



Regenerative Medicine Programme: Developing Therapeutics

**COMPETITION FOR FAST-TRACK
COLLABORATIVE R&D FUNDING**

MARCH 2010

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Summary

As part of a £21.5m programme in Regenerative Medicine, the Technology Strategy Board is to invest up to £4m in fast-track collaborative research and development projects in the area of regenerative medicine therapeutics.

Our aim is to support businesses in the preclinical or clinical development of regenerative medicine therapeutic products.

Projects must be collaborative and led by a business, and proposals must clearly state the benefits to business. Total project costs should be no greater than £400k; consortia seeking larger sums should contact the competition helpline.

The competition opens on **8 March 2010**. Successful projects are expected to start in **July 2010** and may range from focused basic research (attracting up to 75% public sector funding), through to applied research (attracting up to 50% public sector funding) and experimental development (25% public sector funding).

Projects must be completed by **31 March 2011**, and may apply to participate in a longer-term collaborative R&D initiative that will launch in early 2011.

Challenge

To enable the preclinical or clinical development of previously-identified therapeutic candidates – that can replace or regenerate human cells, tissues or organs to restore or establish normal function – to create regenerative medicine products.

Background

Regenerative medicine is a multidisciplinary approach that spans tissue engineering, developmental and stem cell biology, gene therapy, cellular therapeutics, biomaterials (scaffolds and matrices), nanoscience, bioengineering and chemical biology. It may involve:

- transplanting stem cells, progenitors or tissue
- stimulating dormant repair processes
- cells as delivery vehicles: genes, cytokines, small molecules
- engineered cells (synthetic biology).

Regenerative medicine has already provided significant medical advances in areas such as skin regeneration for burns patients, and it has the potential to offer cures or treatments with long-term benefits.

The number of UK companies working in regenerative medicine has been growing since 2003. The UK is a world leader in this area, with a strong academic science base and a supportive clinical and regulatory environment. If the UK is to fulfil its potential in this field, a number of development challenges need to be overcome so that businesses can successfully exploit promising discoveries.

It is within this context that we launched the Regenerative Medicine Programme. To ensure that UK businesses can achieve a commercially competitive edge with global impact, we aim to:

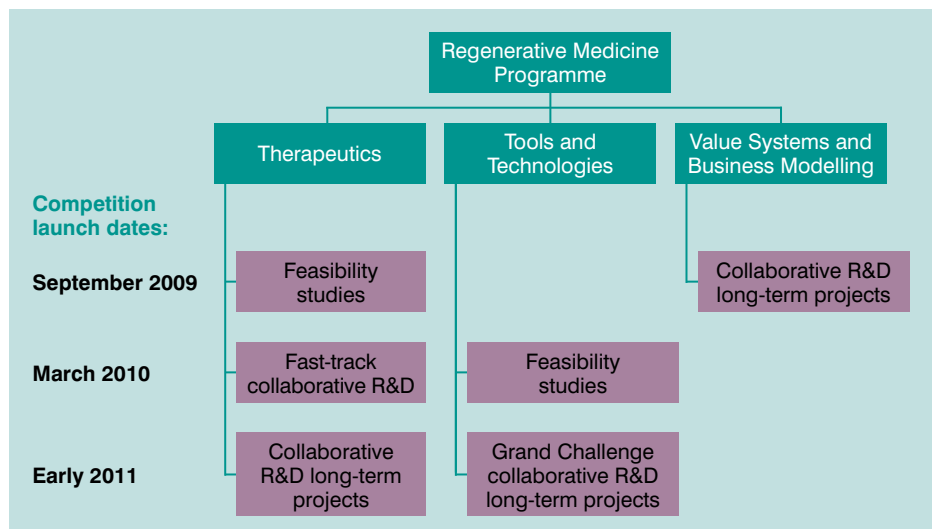
- underpin the best regenerative medicine businesses in the UK, and
- build a connected regenerative medicine community by forming well-linked programmes of work and activities to develop medicines and technology platforms.

We launched this programme of competitions in September 2009 and are investing up to £18m to support priority areas of collaborative R&D activity and the development of partnerships (see figure).

We are developing the programme in partnership with the Medical Research Council, the Engineering and Physical Sciences Research Council, and the Biotechnology and Biological Sciences Research Council, which are providing co-funding of approximately £3.5m towards competitions in the area of regenerative medicine tools and technologies.

