Results of Competition: Biomedical Catalyst 2018 Round 2 Primer Award

Competition Code: 1808_BMC_R2

Total available funding is £8m

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
HYPHA DISCOVERY LIMITED	From O to N: engineering the gap	£471,954	£330,368
University College London		£201,922	£201,922

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
Metabolites of drugs often need to be investigated and tested as part of regulated safety assessments during drug development. _N_-glucuronides are a class of metabolites increasingly observed as a significant route of drug elimination and are most likely to exhibit transporter-mediated pharmacologic activity and drug-drug-interactions. However, _N_-glucuronides are often difficult to produce in scalable amounts needed for evaluation during these trials, thereby creating a healthcare need for accessing these metabolites. Glucuronides are produced by uridine 5'-diphospho-glucuronosyltransferases (UGTs), enzymes expressed by many organisms from microbes to humans to facilitate elimination of xenobiotics. There are many subtypes which catalyse the glucuronidation of different compound types, including UGTs which specifically _N_-glucuronidate drugs. The project, in collaboration with University College London, addresses this clinical need through provision of engineered UGT-based biocatalytic solutions to provide a mechanism for obtaining scalable quantities of _N_-glucuronide metabolites for characterisation, which will enhance the development and application of new medicines by providing a more comprehensive understanding of a drug's pharmacology, disposition, drug interaction risk and toxicity.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
MEDIDESIGN LIMITED	Allergy Learning: Early Review/Testing & Efficient Diagnosis (ALERTED)	£302,419	£211,693

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
An urgent need for radical change in allergy diagnostics is illustrated by: 1. Rapid growth in number of allergy sufferers e.g. incidence of food allergy in UK children doubled in 10 years, 44% of UK adults now have an allergy (_Mintel, 2010)_ 2. Lengthening waiting times for allergy testing (commonly over 2 years) 3. The EU's annual indirect avoidable cost of untreated allergies is estimated at between €51bn and €155bn (_The European Academy of Allergy and Clinical_ _Immunology, 2016)_ The ALERTED Primer study ('Allergy Learning: Early Review/Testing & Efficient Diagnosis') will develop novel integrated modular technology to address these challenges, targeting low-cost, efficient, reliable, allergy diagnostics, empowering patients and clinicians, reducing waiting times and cost per patient, while providing potentially long-term epidemiological information. The project seeks to combine new technology with a step-change in methodology and treatment. It is anticipated that early diagnosis of allergies allowing for prompt treatment will avert avoidable crises and substantially improve patient experience and outcomes.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
ATELERIX LIMITED	Extension of shelf-life for cell therapies at room temperature	£66,422	£46,495
CELL THERAPY CATAPULT LIMITED		£132,278	£132,278
REXGENERO LIMITED		£74,417	£52,092

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
Therapies using live cells offer the possibility of treatments for diseases and conditions that cannot be approached by conventional drugs. Cells are being investigated for their abilities to reverse blindness, re-grow bone and nerves, restore the immune system and treat cancers for which there are no effective drugs. Living cells, however, are fragile and short-lived outside their natural environment. A common approach to address these issues is to freeze the cells for storage but this causes problems when the cells are thawed again for injection into the patient. Many cell therapies simply cannot be frozen and for these products complicated and expensive logistics are required to ensure their delivery to the hospital and the patient before their shelf life expires. A technology has been developed that enables the storage and transport of unfrozen human cells, thereby preserving and extending their functional viability. The technology has been shown to be effective with a wide variety of cell types. This technology has the potential to make cell therapies widely available to many more patients who need treatment. The proposed project will explore options for stabilising the active cells contained within a specific cell therapy product, preventing their deterioration and therefore extending the shelf-life. The product is being trialled in a clinical stage program and is therefore an excellent exemplar to demonstrate the potential of the technology. Extending the shelf-life is necessary to ensure that hospitals have flexibility to schedule operating theatres to administer the product and therefore enable as many patients as possible to be treated with novel, potentially curative therapies. Managing global logistics by this approach can also allow for more efficient manufacturing (fewer manufacturing plants needed, for example), reducing the costs of production and making the therapies more affordable and widely available.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
BACTEVO LIMITED	Transforming Drug Discovery by Nanoscale Chemistry and Screening Enabled by Machine Learning	£829,892	£580,924

