

Innovate UK

Results of Competition: Biomedical Catalyst 2017 Round 3: Early Stage

Competition Code: 1707_CRD_HEAL_BMC2017_R3_ES

Total available funding is £10m

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
GENDRIVE PLC	A novel pathogen capture sample preparation device for point of care TB diagnostics on the genedrive molecular diagnostics platform	£1,846,597	£1,107,958

Project description - provided by applicants

Currently there are limited Point-of-Care (PoC)-applicable sample processing methods needed to recover infectious disease targets from clinical samples prior to molecular diagnostic testing. This means analysis is restricted to centralised laboratory facilities and this significantly impacts time to result and subsequent treatment, and cost to the healthcare provider. Many field portable molecular testing systems fail to achieve PoC use as the upstream sample preparation workflows needed to support them are overly complex, equipment intensive and costly - precluding their deployment in decentralised settings. This project will be technology enabling and will capitalise on our existing derisked workflow that will initially improve sensitivity of our existing test for MTB in decentralised non-laboratory settings by an order of approximately 100-fold. This will enable diagnosis of patients with low levels of bacterial infection and also permit stratification for receipt of appropriate anti-infective treatments. This technology has the opportunity to change the way blood borne viral diagnostics are conducted in decentralised settings in resource limited countries, providing improved patient care and more timely therapy, and ultimately positively impacting on global health challenges in infectious diseases. It seeks to integrate existing technologies to realise a true PoC TB workflow for decentralised use in low-income countries with highest disease burden. The project outcome will be a low cost, sample preparation consumable device that overcomes the traditional user complexity, biosafety and equipment barriers needed for successful PoC application. The device will enable decentralised testing of TB in sputum but will also be broadly applicable for a range of other clinical sample types and infectious disease agents, and in established healthcare settings in developed countries.

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ANACAIL LIMITED	Novel Ozone Based Sterilizer for Medical Device and Life Sciences	£480,565	£336,396

Project description - provided by applicants

The current grant will allow Anacail Ltd to validate a product concept by building a proof of principle machine which can sterilize single use medical devices, and simultaneously pack them in a sealed primary pack, at point of manufacture. The market need for such a device is the common requirement across all medical and healthcare devices for sterility. Traditional techniques such as radiation or ethylene oxide are either damaging to materials, or can leave toxic residues on devices. The increasing sophistication of modern medical and healthcare devices in terms of advanced materials and surface treatments and the integration of electronics and optics, exacerbates these drawbacks. Furthermore, the use of hazardous or toxic chemical presents a significant health and environmental risk as these materials must be stored and disposed of in a safe and responsible manner. Anacail has developed a technology which is based on ozone, a naturally occurring allotrope of oxygen, which, once the sterilization is complete, decays back into native oxygen. This renders the technology environmentally benign and relatively safe to handle as there are no toxic chemicals for storage transport or disposal. Ozone is already recognised as a sterilant by regulatory authorities such as the FDA (<https://www.fda.gov/downloads/MedicalDevices/.../ucm109897.pdf>) which can remove significant hurdles to its adoption. Ozone has not been more widely adopted as a sterilant because of two key drawbacks: When used as a conventional chamber based steriliser, its is relatively slow acting compared with alternatives, and it historically uses pure oxygen as a feedstock gas, which creates significant flammability issues. Anacail has recently patented a non hazardous gas composition which only contains 21% oxygen, yet can provide high ozone concentrations. This removes the flammability issues which in turn allows Anacail to inject this gas into a bag, which is then sealed. The bag contents are sterilized, and then the ozone in the bag decays back to oxygen, leaving no residues. The benefit to society for this technology is to reduce the incidence of healthcare acquired infections, provide increased safety in terms of reduced use of hazardous chemicals or radioactive sources, and reduce environmental impact associated with use, storage and disposal of hazardous chemicals. Once developed, the technology can be adapted for application in healthcare and hospital environments, opening up a second market and directly addressing healthcare acquired infections.

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IGEM THERAPEUTICS LIMITED	Development of a novel immuno-oncology drug targeting solid tumours	£1,454,568	£1,018,198
Project description - provided by applicants			
IGEM-C is an IgE-based antibody targeting a melanoma antigen. The project involves the evaluation of a number of novel variants of the prototype for efficacy, manufacturability and stability. The antigen target for IGEM-C is found in many different solid tumours, and part of the project will be to develop animal models for these indications. The chosen variant will be evaluated for efficacy in the new animal models. A GMP manufacturing process will be developed and preclinical studies will be planned which are compliant with regulatory requirements for a Phase 1 clinical trial in patients with solid tumours bearing the target antigen for IGEM-C. The overall aims of the project are to select the preferred clinical candidate, expand the indications that it could target, and carry out all the essential steps to allow IGEM-C to progress rapidly towards a Phase 1 trial once the project is complete.			

