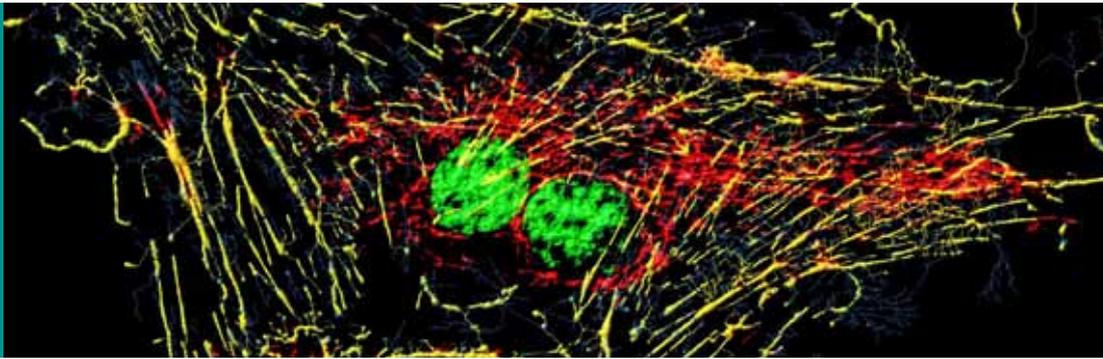


Technology Strategy Board

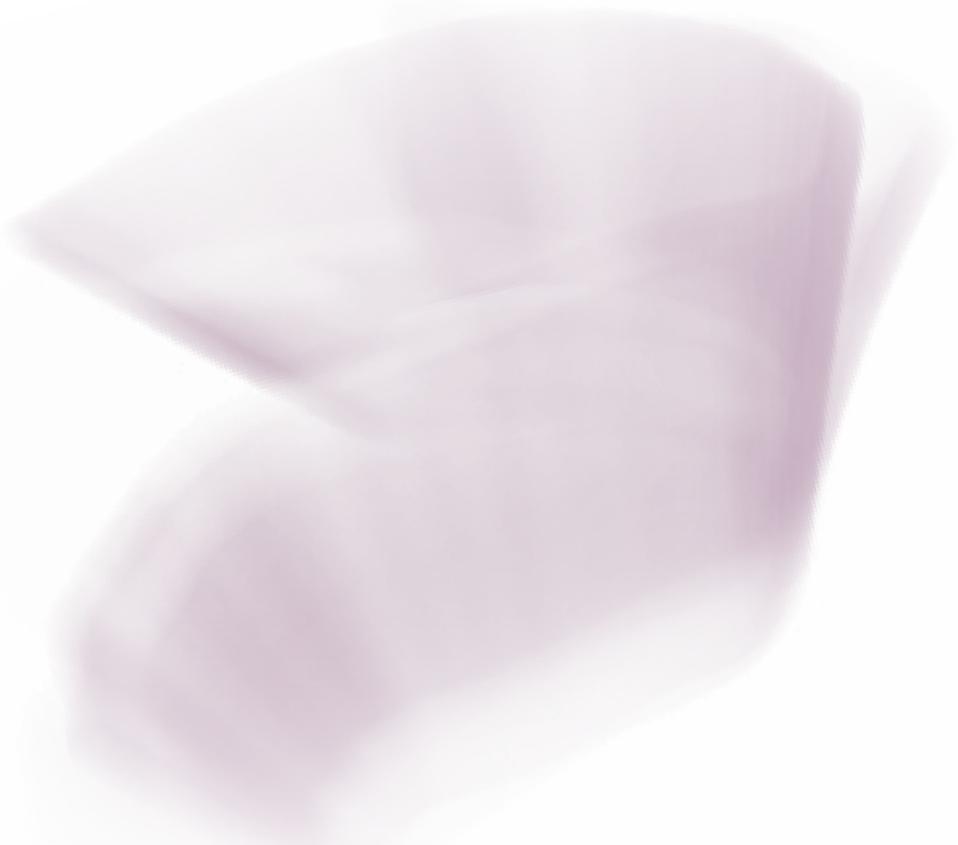
Driving Innovation



Advancing Regenerative Medicines and Cell Therapies

**COMPETITION FOR SINGLE-COMPANY
AND COLLABORATIVE R&D FUNDING**

JUNE 2014



Llywodraeth Cymru
Welsh Government

Advancing Regenerative Medicines and Cell Therapies

COMPETITION FOR SINGLE-COMPANY AND COLLABORATIVE R&D FUNDING

Summary

The Technology Strategy Board and the Welsh Government are to invest up to £8m in single-company and collaborative R&D projects to support the UK's burgeoning regenerative medicine and cell therapy industry.

Our aim is to help advance the industry by addressing sector-specific challenges related to preparing novel treatments for use.

This competition will focus on the preclinical testing, clinical development and manufacture of regenerative medicines and cell therapies, and the development of associated underpinning tools and technologies.

