Results of Competition: Investment Accelerator: Innovation in Precision Medicine

Competition Code: 1804_PM_INVESTMENTACCELERATOR

Total available funding is £6,926,125

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
NIDOR DIAGNOSTICS LIMITED	Precision diagnosis of irritable bowel syndrome (IBS): stratifying patients via a positive diagnosis and the right treatment strategy	£892,848	£446,424

Irritable bowel syndrome (IBS) is a chronic (life-long) gastrointestinal disorder, which negatively impacts upon the quality of life of the circa 10% of affected adults worldwide. IBS sufferers experience severe abdominal pain, bloating and a change in bowel habit (e.g. diarrhoea) making everyday life challenging. Due to a lack of a diagnostic test, the current health guidelines advise clinicians to rule out other disease before the diagnosis of IBS is recognised. This means patients are exposed to lengthy invasive tests highlighting what the patient does not have (e.g. Crohn's disease, cancer etc.), rather than from what the patient is suffering. This process can take many months or years, can lead to a breakdown in trust between the patient and the clinician/GP, and is costly (in terms of time, resource and money) to the health service. When an IBS diagnosis is agreed, treatment can take months to show evidence of working --further stretching patient trust. Unfortunately, only a proportion of patients will respond to the initial treatment, which is a restricted diet (either due to poor diet compliance or the inability of the patient to respond _per se_) and drug treatment is then used as a last resort.

Nidor has developed new diagnostic tests that give for the first time a positive diagnosis of IBS and additionally stratify patients into which type of therapy would be most effective. This is a technology that enables early and accurate diagnosis to inform patient treatment thereby improving patient outcomes and reducing healthcare costs. This will reduce the demand for invasive investigations, improve patient satisfaction, and reduce the prescription of unnecessary drugs while rapidly servicing the patient's needs.

The award of the grant will enable the collection of suitable patient samples for the test validation, develop the in-house manufacture of the sensor and the mark 1 instrument to a recognised quality standard, refine the data analysis techniques of the sensor results and provide an estimate of the financial savings the tests could deliver to the NHS. The project is expected to take 21 months and will allow Nidor to validate the test(s) to a point where it can be offered as a centralised laboratory testing service to improve patient outcomes.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
CELL MOGRIFY LIMITED	Accelerating regenerative cell therapies with data-driven cell conversions.	£836,500	£418,250

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Our understanding of biology and advancements in technology are rapidly changing the way that we both diagnose and treat disease. One area where this change is being experienced is in the area of cell therapy, an area of medicine which involves treating disease by replacing or regenerating patient tissues in order to overcome disease. These tailor-made therapies have the potential to completely change the way that we treat disease since their aim is not is treat the symptoms of a disease but to restore the diseased tissue to its original state. One of the main bottlenecks in cell therapies reaching the clinic is the development of efficient, safe and scalable sources of cells. At present the cells either need to extracted and sorted from the patient or a donor or they are derived via experimental protocols that take years to develop. Cell Mogrify is revolutionising this process through the introduction of its data-driven approach to finding ways to generate any human cell type, allowing us to vastly reduce the development time. Our approach utilises cutting-edge bioinformatic tools that we have developed along with world-class experimental expertise in order to use information extracted from patients cells to predict how to generate that cell outside the body. Typically these cell conversions are performed by artificially over-expressing transcription factors, the biological master regulators of the cell, in order to create cells outside of the body that can later be transplanted to the diseased area of a patient. However in certain circumstances having to perform this reprogramming outside of the body or using transcription factors can be a regulatory or operational roadblock. To this end we have also developed ways to replace these transcription factors with small molecules, allowing us to safely convert between cell types either externally or directly at the disease site. To date Cell Mogrify have utilised the technology to bring one cell therapy to an advanced preclinical stage. This proposal will allow us to demonstrate that this approach is however general for any cell therapy and as such that it is a platform technology for the cell therapy market. In order to do this we will take three further products, at various stages of development, to a preclinic state. In doing so we will both create three new cell therapy products as well as providing a proof of principle for the platform.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
CLINSPEC DIAGNOSTICS LIMITED	ClinSpec Dx: Serum Diagnostics for Cancer	£517,187	£258,594

ClinSpec Dx is developing the world's first cost-effective blood test for brain cancer and aims to develop other fast, sensitive blood tests for the early detection of other cancers and other diseases. Our next-generation liquid biopsy diagnostic approach analyses the entire biomolecular complement of human serum and when combined with our machine learning / artificial intelligence algorithms provides a disruptive capability to enable early and accurate diagnosis of brain tumours and inform patient treatment.