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CAMBRIDGE RESPIRATORY INNOVATIONS LIMITED	Secure Communications, Analysis and Alerts for Respiratory Diagnosis (SCAARD)	£422,564	£295,795

Project description - provided by applicants

There is a substantial market opportunity for a low-cost personal medical device which can be used by a patient to help monitor and manage their respiratory condition. In the UK alone there are over 800,000 people with Chronic Obstructive Pulmonary Disease (COPD), as well as 5.4 million people with asthma. Globally WHO estimates that there are 64 million people with COPD and 335 million people with asthma. **It is widely acknowledged that many respiratory conditions are poorly managed due to the lack of an effective personal monitor which** **measures lung performance in a convenient and cost effective manner.** **This results in a high level of respiratory exacerbations, sometimes resulting in permanent lung damage and often resulting in avoidable, high cost hospital admissions. Cambridge Respiratory Innovations Limited (CRiL), of Swavesey Cambridgeshire, has identified a clear unmet need from both patients and healthcare professionals for a "connected" personal respiratory monitor. Doctors, respiratory nurses and patients are dissatisfied with current devices, which are peak-flow meters and spirometers (both of which require forced expiratory manoeuvres and are technique dependent). **CRiL has developed the N-Tidal Respiratory Management System, based on measuring CO2 in normal tidal breathing. Driven by the N-Tidal B personal respiratory monitor, N-Tidal will ultimately facilitate correct diagnosis and monitoring of COPD, asthma and other chronic respiratory conditions.** Innovate UK is funding research which will:

1. Create the main N-Tidal Patient Database, with appropriate N3/HIPAA secure communications.
2. Create a secure "handshake" between the central N-Tidal Database and the RESPO (Replaceable Enclosed Sensor Paired Optics), which is an intelligent N-Tidal consumable, essential for measuring the TBCO2 waveform.
3. Ensure the integrity of the N-Tidal data and the alerts.

The RESPO handshake is the most innovative element in this project. It is an essential component of the N-Tidal B. The RESPO is a time-based consumable which will be prescribable and will provide the revenue streams for N-Tidal. Its use will link the patient, the device and the database, validating that the data analysis and time period has been funded. **The RESPO handshake will ensure continuity of revenue streams funding N-Tidal, protection against counterfeit consumables and allow for differential pricing by cardio-respiratory condition and geographic market.** It is a critical component for the successful commercialisation of the N-Tidal. This Innovate UK funded research will complete the digital health infrastructure, enabling CRiL's N-Tidal personal respiratory monitor to transform the management of respiratory conditions in the UK and internationally.

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SENTINEL ONCOLOGY LIMITED	Development of a new drug for the treatment of glioblastoma multiforme	£1,717,655	£1,202,359
Project description - provided by applicants			
Glioblastoma multiforme (GBM) is one of the most common forms of brain cancer and is currently very poorly treated. Most patients have an average survival of less than 15 months and the five-year survival prognosis is less than 5%. The most recent new drug approved for the treatment of GBM was temozolomide, approved in 2005. There is a clear unmet need for new drugs to treat GBM and Sentinel Oncology will develop a new drug called SOL288 as the main objective of this project.			

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JOINTMEDICA LIMITED	Development of an innovative biocompatible hip resurfacing system	£1,310,844	£589,880
Project description - provided by applicants			
<p>The overarching objective of this project is to develop an innovative solution for hip resurfacing indications. Current solutions available for hip resurfacing have been marred by poor results in patients, especially due to issues related to the metal-on-metal construction of these devices and the release of metal particles. The aim is therefore to develop an advanced resurfacing system (Polymotion) that will provide a unique biocompatible bearing and superior wear performance without the risks associated with conventional bearing offerings. Recent advances in polyethylene material technology, coupled with encouraging mid-term clinical results, offer Jointmedica (JM) a biocompatible low-risk alternative to metal-on-metal, which is expected to offer a low adverse reaction risk coupled with superior performance and lower wear. Total hip replacement procedures are reasonably successful in elderly and relatively inactive patients. However, replacement hip joints wear out quickly in younger, more active patients, leading to an inevitable and costly revision surgery and associated complications. Development of the innovative solution proposed herein will provide better stability, longevity and higher levels of patient activity than traditional hip replacement, restoring the quality of life of those affected and reducing healthcare costs.</p>			

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CAUSEWAY THERAPEUTICS LIMITED	microRNA therapy in tendon disease	£1,869,846	£841,431
University of Glasgow		£133,976	£133,976
Project description - provided by applicants			
One in 10 people will suffer from some form of tendinopathy during their lifetime, yet currently, the best treatment remains physiotherapy which only benefits 50% of cases. Despite recent advances in biological therapy, there remains no effective treatment for tendinopathy. Research at Causeway Therapeutics uncovered the molecular mechanism that causes damaged tendons to develop tendinopathy. This insight led to the development of TenoMiR that directly targets the key features of the disease. Treatment with TenoMiR effectively restores tendon structure and function. Causeway Therapeutics' objective is to **develop the world's first microRNA therapy revolutionising the treatment of soft tissue tendon injuries.** This grant will drive the development of TenoMiR through to a phase 1/2a clinical trial in humans.			

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