagnostics which can potentially significantly lower measurement costs and improve diagnostic testing. This would lead to a reduction in costly drugs given to people misdiagnosed and also early diagnosis will ensure patients get the appropriate treatment leading to improve outcomes. Exploitation of these project results will lead to development of prototype that can used for clinical validation and clinical utility studies.

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