Proposals must be business-led, and can be collaborative or single-company. We expect to fund industrial research projects, with a business partner attracting up to 50% public funding for their eligible project costs (60% for SMEs). We expect projects to last between one and three years, and total project costs to range in size from £500k to £2.5m, although we will consider projects outside this range.

This is a two-stage competition that opens for applicants on **2 June 2014**. The deadline for expressions of interest is at noon on **16 July 2014**.

A briefing event and webinar for potential applicants will be held in London on **10 June 2014**.

Background

In the UK it is estimated that 30% of the population suffers from a chronic disease where there is no cure or where treatment is inadequate, and chronic disease management is thought to account for 70-75% of all UK healthcare costs. Regenerative medicine is an emerging industry with the potential to offer treatments for numerous serious and intractable chronic conditions.

Regenerative medicine is a broad term for innovative medical therapies that aim to replace or regenerate human cells, tissues or organs, to restore or establish normal function. It is not a single technology but a multidisciplinary approach, which can bring together tissue engineering, developmental and stem cell biology, gene therapy, cellular therapeutics, biomaterials (scaffolds and matrices), nanotechnology, bioengineering and chemical biology.

Regenerative medicine and cell therapy, defined as the use of one or more viable human cell types to treat a medical condition, offer potential solutions to deliver effective treatment or cure for many chronic conditions. They also offer possible treatment for conditions that are currently considered 'undruggable,' lying beyond the reach of traditional drug-based or biopharmaceutical approaches. In addition, associated non-regenerative cell-based technologies are being developed that use viable cells as therapies, including cell-based cancer vaccines, and cell-based immunotherapy for cancer.

The potential of regenerative medicine and cell therapy is underpinned by the history of the safe and successful clinical use of bone marrow transplants, to regenerate the blood and immune systems of patients with leukaemia, lymphoma, severe aplastic anaemia or inherited metabolic diseases. There have also been significant medical advances in skin regeneration for burns patients and the treatment of diabetic foot ulcers, and clinical trials of innovative treatments are currently underway for conditions such as diabetes, liver disease, neurodegenerative disorders and spinal cord injuries. It has been estimated that annual product sales in the global regenerative medicine market will exceed \$5bn by 2021.

The UK has strengths in regenerative medicine, including a world-leading research base, a unified healthcare system providing access to large numbers of patients, and a highly organised blood transfusion and transplant service. The UK is at the forefront

of much of the underpinning science in this area, and regenerative medicine has been recognised by the Government as one of 'eight great future technologies' in which the UK can be world-leading.

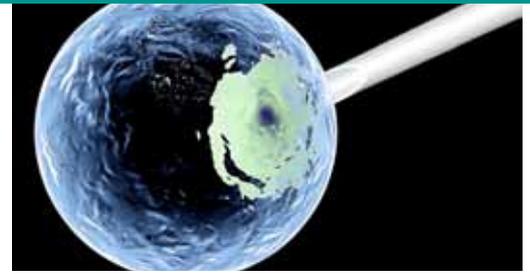
The development and production of regenerative medicines and cell therapies is complex, and if the UK is to fulfil its potential in this field, a number of challenges need to be overcome so that businesses can successfully exploit promising discoveries. Barriers include designing early-stage clinical development programmes, manufacturing cellular therapies at commercial scale, negotiating a complex regulatory landscape, and finding an optimal business model. These challenges are elaborated-upon in the joint Research Councils/ Technology Strategy Board *Strategy for UK Regenerative Medicine*, published in March 2012, which can be found at <http://www.mrc.ac.uk/Newspublications/News/MRC008536>.

To further support the growth of the UK cell therapy industry, we established the Cell Therapy Catapult in 2012 (<https://ct.catapult.org.uk>), as part of the Technology Strategy Board's network of Catapult technology and innovation centres. The Cell Therapy Catapult provides access to technical, regulatory, clinical and financial expertise and infrastructure, enhancing the UK's key strengths in this area, and enabling the UK to be a global leader in the development and rapid commercial exploitation of cell therapies.

Scope

This competition seeks to advance the rate of development and commercialisation of regenerative medicines and cell therapies by addressing specific challenges which are faced by those working in this sector. The competition has two streams:

- support for preclinical and clinical development of novel therapies
- support for developing underpinning tools and technologies.



Stream 1: support for preclinical and clinical development of novel therapies

This competition is open to applications that address the range of complex development challenges faced by researchers. Projects should cover one or more of the following areas:

Preclinical testing, for example:

- improving/testing for safety and/or efficacy
- improving and measuring the cell environment
- modulating immune response to improve the survival and efficacy of implanted cells/tissues
- mobilising the body's own stem cells to begin the repair process
- characterising and improving cell migration and localisation
- identifying and controlling stem cell differentiation.