Early detection and tailored treatment are major goals for world health agencies, both to save costs and improve survival. However, this means a wider population of symptomatic patients must be tested, the majority of which are healthy.

ClinSpec Dx Triage ID is uniquely positioned for early detection of brain cancer because it

*uses a simple infrared method, designed to comfortably provide a cost-effect test for healthcare agencies

*does not require the expensive reagents or sample prep used in genetic tests

*provides a yes/no result in minutes and has low staffing and infrastructure costs.

Based on preliminary Health Economics, the Triage ID test is potentially cost saving when used to assist GPs in more accurately prioritising patients for brain scans. We conservatively estimate savings to the NHS of £12M per annum, by reducing unnecessary brain scans. Improved survival and quality of life will also reduce the economic burden on health services.

We have developed the ClinSpec Dx Triage ID on 724 patients from biobanks worldwide achieving 91.5 % and 92 % sensitivity and specificity respectively. By April 2019 our clinical feasibility study will have recruited 600 patients (currently at 200 patients) who are visiting NHS Lothian for an open access CT programme. This enables us to test our disruptive approach within a clinical setting and on our specific target population. The key objectives and focus areas for this project are to:

- 1)Undertake a statistically significant diagnostic accuracy test of the ClinSpec Dx Triage ID on a 600-patient post clinical feasibility study
- 2)Develop our multi-centre clinical trial to enable the collection and analysis of a further 98 serum samples to achieve a total of 1586 serum samples.
- 3)Understand the ability of the ClinSpec Dx Triage ID to group and route patients for further imaging and treatment based upon
- a.Cancer vs. Non-Cancer Status
- b.WHO Grade and Pathological Classification of Brain Tumour

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c.Identification of particular genotypic features of the tumour such as MGMT and IDH status		

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
MSCTRAIL THERAPEUTICS LTD	Investigating the therapeutic potential of biomarker targeted MSCTRAIL in malignant pleural mesothelioma	£1,277,217	£638,608

Malignant pleural mesothelioma (MPM) is a cancer affecting the lining of the lungs. It is usually caused by asbestos exposure and the number of cases is increasing with more than 2,500 cases per year in the UK. Mesothelioma is very difficult to treat and is incurable; the average life expectancy from diagnosis is 12-18 months. We have developed a new, genetically modified cell therapy that is able to find and kill cancer cells without affecting healthy cells. Our laboratory data shows that this cell therapy, a mesenchymal stromal cell (MSC) and gene therapy (called TRAIL) kills most malignant mesothelioma cells and is more effective than the chemotherapy drugs we currently use in patients. Used together they are extremely potent. In addition we have identified which patients' cancers the therapy is most likely to be effective against, using a biomarker (loss of a protein in cells called BAP1).

The aim of this research project is to test whether this novel cell and gene therapy is effective in treating patients with MPM, more than half of whom carry that biomarker.

We and other teams have shown MSCs are attracted to sites of cancer. We have modified these MSCs to express a protein called TRAIL that kills cancer cells but not normal cells. This means the MSCs can deliver TRAIL directly to the tumours and work at the site of the cancer. We have shown that these TRAIL-carrying MSCs kill a high percentage of mesothelioma cells from different patients and in particular those cells that don't express the protein BAP1\. When MSCTRAIL is given to mice with mesothelioma the growth of the tumours is significantly reduced.

