

## Results of Competition: Biomedical Catalyst 2018 Round 2 Late Stage

Competition Code: 1808\_BMC\_R2\_LS

Total available funding is £10,000,000

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
SKIN ANALYTICS LTD	Late stage development of a skin cancer detection service	£1,071,571	£750,100

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

Skin Analytics has developed an Artificial Intelligence (AI) solution for the detection of skin cancer from images taken by a smartphone camera with a dermoscopic lens attachment. Our vision is to reduce the number of deaths from the disease while significantly reducing the cost of finding skin cancer.

We have shown our skin cancer detection service (called DERM) can identify cases of malignant melanoma (MM), Basal Cell Carcinoma (BCC) and Squamous Cell Carcinoma (SCC) with a high degree of accuracy from historical images of skin lesions. We have conducted a clinical validation study with seven NHS Trusts on the melanoma detection algorithm, and in this project we will do the same for the non-melanoma skin cancers (NMSC). We will also conduct research into whether we can detect changes in lesions over time, which would be important for doctors who want to 'watch and wait' suspicious lesions. This project includes the clinical studies required to complete this work.

A large part of the project aims to integrate DERM into the NHS. This involves both the technical integration with the systems used by GPs etc, and securing the relevant regulatory clearances, but also gaining an understanding of the patient pathways and how DERM might affect them, exploring barriers to adoption, and gaining user feedback on the software. We will also conduct an initial health economic analysis of the costs/benefits of a skin cancer service in the NHS.

At the end of the project Skin Analytics will have sufficient clinical, user experience, health economic data and regulatory clearance to support the implementation of DERM in different clinical practices across the NHS.

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

## Results of Competition: Biomedical Catalyst 2018 Round 2 Late Stage

Competition Code: 1808\_BMC\_R2\_LS

Total available funding is £10,000,000

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
DIURNAL LIMITED	Novel Modified Release of T3 for the Effective Treatment of Hypothyroidism	£1,392,971	£626,837

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

\*\*Diurnal (in conjunction with its sub-contractor Quotient Sciences) aims to change the paradigm for the treatment of hypothyroidism by developing a, first-of-a-kind, modified release formulation of\*\* \*\*triiodothyronine (T3) and demonstrating physiological thyroid hormone replacement in Phase 1 clinical trials.\*\*

This project directly addresses the first wave challenges set out by the Industrial Strategy Challenge Fund (ISCF) of developing first-of-a-kind technologies for the development of new medicines to accelerate patient access to new drugs and treatments. This experimental development project builds upon existing scientific evidence that T3 could offer a better treatment option for the estimated 400,000 UK hypothyroid patients who don't feel well on levothyroxine (T4) monotherapy. These patients suffer from persistent depression, fatigue, obesity and poor quality of life as highlighted by current clinical guidelines and patient organisations, and there has been no product innovation in over 50 years. There is evidence that combination therapy with T4 & T3 would improve health however, current T3 options do not restore physiology because of a lack of appropriate formulations and patients often seek to complement the treatment with supplementary T3 sourced from off shore pharmacies. Available T3 formulations provide un-physiological T3 levels because of a very short serum half-life, which means patients require up to three doses of T3 per day and are at risk of high T3 levels that can cause cardiac arrhythmias. Diurnal will develop a modified release T3 formulation that will overcome the short half-life of T3 and provide the physiological level and rhythm of T3. This will be done using the Quotient RapidFACT technology and the formulation will be tested in healthy volunteers in a Phase 1 clinical trial. A successful outcome, in conjunction with Diurnal's product development experience, would allow the project to move rapidly to later phase clinical trials and improve the health outcomes of patients in the UK and potentially millions of sufferers worldwide who are afflicted by hypothyroidism.

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

## Results of Competition: Biomedical Catalyst 2018 Round 2 Late Stage

Competition Code: 1808\_BMC\_R2\_LS

Total available funding is £10,000,000

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
SENSE BIODETECTION LIMITED	Development of an instrument-free molecular diagnostic test for Influenza and RSV	£3,887,983	£1,749,592

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

Infections that affect patients breathing, such as influenza and respiratory syncytial virus (RSV), cause over 6 million hospital admissions and c.700,000 deaths globally each year. They particularly impact over 65s, under 5s and patients with chronic disease, e.g. COPD. There is an important need to improve the diagnosis and treatment of respiratory illnesses, including permitting antiviral drugs to be used when they are most effective and cutting the use of antibiotics when they are not required. Laboratory diagnostic tests for influenza and RSV which detect the genetic material of the viruses are very accurate but need complex equipment, which necessitates a central testing location and the associated operating systems which add costs and cause delays. Rapid point-of-care tests, similar to a pregnancy test, are available for influenza and RSV and have been used in the USA since the early 1990s. They are cheap and convenient but miss many cases of infection and are unreliable. We have developed a single-use molecular test device that brings the gold standard performance of laboratory machine tests into a rapid, disposable, point-of-care test format. The product is highly flexible and may be readily adopted outside of central laboratories. The benefits of our test include improved treatment of patients, fewer hospitalisations, better use of antibiotics, fewer deaths and significantly lower overall healthcare costs. Future use by hospitals, GPs and nursing homes would also enable more effective infection prevention and control.

