Innovate UK

Results of Competition: Biomedical Catalyst 2017 Round 4: Primer Award

Competition Code: 1711_CRD_HEAL_BMC2017_R4_PRIMER

Total available funding is £6.5m

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
CONGENICA LTD	Next Generation Prenatal Screening - Improving Detection, Diagnosis and Treatment of Genetic Disease	£693,317	£415,990

Project description - provided by applicants
All expectant parents hope for an uneventful pregnancy, a trouble free birth and a healthy baby. Unfortunately, complications of pregnancy may occur with implications for both the mother and the unborn child. As part of the patient pathway for pregnant mothers, the National Health Service provides monitoring and screening programmes as the standard of care to ensure the health and wellbeing of mother and child. These include physical examinations, blood tests and ultrasound scans. These are used to determine gestational age of the pregnancy, determine if the child is at risk from Down's syndrome (and rarer chromosomal abnormalities) and to ensure that the baby is developing normally (e.g. heart, brain, kidneys and skeletal growth). If the blood test results indicate that there is a high risk of Down's syndrome, amniocentesis is offered to the parents. An amniocentesis and genetic testing may be used to confirm or disprove the result. Amniocentesis carries a small but definitive risk of miscarriage (0.5-1, significant technological advances have been made that mean it is now possible to perform the same test ""non-invasively"". This relies on the fact the DNA from the baby is present in the mother's blood. A simple blood test from the mother is all that is required, removing the risk of miscarriage. Non-invasive genetic testing for Trisomy 21/Down's syndrome (and two additional disorders - Trisomy 13/Patau syndrome and Trisomy 18/Edward's syndrome) will be introduced into the NHS in 2018\. This project is focussed on the development of a non-invasive screening test that significantly extends the number of inherited or acquired genetic conditions that can be detected. This is particularly important when ultrasound scanning (in the first and second trimester) reveals structural defects in the baby's major organs. Ruling in or ruling out genetic causes of these defects can radically alter the management of the pregnancy. Earlier and improved diagnosis of severe genetic disorders enables appropriate care and treatment planning following birth and in some cases early interventions can significantly improve clinical outcomes.""

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M-SQUARED LASERS LIMITED University of St Andrews	Wavelength Modulated Raman Spectroscopy for Tuberculosis Detection	£203,891 £203,313	£122,335 £203,313
Project description - provided by applicants			
Tuberculosis is now established as the most important cause of death due to infectious disease, yet treatment has not improved in years. Relapse after successful treatment is the major barrier to shorter therapy for tuberculosis as has been confirmed by recent tuberculosis clinical trials where more bactericidal regimens have failed due to higher relapse rate. Through the use of background-free Raman spectroscopy the partners have demonstrated the ability to identify drug resistant tuberculosis cells. The aim of this project will be to develop a demonstrator system that can be more extensively trialled. The system will be further optimised for high throughput operation. Drug resistant tuberculosis has a significant burden on society and is estimated to cost £50,000--£70,000 to treat, almost 10 times that of 'normal' Tuberculosis. Combating drug resistant disease is considered one of the centuries most significant challenges, and requires tools such as these to make progress.			

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EDINBURGH BIOSCIENCES LTD.	Assessment of Cataract Photobleaching Therapy in Animals	£465,447	£325,813

Project description - provided by applicants

As the population grows older the instances of cataract increases. This disease causes cloudiness of the lens of the eye and leads to visual impairment and blindness. Cataracts are the leading cause of blindness affecting over 51, relying on the subjective judgement of the opthalmologist using a slit lamp microscope. The only treatment is by surgical intervention to substitute the natural lens with a plastic replacement. This project is based on significant research by Edinburgh Biosciences Ltd and partners into cataract formation, diagnosis and LED photobleaching treatment notably using extracted lenses and eyes. It will confirm laboratory experiments and translate into live data from a complete living eye confirming both the safety and ability to reverse cataract damage. Thus proving LED photobleaching is a non-invasive alternative to surgery. Furthermore monitoring the effects of LED treatment could reduce the development of cataracts to the point where they affect the quality of life. Success would enable patients to retain the natural lens with the advantages of avoiding surgery, removing the post-operative risks and maintaining the adaption capability of the natural lens. Such treatment would improve the quality of life for the increasing number of cataract sufferers while reducing the £330 Million cost of cataract surgery in the UK. Since cataract is a global problem, the market for an efficient solution is also global.