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
Nanna Therapeutics has invented a ground-breaking technology which will change the way the pharmaceutical industry discovers new drugs, giving the UK economy a major advantage. This proposal is focused firmly on the discovery of new drugs to show how this technology works, the direct output being starting points for new medicines in cancer, heart disease and inflammatory diseases, such as arthritis. Within pharmaceutical companies, creation of a new drug is a production line-type process made up of several linear segments, all of which need to be completed before you proceed. Moreover, limits on existing chemical technology mean that the inputs to the process (new chemicals) are severely restricted limiting the chances to find new drugs. Nanna Therapeutics aims to completely remove this production line, replacing it with a miniaturised parallel system where there are no limits on the inputs, thus enabling the generation of cheaper, effective medicines to more diseases. The technology allows more chemicals to be made and immediately assessed in a very wide range of tests checking not only whether they could treat the disease, but also their suitability as safe drugs. Machine-learning or Artificial Intelligence can sort this data allowing scientists to handle and exploit the enormous data volumes involved and select the most safe and effective medicines for patients. The added advantage of this technology is that the miniaturisation means for the first time scientists could actually start the whole drug discovery process off using cells from a people with a disease, rather than artificial models trying to mimic the disease, giving more chance of successful therapies emerging from clinical trials. This means, better, faster delivered, cheaper medicines. This has exciting implications as it also opens up the possibility of providing treatments to diseases, which currently would not be seen are economically viable and fast responses to new emerging or threat diseases. By including more tests to assess if a compound is safe, we also see a potential to massively reduce the need for animal testing and further reduce the risk to patients in the first phase of clinical testing. Once established this technology can be used wherever there is a need for new chemicals, including electronics, textiles, food and farming. Such enabling technology could facilitate the growth of many industries and make the UK once again a leading force in the chemical industry, generating many new jobs and wealth to the country.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
IGEM THERAPEUTICS LIMITED	Discovery of next generation HER2 antibodies for the treatment of cancer	£747,453	£523,217

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
IGEM Therapeutics Ltd aims to develop a novel HER2-targeted antibody that will address a number of unmet clinical needs. It will exploit innovative animal models, novel HER2-binding antibody domains and its innovative IgE platform technology. IgE provides a completely unique anti-cancer mode of action which enables our products to be clearly differentiated from IgG-based therapies. IGEM aims to attain a leading position in the global immune-oncology market which is forecast to reach $28 billion by 2025\.

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Results of Competition: Biomedical Catalyst 2018 Round 2 Primer Award

Competition Code: 1808_BMC_R2

Total available funding is £8m

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
DIOSYNVAX LTD.	Digital Immune Optimized and Selected Pan-Influenza Vaccine Antigens (DIOS-PIVa)	£1,466,526	£1,026,568

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
There has never been a greater need for better influenza (Flu) vaccines to replace traditionally produced seasonal Flu vaccines that generate variable levels of protection. Seasonal Flu vaccines are imperfect and fail from time to time resulting in huge economic costs to the NHS and other national health services in this country and globally, when they fail. There is a large global market, with WHO estimates of the world-wide influenza vaccine market to be worth $2.9-3.8 billion alone. There has never been a greater need for a new next-generation of universal influenza vaccines to replace traditionally produced seasonal Flu vaccines, with next generation Flu vaccines that also offer additional protection from pandemic influenza strains. The new innovative vaccine technology developed by DIOSynVax Ltd has the potential to change the way vaccines are made. It's unique vaccine accelerator platform utilizes novel high-throughput, computationally generated vaccines especially suited for highly variable RNA viruses like Influenza viruses. The DIOSynVax technology platform has already demonstrated impressive proof of concept pre-clinical vaccine protection against some of the most notorious haemorrhagic fever viruses such as Ebola, Lassa and Marburg viruses Based on the DIOSynVax Ltd's technology, the DIOS-HFVac3 vaccine has been selected to undergo human trials in the UK. The DIOS Digital, Immune Optimised, and Selected (DIOS) vaccine accelerator technology offers 3 key attributes needed for more effective Flu vaccines: 1.marked breadth of protection 2.accelerated development 3.depth of response and durability for sustained protection_._ This project will apply the proven DIOS technology to the Influenza vaccine problem. The resulting PoC data will result in improved DIOS pan-Flu prototype vaccine candidates which have the required broad immunogenicity and ultimately towards a Universal Flu vaccine protection profile against heterologous (including pandemic strains) Influenza challenges. The DIOS vaccine accelerator technology is a game-changer that has the potential to generate progress the development of dramatically improve protection of people against the broadest possible array of influenza virus threats.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
C-MAJOR LIMITED	Auto-retractable safety syringe for aspiration and injection	£692,917	£485,042