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

## Results of Competition: Biomedical Catalyst 2018 Round 2 Late Stage

Competition Code: 1808\_BMC\_R2\_LS

Total available funding is £10,000,000

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
CAUSEWAY THERAPEUTICS LIMITED	A first-in-patient trial of TenoMiR a microRNA replacement therapy for tendinopathy.	£1,797,176	£1,258,023

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

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 allow Causeway to demonstrate TenoMiR's safety and effectiveness in patients suffering from tendinopathy.

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



## Results of Competition: Biomedical Catalyst 2018 Round 2 Late Stage

Competition Code: 1808\_BMC\_R2\_LS

Total available funding is £10,000,000

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
ACURABLE LIMITED	A wearable technology for diagnosing sleep apnoea in children	£1,172,750	£820,925

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

Acurable produces the first truly wearable medical device able to accurately diagnose sleep apnoea in a non-invasive way. Acurable's patented technology is a major engineering innovation and the product of 10 years research at Imperial College London.

Our solution uses a non-invasive wearable sensor (AcuPebble) to monitor acoustic signals of the patient and then applies sophisticated signal treatment algorithms to extract from them the main parameters required for the diagnosis of sleep apnoea. Results from a preliminary clinical study in adults yielded excellent results on the efficacy of a former, suboptimal, version of the device detecting respiratory apnoea events in a clinical setting. The results were published by BMJ Open in 2014\.

This project application covers the scientific and technical work required to modify the technology so that it can also be used in children.

Throughout the course of this project: (1) We will conduct a clinical study to gather acoustic signals with the AcuPebble sensor from children who are also undergoing the standard sleep diagnosis method. These signals will be used to carry out research work leading to modification of the existing algorithms to optimize them to the physiological characteristics of the pediatric population; (2) Based on the same clinical study, the AcuPebble software will be modified to provide outputs that are relevant for diagnosis of the pediatric population; (3) The modified algorithms and system outputs will be validated to prove clinical efficacy; (4) Usability studies will be carried out leading to user interfaces customized for the specific needs of the pediatric user case; (5) A clinical evidence dossier as required by regulatory bodies will be created; (6) A data platform/user interface will be created, to allow the use of AcuPebble, not just for automatic diagnosis, but also as a signal collection research tool, that can be used to carry out research in a wider range of pediatric diseases.

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

## Results of Competition: Biomedical Catalyst 2018 Round 2 Late Stage

Competition Code: 1808\_BMC\_R2\_LS

Total available funding is £10,000,000

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
OXULAR LIMITED	Novel Treatment of Retinoblastoma	£2,846,764	£1,992,735

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

The aim of this project is to advance development of a new drug product and drug delivery device for the treatment of Retinoblastoma, a childhood cancer of the eye. This type of ocular cancer affects children globally and often result in loss of vision or spreading of life-threatening cancers to other parts of the body. Visual impairment and blindness cause a considerable economic burden for affected children and caregivers.

The ocular drug delivery device is designed to precisely deliver drugs to the specific site of the cancer in the eye. This is done in a less invasive manner than existing treatments and causes significantly less physical trauma to the patient and mitigates the potential to spread the cancers around the patient's body. The drug product aims to deliver safe and robust local treatment while reducing side effects that come from systemic treatments.

The critical project outcome is the safe and effective treatment of children with Retinoblastoma measured by eradication of the cancers and reduced rates of recurrence over the current standard of care. Demonstration of the device's clinical effectiveness includes completion of a safe injection procedure and successful delivery of the treatment to a specific location in the eye of Retinoblastoma patients.

Fabrication of the device and drug uses highly specialised production mechanisms. The combination of these innovative components along with clinical data will expand an already strong intellectual property position.

Public funding will help advance this innovative device through first clinical trials, allowing continued advancement of ocular cancer research programs that could one day become innovative treatments for children with significant unmet needs.

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

## Results of Competition: Biomedical Catalyst 2018 Round 2 Late Stage

Competition Code: 1808\_BMC\_R2\_LS

Total available funding is £10,000,000

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
INGENZA LIMITED	Enzyme-enhanced safe placement of paediatric nasogastric feeding tubes	£156,396	£109,477
Imperial College London		£84,600	£84,600