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PROCARTA BIOSYSTEMS LIMITED	Preclinical development of novel DNA-based antimicrobial agents	£1,247,280	£873,096

Project description - provided by applicants

Procarta Biosystems is an antibiotic drug discovery and development organisation with a unique platform that can identify new targets for antibiotics as well as discovering new drugs to kill even the most resistant bacteria. Procarta has discovered a new type of antimicrobial that kills bacteria by blocking their gene expression through a novel mechanism. These are short fragments of DNA that invade the bacterial cells to treat serious infections such as sepsis, complicated urinary tract infection and complicated intra-abdominal infection with the lead molecule, PRO-202, progressing to preclinical development. These infections are extremely hard to treat, particularly with the rise of resistance. The company is developing PRO-202 as a antimicrobial to treat infections caused by Gram-negative bacteria, which in some cases are untreatable with currently available agents. Intended uses are to both treat acute infections, such as sepsis, and also to improve health by modifying the gut microbiome, by removing bacteria associated with disease. Successful completion of the project will lead to a potential new medicine ready for testing in man, which is the next step in creating a drug. By changing the sequence of the DNA fragment in our potential medicines we can selectively and specifically target different bacteria, meaning that the first demonstration of the technology will validate our platform and may lead to multiple new antibiotics.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
ATTENBOROUGH DENTAL LABORATORIES LTD	Apollonia – the next level of dental care	£135,066	£94,546
C21 IOT LIMITED		£97,076	£67,953
ICMEA-UK Ltd		£199,161	£139,413
M-SQUARED LASERS LIMITED		£108,916	£65,350
University of Leeds		£173,717	£173,717
University of St Andrews		£172,829	£172,829
VALE INNOVATION LIMITED		£58,474	£40,932

Project description - provided by applicants
Lifestyle dependent acid-induced erosion of dental enamel is common in the world's population (76, common in diabetes, and from regurgitation e.g. anorexia. Chronic cases severely compromise lifestyle. In extreme cases, the tooth requires extraction, to be replaced with a transplant/ implant. Restorative intervention for children (<12 years) is especially difficult, as tissue is softer with more protein content. At present there is no permanent solution for the management of TSL. The objective of this project is to deliver a prototype device integrated with diagnostic imaging and materials delivery system for restoring acid-eroded enamel. Previous ex vivo work has demonstrated during pulsed-laser-sintering of damaged enamel with bio-minerals generates minimum heat. For clinical commercialisation, this technology requires a commercially available ultrafast (femtosecond (fs)) high-repetition rate laser, materials delivery system, diagnostic imaging techniques (e.g. optical coherence tomography - OCT) and an accurate method of monitoring the temperature, all integrated into a device that fits comfortably inside mouth. The consortium of two universities (Leeds -- UoL and St. Andrew's -- USTAN), a dental company (Attenborough Dental -- AD), a laser company (M Squared Lasers -- MSL), a mechanical engineering and fluid handling specialist (ICMEA (UK) -- ICMEA), an electronics specialist (C21 IoT -- C21) and a materials/physics innovation company (Vale Innovation -- VI) are uniquely positioned to take this development forwards. By developing a simple system for treating TSL the consortium believe they can eliminate dental pain for millions in the UK alone and restore dietary and other lifestyle choices for thousands that are more severely affected.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
ANASTASIS BIOTEC LIMITED	Developing a specific NOTCH pathway inhibitor as a prostate cancer stem cell therapeutic	£472,600	£330,820
Project description - provided by applicants			
Cancer relapse and metastatic spread is a serious health problem and may be caused by the inability to destroy all residual tumour cells, particularly the residual and resistant cancer stem cell (CSC) sub-population. Killing CSC has been a major technological challenge as they share similar cell pathways and features with critical normal stem cells. NOTCH signalling is a major pathway in CSC but several approaches developed to block NOTCH such as antibodies and small molecule gamma-secretase inhibitors (GSIs) have shown toxicity and limited clinical benefit. We have discovered and developed a novel peptide inhibitor of the NOTCH pathway, named Syntana-4, that has the potential to kill CSC and in combination with other treatments such as chemotherapy, reduce the likelihood of relapse and tumour recurrence and metastasis. In this project, we propose to test Syntana-4's stability after contract manufacturing, biological efficacy and safety in a variety of NOTCH mutated cancer models to support its clinical development for prostate cancer which has high levels of activated NOTCH.			