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
Occupational exposures of healthcare personnel to bloodborne pathogens are frequent events in hospitals / medical settings. A needle-stick injury occurs when a syringe that has been in a patient accidentally punctures another person's skin. They have the potential to transmit blood-borne infections, including hepatitis B virus, hepatitis C virus and human immunodeficiency virus (HIV). The WHO estimated that ~3 million healthcare workers are exposed to blood borne pathogens each year due to needlestick injury. The HSE has estimated that there are 100,000 annually needlestick injuries in the UK each year, although the true figure may be higher as many cases go unreported. C-Major is developing a unique patented safety syringe that can be used for injection and also for collecting blood samples.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
ORTHOSON LIMITED	Restoring performance of the spine with a minimally invasive procedure, performed through a needle	£1,717,254	£1,202,078

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
Lower back pain is a worldwide health problem, affecting up to 85 % of people at some point in their life. It is often caused by degeneration, due to ageing of the intervertebral disc, which is located between two vertebrae and allows bending and twisting of the spine as well as resilience under compression. There is presently no method for repairing or replacing the intervertebral disc once it becomes damaged. As a result, patients with persistent back pain are typically offered physiotherapy or medication, which fails to address the underlying cause of pain and the associated loss of load-bearing capacity. In extreme cases, a surgeon operates to perform spinal fusion, whereby two adjacent vertebrae are fused together so as to eliminate that disc joint altogether: this is a major operation with a high failure rate which ultimately increases stresses on spine segments, causing subsequent degeneration. The overall aim of the present project is to enable the development of a new method to replace the disc, alleviate pain and restore movement without the need for major surgery. The whole procedure is designed to work with the insertion of a single, fine needle into the disc. This is used to inject a small amount of tiny gas bubbles into the centre of the disc. These are encouraged to oscillate violently by application of ultrasound from outside the body, which enables them to break the disc around them and create a void. A liquid material is then injected through the same needle that was used to introduce the bubbles in order to fill the void, which sets into a gel-like material that performs as a healthy disc. The specific aim of the project is to produce a prototype, stand-alone device that has all the right features to enable this technique to be used in hospitals. This will involve building a support gantry to couple the ultrasound to the patient's skin, a guiding system to introduce the needle into the disc safely, software to deliver, guide and monitor the treatment, and a gel recipe that can be efficiently manufactured and injected into the patient. The vision is to make this system sufficiently easy and safe to use that it does not require a major operation or significant hospital stay, and can help hundreds of thousands of patients not only with pain relief but with returning to a more active lifestyle.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
DJS ANTIBODIES LTD	Antibodies for the treatment of chronic kidney disease: Technical proof of concept	£1,077,049	£753,934

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
It is estimated that 15.1% of adults will develop advanced chronic kidney disease (CKD) during their lifetime. In the UK, NHS spends £1.23 billion treating CKD each year, with approximately £500 million being spent on dialysis for patients with end-stage renal failure. These patients need to visit hospital at least 3 times weekly for sessions of 4-6 hours, and are limited to 700 mL fluid intake per day. Keeping these patients off dialysis is a therefore a major healthcare challenge. However, even among CKD patients who do not need dialysis, the mortality rate is 36 times higher in patients aged 16-49, and 12 times higher in patients aged 50-64, than age matched controls. In spite of the enormous need, CKD patients are poorly served by current treatments. The only medications with any proven benefits are renin-angiotensin system inhibitors, which work by controlling blood pressure. However patients on these medications still experience progressive kidney loss. There is therefore an urgent need for new treatments that work through separate mechanisms, which can be layered on top of the existing standard-of-care. There is significant evidence for the role of a single cell membrane protein in fibrosis and vascular leak -- processes central to the progression of CKD. Unfortunately, this protein has proven difficult to drug. A small molecule inhibitor recently showed significant benefit in a Phase II clinical a different disease, where fibrosis and vascular leak are also pathological. However, the inhibitor also showed off-target toxicity. Other companies have struggled to produce molecules that fully inhibit signalling by this target. DJS Antibodies has addressed this target by leveraging our unique antibody discovery platform. In previous work, we discovered the world's first lead mAbs that bind to the target and have functional properties. Now we plan to develop these lead antibodies into development candidates, and test them in human and rodent models of disease to obtain a comprehensive preclinical proof-of-concept data package. Success in this project will directly result in DJS either partnering our antibody for development with a major pharma partner, or raising Series A investment to develop the lead candidate to IND approval. With a best-in-class therapeutic supported by rodent _in vivo_ and human _ex vivo_ data packages, DJS will be positioned to exploit the significant commercial opportunity associated with this huge unmet medical need.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
SAW DX LIMITED	Low Cost Sample Preparation System for Detection of Respiratory Pathogens at Point of Care	£1,429,837	£1,000,886
University of Glasgow		£65,454	£65,454