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

This project aims to demonstrate the significant safety and cost benefits of a novel enzyme-enhanced test-strip that rapidly substantiates the correct placement of nasogastric feeding tube in infants and neonates - patient sub-groups for which tube placement errors confer very significant clinical risks and costs. Several hundred thousand nasogastric (NG) feeding tubes are used by the NHS every year in paediatric and neonatal care. Tube misplacements in all patients can and do have disastrous consequences, including patient death. Current safety guidelines and standard UK hospital practice require a test for NG tube aspirate to show pH5.5 or lower prior to feeding or medication, intended to indicate correct stomach location by the presence of gastric hydrochloric acid. The pH test-strips currently employed to this end solely measure gastric HCL and are frequently misinterpreted. This limitation of the only bedside assay currently recommended by the NHS, results in unnecessary confirmatory chest X-rays which, quite apart from being particularly undesirable in infants and neonates, are themselves susceptible to further misinterpretation. In addition to greater clinical risks, the costs are also disproportionately high for this vulnerable patient group. We have developed a novel enzyme-enhanced test-strip to verify correct tube placement which, in recent studies on adult patients in UK hospitals, has proved to be significantly more reliable and accurate than current recommended NHS practice, while lowering costs and requiring no extra user training. The test-strip is innovative in detecting the activity of stomach-specific Human Gastric Lipase enzyme (HGL) to augment the acidic pH response of gastric acid and thereby provide a far more sensitive and selective means to confirm safe and correct NG tube placement. This project will further validate the technical performance of this new test-strip in the infant patient sub-population to quantify its capability to reduce clinical risks, costs and length of hospital stay. Greatly improved safety and reduced confirmatory X-rays in UK paediatric care will prove highly beneficial to the adoption of this new test overseas. Whereas NG tube placement practice worldwide varies greatly for adults, the repeated exposure of infants and neonates to X-rays is universally considered unacceptable. The project will include a non-invasive clinical trial within the paediatric ward at St. Mary's hospital, Paddington, London. Data on clinical utility and health economics will be collected to assess the positive impact of the new test-strip's application and further promote its adoption by the NHS and healthcare providers worldwide.

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

## Results of Competition: Biomedical Catalyst 2018 Round 2 Late Stage

Competition Code: 1808\_BMC\_R2\_LS

Total available funding is £10,000,000

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
LIGHTPOINT MEDICAL LTD	Clinical evaluation of a miniaturised cancer detection probe	£1,228,905	£860,234

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

Cancer is one of the leading public health challenges in the UK. Someone is diagnosed with the disease every two minutes. Cancer currently costs the UK £18.3B per annum in healthcare expenses and lost productivity. With predictions that by 2020 almost half of the population will be diagnosed with cancer within their lifetime, the health and economic implications for the UK are considerable.

Surgery remains one of the primary treatment options for cancer patients, but is very often unsuccessful, largely due to the incomplete removal of cancerous tissue, or the cautious excision of healthy tissue.

Surgery often fails because there is no way to accurately detect cancer in real-time during surgery. Surgeons are completely dependent on their naked eye and sense of touch to identify all of the cancerous tissue. With the move towards minimally-invasive, key-hole and robotic surgery, surgeons have now even lost their ability to use their sense of touch and their field of view is increasingly restricted. Numerous technologies have attempted to address the pressing medical need to detect cancer during surgery but none have proven sufficiently accurate and cost-effective.

This project will rapidly advance the development of a miniaturised intra-operative cancer detection probe, EnLight, which is fully compatible with minimally invasive key-hole surgery and robotic surgical systems. The technology potentially offers rapid and high diagnostic performance for intra-operative cancer detection. Laboratory proof-of-concept for the probe has been achieved. This project will evaluate the clinical effectiveness of the technology for detecting cancer during prostate cancer surgery, which is the first priority cancer indication. At the conclusion, this project will deliver the necessary clinical data to establish safety and performance to help secure regulatory approval in the EU and US to initiate commercialisation and clinical translation.

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



## Results of Competition: Biomedical Catalyst 2018 Round 2 Late Stage

Competition Code: 1808\_BMC\_R2\_LS

Total available funding is £10,000,000

Note: These proposals have succeeded in the assessment stage of this competition. All are subject to grant offer and conditions being met.

Participant organisation names	Project title	Proposed project costs	Proposed project grant
CYCLACEL LIMITED	Assessment of CYC065 as a single agent in patients with relapsed/refractory AML	£727,628	£436,577
University of Birmingham		£357,317	£357,317
University of Glasgow		£24,301	£24,301

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

CYC065, a second generation CDK2/9 inhibitor, has been evaluated in a first-in-human, Phase 1 trial in patients with advanced solid tumors and a recommended Phase 2 dose established. The study demonstrated that CYC065 durably suppresses MCL1, a member of the Bcl-2 family of survival proteins. CYC065 is mechanistically similar but has higher dose potency, in vitro and in vivo, and improved properties compared to seliciclib, a first generation CDK inhibitor. Similarly to FDA approved CDK4/6 inhibitors, CYC065 is investigated in combination with other anticancer drugs, including Bcl-2 inhibitors, such as venetoclax, or HER2 inhibitors, such as trastuzumab. Preclinical data show that CYC065 may benefit patients with adult and paediatric haematological malignancies, including acute myeloid leukaemias (AML), acute lymphocytic leukaemias (ALL), and in particular those with MLL rearrangements, chronic lymphocytic leukaemias (CLL), B-cell lymphomas, multiple myelomas, and certain solid tumors, including breast and uterine cancers, and neuroblastomas.

The objective of this project is to evaluate safety and activity and recommend the most desirable dose of CYC065 for further testing in a phase II clinical trial, in patients with poor prognosis AML including those with the rearranged mixed lineage leukemia (\_MLL\_) gene. A key component of the project is the incorporation of pharmacodynamic and exploratory patient stratification markers. Depending on the outcome of the study, CYC065 would then be evaluated in expanded Phase 2 development.

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