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
IONTAS LIMITED	Creating novel Nav1.7 inhibiting antibodies for the treatment of chronic pain	£794,626	£556,238

Project description - provided by applicants

One in three adults will experience chronic pain (persistent pain lasting more than three months). Effective treatment for often highly debilitating chronic pain is limited and problematic: the most commonly prescribed medications are opioids (e.g. codeine, fentanyl, morphine) which have serious side-effects**.** To address the lack of safe, non-addictive and effective pain-killers for chronic pain, IONTAS aims to develop an alternative, non-opioid medication. Pain signalling in the nervous system is driven and maintained by an ion channel called Nav1.7\. By selectively blocking the persistent, over-activation of Nav1.7 found in chronic pain we aim to alleviate this debilitating condition. The venom of a tarantula includes a small ""knotted"" protein that is known to block Nav1.7\. This tarantula-derived "knottin" protein is unsuitable as a therapeutic since it exhibits unwanted cross-reactivity in the body and is rapidly removed from the blood circulation. We have created a hybrid molecule (a ""KnotBody"") by fusing this tarantula knottin within the recognition surface of an antibody. This KnotBody is designed to address the problems of rapid removal from the blood and unwanted cross-reactivity. Through this funding, IONTAS will develop our existing prototype KnotBody molecules into a safer, effective and more specific drug candidate aimed at improving the quality of life of chronic pain patients whilst providing a solution to the growing, global opioid crisis.

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CELLESCE LIMITED	Patient-derived breast cancer organoids to transform drug discovery screening assays	£276,901	£193,831
Cardiff University		£275,168	£275,168

Project description - provided by applicants
There is an urgent and unmet medical need to discover and develop new disease-modifying breast cancer therapeutics that specifically target diseased cells and minimise adverse side-effects. One of the hurdles to be overcome in identifying new treatments is the availability of a test system that accurately predicts the efficacy of novel compounds for further development in the clinic. The use of tumour organoids will potentially revolutionise the pre-clinical testing of novel therapeutic compounds. Organoids are fully representative, three-dimensional miniature versions of the patient tumour tissue from which they are derived. Donated tissue (given with full patient consent and ethical approval) is processed in the lab to grow into multicellular structures that recreate the anatomy and disease pathology of the original tumour. They are grown in 3D in a dish rather than in an animal and can be expanded in number over a few weeks. These organoids can then be used in drug screening, potentially enabling the determination of targeted therapies for individual patients. Multiple organoid lines representing many different forms of breast cancer can be used in a more general screen for novel treatments, or to test novel combinations of drugs and treatment regimens. Until recently, organoids could only be grown and expanded manually on a small scale, for academic research, limiting their wide-spread commercial use. However, recent advances in bioprocessing technology made by Cellesce, a biotechnology company resulting from a collaboration between scientists from Bath and Cardiff Universities, have enabled the expansion of organoids on a commercial scale. The proprietary method involves seeding established cancer organoid lines into a bioreactor under carefully controlled conditions, to encourage optimal growth and yield. The resulting organoids are subject to rigorous quality control to prove their suitability for use in large scale assays by both commercial and academic institutions. Presently, Cellesce specialises in human-derived colorectal cancer organoids, based on a set of tumour organoid lines generated by, and licensed from, Cardiff University. Published research has shown that human breast tumour organoid lines can similarly be established from patient breast tumour tissue. Combining Cardiff University's research expertise in mammary and organoid biology and Cellesce's proprietary technology and experience, we believe that the large -scale bioprocessing of patient-derived breast tumour organoids will be possible. These organoids will then be made available for the pharmaceutical industry, contract research organisations (CROs) and academic institutions worldwide.

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EMERGEX VACCINES HOLDING LIMITED	Generation of a clinical universal flu vaccine candidate	£1,399,026	£979,318