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
SAW-Dx is developing a sample preparation system to enable immediate molecular diagnostic testing at the point of clinical care for Infectious Disease (ID). ID will cause 10M deaths/year globally by 2050\. The recent UK Government-commissioned O'Neil report on AntiMicrobial Resistance (AMR) called specifically for the use of new rapid diagnostic tests to reduce the spread of AMR. Multiplexed analysis and detection of nucleic acids are core requirements for the direct identification of specific pathogens required to initiate an informed treatment. Nucleic acid tests are notoriously challenging to perform rapidly, at the point-of-care, due to difficulties in purifying the nucleic acid biomarkers at low concentrations. SAW-Dx believes that its proprietary sample preparation technology has the potential to significantly simplify diagnostic workflows (in load-and-go systems) and thereby catalyse market growth by enabling wide access to a broad ID nucleic acid based test menu across the global ecosystem of low-complexity test settings. In particular, SAW-Dx's solution will enable testing in doctors offices, field settings and even retail pharmacies. The demand for molecular Point-of-Care technology is high, however we note significant gaps in competitive offerings and repeated market launch delays for competitive products. SAW-Dx plans, with the University of Glasgow and the NHS, to enhance precision ID management by developing its unique sample preparation technology as a front-end enabler for its own detection platform . The SAW-Dx technology will facilitate early detection and precision management, drive down healthcare cost, and reduce onward transmission risk across the ID spectrum. SAW-Dx's technology is both highly differentiated and proprietary, with several patents already issued, whilst the proposed project consortium already has a successful track record of collaboration. By the end of the project, the sample preparation system will have been demonstrated in several different types of clinical samples, and will be ready for incorporation in a formal clinical trial. The current intellectual property position will also have been further strengthened. From a corporate development perspective, SAW-Dx will also have partnered with one or more leading molecular diagnostic companies to demonstrate integration and initiate co-development options with their platform(s). The project will make a significant impact on public health by enabling rapid and precise management of ID in diverse clinical settings available to large numbers of target patients. The project cost (~£1.3M) is modest given the projected return, including 100 potential new jobs and projected annual revenue of nearly $20M by 2025\.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
APPLIED NANODETECTORS LIMITED	POC-Breath test for home management of respiratory disease	£262,926	£184,048

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
Chronic Obstructive Pulmonary Disease (COPD) and asthma are leading causes of morbidity and mortality worldwide and have a significant economic and social burden. Significant challenges include delays in an accurate diagnosis, maintaining good disease control and the identification of exacerbations, which consume a disproportionate share of expenditure due to the high cost of treatment and hospital admissions. As a result, there is an unmet need for non-invasive, simple tests that can diagnose and monitor these conditions accurately. Breath analysis is one such non-invasive test whereby small quantities of volatile organic compounds (VOCs) can be detected in human breath; they form a personalized signature fingerprint of components that can be used for early diagnosis and disease monitoring. We plan to develop a standardized handheld breath test system (early prototype tested in the laboratory) to be used by clinicians and patients that could allow detection of exacerbations earlier and optimising accurate treatment depending on the pathological driver of the exacerbation. This would form part of a self-care program and home monitoring solution to guide personalized treatment plans in less than one minute. Our innovative new breath test system would be handheld, easy to use and internet enabled and significantly cheaper. It would use our unique sensor chip that can monitor many gases simultaneously with high accuracy and high sensitivity.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
OXFORD HEARTBEAT LTD	PreSize Stenting - medical software that allows pre-operative rehearsals of stenting surgeries to reduce complications	£996,980	£697,886

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
Our goal is to make cardiovascular surgeries more efficient and safe. This project develops the PreSize Stenting Platform, a novel solution that helps clinicians plan and rehearse stent placements inside blood vessels. Using cutting-edge computational modelling, we make the best use of available patient scans and stent device mechanics to accurately predict the behaviour of devices inside each patient's vessel configuration. This allows clinicians to optimise device selection, reducing the number of complications and the associated cost of stenting surgeries for hospitals and our society. We are a start-up company specifically created to bring this technology to hospitals. We are currently incubated by The Royal Academy of Engineering. The results of our previous projects have received numerous awards, including the NHS Innovation Award 2017 from Health Enterprise East (HEE). Oxford Heartbeat was also the national Winner at the prestigious Medilink UK Healthcare Business Awards 2017, the Finalist of Pitch@Palace organised by His Royal Highness The Duke of York and was recently named the "Best Healthcare Start-up of 2018" by WIRED magazine. We were also featured in two Forbes articles as "founders striving to change the world" and "one of the new British start-ups to watch closely", and two WIRED articles: "These are the healthcare start-ups you need to know about" and "From AI doctors to 3D X-rays, the future of healthcare is already here", as well as in The Times, Financial Times, etc. Our aim is to grow Oxford Heartbeat to be the leading provider of clinical decision support tools, to improve healthcare and define the medicine of tomorrow.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
SAAT MEDICAL LIMITED	DiagnOSA - a system to diagnose obstructive or central sleep apnoea from a home setting	£359,181	£251,427