In order to test whether this treatment works, we will run a clinical trial in patients who have been diagnosed with MPM whose tumours do not express the BAP1 protein and are due to have the current recommended chemotherapy treatment. Patients will be allocated randomly to receive either the standard chemotherapy alone or the same chemotherapy but in combination with MSCTRAIL. Each patient will receive three doses of MSCTRAIL delivered by injection into a vein. Each dose will be given 3 weeks apart and at the end of 12 weeks they will have a scan of their chest to assess whether the mesothelioma has reduced in size.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
MICROBIOSENSOR LIMITED	Same-day Test for Antibiotic Resistance (STAR)	£1,242,950	£621,475

The misdiagnosis and incorrect treatment of Urinary Tract Infections (UTIs) is a significant global healthcare problem and a contributory factor to growing antibiotic resistance levels. UTIs are the most common non-intestinal infection in women worldwide (over 15-million new infections p.a.). In the UK they are the 3rd most common reason for emergency admission via A&E, with over 180,000 A&E admissions p.a., costing the NHS £434M (2013/14). Due to a delay of 3-days (or more) between sending suspected UTI samples off for hospital tests and receiving the diagnostic results back, doctors are forced to make an educated guess as to the nature of the infection and what the most effective antibiotic treatment might be. This guess is often incorrect and the infection resistant to the antibiotic prescribed. This leads to a worsening of the infection and can result in the patient being hospitalised, introducing short-term risks for patient health and long-term societal risks from growing antimicrobial resistance.

Microbiosensor is developing a simple, disposable medical device to address this market need. The 'Same-day Test for Antibiotic Resistance' (STAR) we propose to develop with Innovate UK funding will miniaturise and simplify conventional hospital microbiology. STAR relies on a colour change reaction to signal the presence of live bacteria and combines i) a disposable 'cassette' device which processes the urine sample via a series of chemical reaction chambers and ii) a re-usable incubator instrument into which the cassettes are inserted, which automates the sample analysis and speeds diagnosis. Instead of sending samples off to the hospital lab, STAR will "bring the lab to the patient", in an easy-to-use format and at a fraction of the cost of existing analytical platforms.

This will allow care homes, pharmacies and GP surgeries to benefit from 'same-day' diagnostic services: testing potential UTI samples and prescribing targeted antibiotic treatments if an infection is detected later that afternoon. A precision medicine approach to UTI treatment will therefore speed the time to an effective treatment, improve patient care and help preserve the dwindling arsenal of effective front-line antibiotic drugs.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
KINOMICA LIMITED	Clinical validation of a revolutionary multi- analyte companion diagnostic platform technology and treatment algorithm for precision medicine	£943,923	£471,962

Acute myeloid leukaemia (AML) is an aggressive form of blood cancer, where only about 20% of patients are expected to survive for 5 or more years after diagnosis. A new drug called midostaurin can triple survival times for some patients and is now available on the NHS. However, only a subgroup of AML patients (~30%) are eligible to receive this treatment and approximately 50% of those will experience no benefit; therefore, only about 15% of AML patients overall actually benefit from treatment. Consequently, many patients are exposed to unnecessary side-effects, are denied the opportunity to be recruited on trials for drugs that may be effective, and the NHS are subjected to unnecessary costs (\>£23M/year) treating patients that fail to benefit.

The diagnostic test used to determine patient eligibility to receive midostaurin is called LeukoStrat(r), which assesses whether an AML patient's cancer cells have mutations in a gene called FLT3\. Patients who are positive for this "biomarker" will receive midostaurin.

Early clinical trials and a recent pre-clinical study by Kinomica's Founders showed that 42-65% of patients _without_ the FLT3 mutation biomarker (representing 70% of all AML patients) responded well to midostaurin, so there is likely a significant number of patients currently classified as ineligible who could benefit from treatment. Midostaurin is currently in the very advanced stages of clinical trials for use in patients without the FLT3 mutation biomarker. Thus the importance of identifying those who will benefit from treatment becomes even greater, as the cost to the NHS to treat patients who will not benefit could triple.