Project description - provided by applicants
Influenza pandemics have been a recurrent health event through-out history. The infamous Spanish Flu of 1918, resulted in up to 100 million deaths - 5,000 infections in Australia is currently making a particularly dangerous UK winter flu season (1). For this reason, governments are particularly concerned about the risks of Influenza pandemics to public health. The UK government 2015 ""National Risk register of Civil Emergencies"" highlighted an Influenza pandemic as one the highest risk events in terms of both impact and likelihood. The register also predicts that the consequences of a pandemic is half the UK population potentially being infected, with between 20,000 and 750,000 additional deaths potentially by its end. Vaccines remain the gold standard of defence against pandemics. Since large scale influenza pandemics can occur rapidly and unexpectedly, resulting from novel strains and mutations, there remains a need for vaccines that can be developed quickly and on-demand while also being effective against those strains and mutations. Current seasonal influenza vaccine technologies do not fit this need. Manufacture of such vaccines is often slow, experiences batch variation, and cannot be scaled to meet the needs of large vaccination regimes. Furthermore, since the pandemic strain will result from a new strain, seasonal influenza vaccines could not be expected to provide any protection against pandemic influenza. This is illustrated by the effectiveness of seasonal flu vaccine ranging from 60, with a desired stock of up to 6 months' supply. However, the UK government has recently highlighted current vaccine technologies inadequate, both in terms of effectiveness and shelf-life. To meet this need Emergex will apply its proprietary gold nanoparticle synthetic T-cell vaccine platform to the generation and validation of a universal Influenza vaccine. Since these vaccines would utilise universal viral epitopes it would be effective against all Influenza strains. The synthetic nature means the vaccine would have extensive shelf-life and the production process fast, cheap and highly scalable. The small nanoparticle size means our vaccines are suited to be administered by a microneedle skin patch, which could be distributed by post, allowing a practical and cost-effective method of mass vaccination.

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METRION BIOSCIENCES LTD	Late lead optimisation of orally available potassium channel inhibitors for the treatment of psoriasis	£637,055	£445,939

Project description - provided by applicants

-- Metrion Bioscience Ltd (Metrion) is an ion channel specialist contract research organisation and has recently begun building its drug discovery and development capability. The company is based at Granta Park, Cambridge, with a core expertise in ion channel drug discovery and neuroscience. Metrion's R&D is focused on designing and discovering molecules for the treatment of debilitating Autoimmune disorders. The management team and advisors have extensive experience in this field and have previously raised significant equity funding and have a track record in delivering molecules to the clinic. -- Metrion is pioneering the discovery of oral medicines with the potential to change the underlying causes of psoriasis. The successful treatments for psoriasis predominantly provide symptomatic relief only, nevertheless this has created a $7bn market. Metrion's approach has the potential to radically modify/halt the progression of psoriasis impacting the patient and the healthcare system. -- Metrion through this grant will exploit its drug discovery expertise to identify small molecule inhibitors of potassium channels which has been linked to autoimmune disease and neurodegeneration. Further modification of these lead molecules subsequent to this project will allow the generation of orally active agents for the treatment of other autoimmune disease.

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LUSSTECH LIMITED	Quick fitting of prosthetic sockets for above knee amputees - (QuickFit)	£308,119	£215,683
HCI VIOCARE CLINICS UK LIMITED		£100,262	£70,183
HEADCHANNEL LIMITED		£249,600	£174,720
South Tees Hospitals NHS Foundation Trust		£83,544	£83,544
Teesside University		£428,852	£428,852

Project description - provided by applicants
In developed countries, more than 90, the comfort is crucial for them to regain a good quality of life. Attaching artificial limbs to the body remains clinically challenging and the conventional way to attach a prosthetic limb to the body is by means of a socket. However, many patients experience serious discomfort wearing a prosthesis because of pain, instability during walking, pressure sores or skin irritation. The conventional design and manufacturing process for a prosthetic socket requires a patient to visit a clinic multiple times over one or more weeks. There has been an attempt to eliminate the socket by directly attaching the artificial limb to the residual bone through osseointegration. However, most (\>60, diabetes related) patients with amputations will not be candidates for this procedure. Of the remaining people with amputations, viable candidates would be limited to those who have a transfemoral or transhumeral amputation. Therefore there is a continuing need for an improved prosthetic socket provision technique that addresses the limitations and challenges highlighted above. Socket related problems mainly emanate from the over-reliance on a skilled prosthetist to determine the load bearing capability across the stump using a ""touch and feel"" technique without quantitative measurements. This project aims to change the subjective approach into a science-based technique so that a good-fit socket can be designed and fabricated within one day. Advanced sensors (QTSS sensor by the business lead Lusstech Ltd, with patent application PCT/GB2016/053943, WO2017103592A1) will be adapted to measure the dynamic pressure distribution between mock-up residual limbs and the socket during simulated gait tests. The data, together with biomechanics analytical models to be developed during the project, will be used to optimise the socket design. Finally a new procedure will be formulated at the end of the project. Once the project is successfully completed through laboratory validation tests, we will start clinical trials to demonstrate the new technique/procedure to the rehabilitation healthcare sector so that prosthetists will have confidence to adopt this solution in their routine practices. The main innovation of the project are: 1. New application of the revolutionary QTSS sensors in healthcare 2. New biomechanical analytical models 3. New procedure for prosthetic socket design which is a step change disrupting existing practices.

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