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
It is estimated that up to 13% of adult men and 6% of adult women in the UK (3.9 million people) suffer from Obstructive Sleep Apnoea (OSA), with only a small percentage only having an official diagnosis. OSA causes breathing to repeatedly stop during sleep. It happens when the throat muscles intermittently relax and block the airway. There is an average of seven years between first symptoms and OSA diagnosis. For people with OSA, their ability to work is reduced, and the quality of life for the person affected and their family can be severely impaired. Health risks for untreated OSA include heart disease, stroke, type 2 diabetes and obesity (sleep-study.co.uk/about-osa/statistics.html). Central Sleep Apnoea (CSA) differs from OSA in that nerve signalling from the brain to breathe again due to low oxygen levels is impaired. With CSA, the signal from the brain to breathe is either not sent or not received. The incidence of CSA is far lower than OSA (1 in 2000 of the adult population). CSA is associated with serious medical conditions including congestive heart failure, stroke, heart attack and Parkinson's disease. This project will enable SAAT Medical to develop a prototype device to diagnose either OSA or CSA in a home setting, relieving pressure on hospital sleep laboratories, and enabling patients to receive a faster diagnosis at lower cost than currently available via polysomnography. This project supports the following activities: *Development of the nasal attachment physical casing, so that air flow can be directed from each nostril and the mouth over strategically placed sensors. *Miniaturisation of the PCB that collects data from the on-board sensors *Development of PCB firmware *Development of data compression software *Development of a database to collect and store data *Create a data visualisation interface *Design algorithms to power event detection tools that will be used by clinicians to diagnose OSA/CSA.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
CELL GUIDANCE SYSTEMS LIMITED	Neurotrophic growth factors co-crystals for disease modifying therapy of Parkinson's disease	£208,615	£146,030
King's College London		£62,772	£62,772

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
Parkinson's disease (PD) is a neurodegenerative disorder that affects around 1% of individuals over the age of 55\. The disease is associated with loss of a relatively small number of cells, called dopaminergic neurons (DNs), which are located deep in the centre of the brain. PD is a progressively debilitating disease with patients currently treated using drugs and therapies to reduce the severity of the symptoms. However, none of the available therapies impact the overall progression of the disease. Therefore, there is an urgent, unmet clinical need to develop a therapy which is able to slow-down or, ideally, reverse the progression of PD. Strong evidence from animal models shows that regenerating DNs can arrest PD progression. The most effective way to promote DN survival is by treatment with neurotrophic growth factors (nGFs) (naturally occurring signalling proteins which are vital for the development and the maintenance of the healthy nervous tissue). nGFs are highly potent molecules which, if deployed systemically (i.e. intravenous), have marked potential for toxicity, causing damage to healthy non-target cells. Consequently, nGFs need to be precisely administered by surgery. nGFs are fragile proteins with very short half-lives, typically of _minutes to several hours_. However, any nGF drug needs to be active for _weeks to months_ in order to have a measurable effect on DNs. Since repeated surgery is impractical, a great focus of research has been the development of technologies and devices to stabilize, and/or provide sustained release of nGFs from a depot which can be surgically delivered to the required location, deep in the brain. We are developing PODS (POlyhedrin Delivery System), a recently developed sustained-release protein technology based on a natural system that evolved in an insect virus lifecycle. By engineering this system, PODS is able to neatly package and protect perfectly formed nGFs inside protein crystals. These protein crystals are highly stable but start to loosen and release their valuable cargo in contact with proteases from living cells. The rate of cargo protein release can be controlled over time, and release over several months has been achieved. We have demonstrated the utility of PODS using rat models of disease. PODS has the unparalleled potential to deliver on the promise of nGFs to provide vital disease-modifying therapy to treat PD. In this project, we plan to evaluate this potential in various PODS crystal formulations containing nGFs in cell-based and small animal models of PD.