The variable response rates for midostaurin treatment in AML (with and without mutated FLT3), suggest that the current FLT3 mutation biomarker and medical test to detect this marker (LeukoStrat(r)) are severely limited. Kinomica's Founders have developed a new and much more accurate way to predict whether an AML patient will respond to midostaurin. Kinomica's approach involves measuring the activity of an important group of proteins called kinases, within a patient's cancer cells. This readout can then better predict whether midostaurin will destroy those cells. Funding is sought so that Kinomica can develop the technology into a clinical test. The realisation that kinase activities are better predictors of therapeutic response than genetic alterations will likely have far wider implications for the development of personalised therapies across many cancer types.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
FEEBRIS LTD	AI-enabled geriatric platform for community health	£1,063,785	£744,650

Globally there is a health workforce crisis, with a shortage of 7.2m healthcare professionals. For the NHS this equates to a 50,000 health workforce gap. These shortages result in restricted access to care, lack of personalised and regular assessment, and delayed identification of diseases and exacerbations. The consequences are most severe for the most vulnerable such as the elderly. In the UK, more than 9mpeople over 65 years live with at least one chronic condition.

Feebris is developing an Al-powered mobile health platform that enables non-medical users, such as carers and community health workers, to identify and monitor complex conditions in the community. This project will develop the geriatric application of the platform, focused on elderly people suffering from avoidable hospitalisations due to respiratory conditions, such as pneumonia, COPD and asthma. The Feebris platform will integrate rich & quantifiable health inputs, derived from diverse health sensors, to perform personalised evaluation of health risks. The Al-engine will process medical history and regular measurements to identify health trends (e.g. frailty) and combine multi-morbidity risk factors into prediction of complications. These advanced analytics will remove the need for a clinical taskforce to be continuously reviewing large volumes of data and instead focus resources on at-risk cases. Consequently, our innovation can both improve patient outcomes, as well as reduce pressures on health system resources.

The development will involve constructing a geriatric measurement system (off-the-shelf sensors & appropriate mobile app) and a unique AI-engine for diagnosis & personalised monitoring of respiratory ACSCs, capable of identifying health issues early to prevent complications. Additionally, the project will also ensure the platform is compatible with existing IT systems for health and care delivery, and compliant with highest regulatory standards for security, clinical performance and efficacy.

The project will be conducted in collaboration with clinical, engineering and business experts. Alongside the technical development of the platform, the project will also involve a clinical study, conducted alongside four elderly organisations which provide elderly care across different settings: independent living, retirement village and care home. The measurements collected during the study will ensure that the platform fits the needs of a variety of elderly people and can address their health challenges regardless of where they live.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
BIOFIDELITY LTD	Novel PPL-based chemistry platform and workflow for ultra-sensitive, low cost detection of gene targets	£997,089	£498,544

The concept of liquid biopsy holds tremendous promise as a method of routine screening, however current methods, although suitable for use in analysing tissue biopsies, are far from sensitive, specific, or inexpensive enough to enable routine use. Current platform chemistries, such as Roche's Cobas platform, currently considered the gold standard, require at least 5% of the DNA found in blood to contain a mutation. This is problematic as often much less than 1%, and frequently 0.1% of the DNA in blood that must be detected will contain this allele. Much of this problem is due to quantity of background genomic DNA present, and which makes highly specific PCR tests from only a few molecules of DNA problematic.

We have developed a highly novel method and chemistry platform which, by combining several novel steps, allows us to detect only a few molecules of mutant allele-containing DNA against a background of genomic DNA. This will allow us to significantly exceed the current limits of detection without requiring novel apparatus, sequencing or digital PCR.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
Echopoint Medical Ltd	Precision Medicine for Coronary Artery Disease with Optical Flow Microcatheters	£1,123,732	£505,679

Echopoint are a UK-based medical technology SME at the cutting edge of enhanced diagnostics. Their first product will address the urgent need for better assessment of blood flow within heart arteries during stenting procedures for heart attacks, enabling a precise diagnosis of the patient's condition and patient-specific recommendations for treatment. This will thereby improve the patients outcome in this life-or-death situation.

They have designed a miniaturised sensing catheter, less than half a millimetre in diameter, that is able to be passed by doctors into the heart to guide treatment of cholesterol blockages within the blood vessels. Uniquely, it is able to sense many different signals at once, such as blood temperature to one thousandth of a degree and the flow of blood within the vessel itself. Combining these highly specific measures with high-fidelity electrocardiogram (ECG) signals will enable an unprecedented level of information about microvascular physiology, and provide a foundation for a wide range of future developments. Supported by the Precision Medicine Accelerator, Echopoint will finalise the catheter and console design, and develop the analytic tools to leverage highly specific patient data to provide clear treatment recommendations to treating physicians. The project will thus accomplish key steps towards the commercialisation of an entirely new fibre-optic sensing platform.