A high-level industrially-focused group comprising industry and academic experts is guiding the development of the programme.

Figure 1: Through the Regenerative Medicine Programme we are launching competitions in three priority areas





Developing therapeutics

The aim of this competition is to enable UK businesses to carry out the preclinical and clinical development of regenerative medicine therapeutic products. Particular development issues that products face, and that proposals in this competition could address, include but are not limited to:

- **preclinical areas:** eg testing efficacy and safety, developing quality control protocols and metrology for particular products
- **formulation and delivery:** eg incorporating products into delivery devices, scaffolds etc
- **preparation for and commencement of clinical trials:** eg preparing for regulatory submission, preparing clinical plans and engaging with clinical trials teams, recruiting patients and commencing clinical studies
- **scale-up and manufacturing:** eg planning and executing the manufacture of batches for preclinical and clinical studies, overcoming scale-up problems.

The competition will enable consortia to accelerate product development to take advantage of future market or funding opportunities, particularly where the participants need to access resources or skills outside their organisation to take the idea forward. Successfully completed projects may be in a position to attract further funding from either the Technology Strategy Board or other funders to enable products to reach the market.

Scope for applications

All applications must address the overall challenge defined in this competition. Projects must address critical preclinical or clinical development issues. Discovering new regenerative medicine therapeutics is not within the scope of this competition. Applications must explain why the

development issue(s) are critical, and exactly what impact the successful completion of the project will have.

Applications must include an overview of the development history of the candidate product, and outline future plans and timeframes for the outputs of the projects (for example, progressing the product to clinic, follow-on clinical studies, regulatory submissions, route to market). Issues relating to ethics and research governance must be identified where appropriate.

Investment allocation and project details

We have allocated up to £4m to fund collaborative R&D projects that address the technical challenge and align with the scope.

Projects must be collaborative and can involve science-to-business or business-to-business interactions. Projects must be industrially led, therefore academics can apply only as a collaboration partner in a collaborative application.

The total project costs should be no greater than £400k. Projects seeking larger sums should contact the competition helpline on 0300 321 4357, as defined in the Guidance for Applicants.

Projects are expected to start in **July 2010** and must be completed by **31 March 2011**. No grant payments will be made for work carried out after that date.

Key dates

Competition opens	8 March 2010
Applicants briefing (optional)	17 March 2010
Registration of intent to submit	22 April 2010 (noon)
Deadline for receipt of full applications	29 April 2010 (noon)
Decision to applicants	11 June 2010
Feedback to applicants	12 July 2010

Projects may range from focused basic research (attracting up to 75% public sector funding), through to applied research (attracting up to 50% public sector funding) and experimental development (25% public sector funding). We anticipate that most projects will involve industry-orientated basic research, and applicants must make a robust case to support the requested level of funding.

Definitions of the above categories of research can be found in the Guidance for Applicants, which will be available when the competition opens on **8 March 2010** (see the Competitions section of our website at www.innovateuk.org).

Applicants will be asked to identify opportunities to disseminate non-confidential findings and related outputs (for example, their experience of the regulatory process or of changes in their exploitation route) after completion of the project to benefit the broader UK regenerative medicine community.

Application process

This is a single-stage competition for development projects that will open on **8 March 2010** and close on **29 April 2010**. Applicants will need to refer to the Guidance for Applicants, which explains in detail how to register and apply (see the Competitions section of our website at www.innovateuk.org).



Further information

For more information about this and other competitions, and details of how to register and apply, please see www.innovateuk.org under Competitions.

Competition helpline:
0300 321 4357

Email:
competitions@tsb.gov.uk

Publicity

The Technology Strategy Board frequently publicises the results of competitions and this includes engagement with the media. All applicants will be given a chance during the competition process to opt out of any publicity. Willing applicants will be asked to provide an agreed form of words for use in publicity material. E-mail pressoffice@tsb.gov.uk with any queries.

The Technology Strategy Board is a business-led executive non-departmental public body, established by the Government. Its role is to promote and support research into, and development and exploitation of, technology and innovation for the benefit of UK business, in order to increase economic growth and improve quality of life.

Collaborative research and development is part of the Government's Solutions for Business portfolio.

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