Formulation and delivery, for example:

- delivering treatments for maximum adoption and effectiveness
- delivering therapies in combination with other treatments
- incorporating products into devices and scaffolds.

Clinical trials, for example:

- defining patient selection criteria
- preparing for regulatory submission
- embarking on early-stage (Phase 1 and 2) clinical studies
- devising methods to determine and improve clinical outcomes.

Manufacture, for example:

- developing good manufacturing practice (GMP) and commercially viable manufacturing processes
- introducing scalable cell culture methods.

Stream 2: support for developing underpinning tools and technologies

This competition is open to applicants who aim to develop key platform technologies to advance the development and commercialisation of regenerative medicines and cell therapies. Proposals should address one or more of the following challenges:

Confirming product safety or efficacy, for example:

- developing new *in vivo* and *in vitro* testing models
- developing companion biomarkers.

Manufacturing treatments at scale, for example:

- bioprocessing
- cell/product characterisation
- volume reduction and improvement of yields
- improving/finding alternatives to growth factor and cytokine use
- cell preservation, transportation and storage
- quality control, formulation, delivery and release
- increasing automation and reproducibility.

In this stream we particularly welcome applications concerned with modernising current methods and processes, which aspire to achieve greater efficiency, or cut the time involved in getting products to market.

Out of scope

Projects relating to the discovery of new therapies are not within the scope of this competition.

Looking for partners to work on your project? Go to **_connect** (www.innovateuk.org/connect) to find collaborators and networks.

Funding allocation and project details

The Technology Strategy Board has allocated up to £7.5m to fund R&D projects that address the technical challenges outlined in the scope above.

In addition, the Welsh Government has allocated up to £500k to support projects that have the potential to have a positive impact on the Welsh economy.

Projects must be business-led and can be collaborative or involve only a single company. Research organisations may participate in collaboration with a business partner, but their project costs should be no more than 50% of the total. We expect projects to last between one and three years. We are primarily seeking to fund industrial research, with a business partner attracting 50% public funding for their eligible project costs (60% for SMEs). We expect projects to range in size from £500k to £2.5m, but we may consider larger projects – in this case, applicants should discuss this with us before making their application.

Where appropriate, we encourage applicants to engage with the Cell Therapy Catapult, or other Catapult centres, depending on the nature of their proposals.

Each partner in a collaborative R&D project can receive funding towards their project costs – the funding is a percentage of the total eligible project costs and varies, depending on the type of organisation and the type of research. For general guidance on how projects are funded see:

www.innovateuk.org/-/funding-rules

To find out whether your business fits the EU definition of an SME, see: http://ec.europa.eu/enterprise/policies/sme/facts-figures-analysis/sme-definition/index_en.htm.



Application process

This is a two-stage competition that opens for applicants on **2 June 2014**.

Stage 1 – Applicants submit an expression of interest, which is assessed.

Stage 2 – We invite selected applicants to submit an application.

All applicants must first register via our website by noon on **9 July 2014**. The deadline for expressions of interest is noon on **16 July 2014**.

The Stage 2 deadline for invited applications is noon on **8 October 2014**.

Applications are assessed on individual merit by an independent panel of experts. The Technology Strategy Board reserves the right to apply a portfolio approach across the different subject areas that this competition covers.

A briefing for potential applicants will be held in London on **10 June 2014** to highlight the main features of the competition and explain the application

process. **Applicants are strongly recommended to attend this event.**

Note: All deadlines are at noon.

More information

For more information and all the documents you need to read before you apply, including the *Guidance for Applicants*, go to the web page for this competition at **www.innovateuk.org** under Funding & Support > Funding competitions.

To apply you must first register with us through the competition page on the website. Registration opens when the competition opens and closes a week before the deadline for applications.

Competition helpline:
0300 321 4357

Email:
competitions@innovateuk.org

Publicity

As part of the application process all applicants are asked to submit a public description of the project. This should adequately describe the project but not disclose any information that may impact on intellectual property, is confidential or commercially sensitive. The titles of successful projects, names of organisations, amounts awarded and the public description will be published once the decision to offer an award has been communicated to applicants by email. Information about unsuccessful project applications will remain confidential and will not be made public. E-mail pressoffice@tsb.gov.uk with any queries.

The Technology Strategy Board is the UK's innovation agency.

We accelerate UK economic growth by stimulating and supporting business-led innovation.

We are a business-led executive non-departmental public body, sponsored and funded by the Department for Business, Innovation and Skills.

Key dates

Competition opens	2 June 2014
Competition briefing	10 June 2014
Registration deadline	9 July 2014, noon
Expressions of interest (EOI) deadline	16 July 2014, noon
Stage 2 opens for invited applicants	4 August 2014
Deadline for invited applications	8 October 2014, noon

The Technology Strategy Board
North Star House
North Star Avenue
Swindon SN2 1UE
Telephone: 01793 442700
www.innovateuk.org