The Echopoint team are made up of recognised leaders in their fields. Top optical, electrical and biomedical engineers are joined by a cardiologist and an experienced medtech business expert who will lead this highly innovative company through to successful commercialisation. The Precision Medicine Investment Accelerator provides valuable assurance and risk-reduction that is required to attract the major private and venture funding. It will enable Echopoint to launch as a new UK based, high-tech University spin out, acceleration the development of its new sensing technologies to bring benefits for patients in the NHS and worldwide.

The platform developed by Echopoint is poised to affect many facets of medical diagnosis by providing enhanced information for doctors and thereby ensuring the most effective and applicable treatment is provided.

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IBEX INNOVATIONS LTD	IBEX Enhanced X-ray Mammography	£1,401,689	£700,844

The project will develop and commercialise novel technologies to radically improve the safety, effectiveness and patient comfort of X-ray breast imaging.

Firstly, the project will adapt the IBEX Trueview(r) gridless scatter correction method for use in mammography and Digital Breast Tomosynthesis (DBT) systems and demonstrate its effectiveness to reduce patient dose and improve image quality in mammograms and DBT reconstructions. The in-vivo and exvivo data generated during this initial phase will be used to market the capability to leading medical X-ray system integrators and secure commercial licence deals within the first year of the project.

Secondly, the project will develop and demonstrate the effectiveness of a prototype 3D X-ray imaging system capable of creating full, high-contrast 3D reconstructions of uncompressed breasts at less patient dose than a standard 2D mammogram and without injected contrast agents. This radical new product has the potential to transform breast screening and cancer diagnosis, especially for women with dense breasts. The ex-vivo data collected during this second phase will be used to inform a commercialisation strategy and a future human clinical study.

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MIRADA MEDICAL LIMITED	Integrated AI-enabled platform for adaptive radiotherapy dose planning	£773,466	£386,733

External Beam Radiotherapy (RT) is a cornerstone of modern cancer treatment, utilized on its own or in combination with surgery and/or chemotherapy. During RT, high energy radiation, generated within a linear accelerator, is directed at a tumour, thereby destroying it, but also inevitably irradiating nearby healthy tissue. It is therefore necessary to carefully plan any RT to maximise the tumour dose while minimising the dose to the healthy tissue. In this process, known as RT planning, teams of clinical experts spend a great deal of time developing a treatment plan prior to its administration.

Typically, a course of therapy lasts 4-6 weeks during which the patient's anatomy may change significantly rendering the plan sub-optimal. Indeed, such changes might result in either too little radiation being delivered to the tumour and/or too much to surrounding tissue. Ideally, the validity of the treatment plan is monitored during therapy and the plan changed as required; this concept is known as Adaptive Radiotherapy (ART).

Multiple studies have demonstrated the clinical benefits of ART, but it is rarely performed in routine clinical practice due to associated increased workload. The latest radiotherapy treatment machines can perform 3D imaging for each daily fraction of the treatment. While today such imaging is predominately used to ensure correct patient positioning there is an increasing desire to fully exploit this capability for monitoring for ART.

The challenge to overcome is how to use this information efficiently. Manual review of the imaging is too labour intensive for clinical implementation. Therefore, there is a need for a system to automatically review all available imaging and identify those patients who may benefit from adaptive re-planning.

This project seeks to develop a proof-of-concept to demonstrate that a substantially automated ART monitoring system is practical for clinical use while also demonstrating integration with market-leading clinical solutions for dose calculation and personalized treatment planning.

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Participant organisation names	Project title	Proposed project costs	Proposed project grant
BreatheOx	Personalised asthma care at home	£931,392	£465,696

Preventable asthma attacks cause significant morbidity, mortality and a massive economic burden. The key reason for this is the failure to identify early warning signs - while to patients it may seem like an attack is sudden, warning signs actually appear days or weeks before the attack happens. However, by the time the patients perceive the symptoms, its often too late and they have to be rushed to the emergency. The extent to which this need is unmet is evident in the statistics from National Review of Asthma Deaths (NRAD), according to which of 1300 people in UK who die each year because of asthma, about 45% die even before they reach the hospital. Even a few hours of early warning could make a difference between life and death.

We are developing an automated, real time and personalised monitoring system to predict and prevent asthma attacks at home.

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EMTEQ LIMITED	Mobile Observation Of Depression (MOOD) platform for digital phenotyping	£1,081,990	£540,995

Emteq Ltd, based at the Sussex Innovation Centre, is developing a wearable digital platform that allows real-time objective monitoring of novel markers of depression.

The World Health Organization (WHO) estimates more than 300m people are living with depression. In the UK, up to 10% of people will suffer from depression at some point in their lives; accounting for over 57m annual antidepressant prescriptions (England, 2014). The rising incidence of depression worldwide is attributed to increased stress and changing lifestyle. The economic cost of treating a patient with depression is £2,085/person/year and productivity losses account for £7.5b annually.

Most precision medicine approaches look for genetic or molecular disease markers. However, whilst some conditions such as cystic fibrosis have and strong genetic influence, twin studies show that for the top ten causes of preventable deaths, genes contribute only a minor predictive role. All of the top ten causes of premature death have a strong behavioural influence, therefore predictive analytics based on digital phenotyping has huge potential to save lives.

Currently, no technology is available for clinicians to measure emotional responses objectively in people with major depression. In clinical practice, assessment and documentation of symptoms and signs relies on the patients' subjective recall and a 'snapshot' of how they are feeling on the day. In this respect, a system for objective monitoring during day-to-day activities could have a tremendous impact on treatment stratification and compliance, and understanding individual drivers of happiness.

We are collaborating with leading specialists in mental health (MindTech, Sussex Partnership NHS Trust), to develop the 'MOOD' platform for use in patient diagnosis, stratification and treatment monitoring.

Sussex Partnership NHS Trust operates from over 260 sites, including community services, and serves a population of 1.55 million people. MindTech is instrumental in ensuring adequate Public Patient Representation, user interface design and advice on clinical pathways.

We have invested heavily in building an international network of commercial and academic partners. Successful project delivery will cement our reputation as leading innovators within the industry and is the first step in an ambitious commercial strategy to disrupt the depression treatment and screening markets.

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CLOSED LOOP MEDICINE LTD	Closed Loop Medicine - Hypertension (CLM-HT)	£1,326,108	£663,054

When a clinician treats a patient with a disease, a routine and common approach is to focus on one aspect of the treatment, for example, prescribing a drug. There may then be many weeks or months before review and it may be with a different clinician. It is hard for them to judge whether the first therapy has worked and they may switch to a different therapy. Some clinicians will take a holistic approach to therapy - they will also prescribe non-drug therapies, which could enhance the effectiveness of the drug. However, this approach is unusual, in part because of lack of time, but also because of problems integrating and synchronising drug and non-drug therapies (e.g. behavioural therapies). The ideal clinician would combine both drug and non-drug therapies, and then review the patient regularly to assess benefits, allowing them to 'close the loop', and modify the treatment, if required, to ensure the best outcome for the patient.

This project enables Closed Loop Medicine (CLM) to work with clinical and technology specialists interested in optimising health through personalised medicine, critically with expertise in the drug, digital health and diagnostics spaces. We are starting with blood pressure because this is extremely common -- one in four adults in the UK has high blood pressure - but it is poorly controlled in a 1/3rd of these patients. This then leads to higher rates of heart attacks and strokes. More recent research has indicated that even better outcomes can be achieved by lowering blood pressure even more than that currently recommended. This would mean that 60% of current adults would need treating and the tighter blood pressure control would be even harder to achieve without causing side effects.

By combining blood pressure measurement, drug and non-drug therapies in a closed-loop via a smartphone app we will demonstrate that we can optimise individual treatment for far more patients. The intent is to also empower patients to feel more in control of their treatment and aware of the broader factors which impact on blood pressure control and to relieve pressures on clinics.

Our vision is to revolutionise the treatment of blood pressure, such that all patients are well controlled, saving thousands of lives through fewer heart attacks and strokes.