Medical Technologies

INNOVATION AND KNOWLEDGE CENTRE

IKC Proof of Concept Awards in Regenerative Medical Devices & Medical Devices with Enhanced Regenerative Functions - Industry Partnership Call

Call for Expressions of Interest

Background

Regenerative devices is a growing area of medical devices that focuses on functionally repairing and regenerating the patient's own tissue and not merely replacing the diseased or damaged tissue with an inert analogue. The global market for regenerative devices (acellular scaffolds, bioactive biomaterials and implants) is estimated to grow at 20% per year to £50bn by 2020, creating a significant opportunity for the industry in the UK. Regenerative Medical Devices have the potential to be delivered in a shorter time frame and lower cost compared to other regenerative medicine therapies such as cell and molecular therapies. This makes regenerative devices more attractive to investors, industry and healthcare providers. Research outputs at Technology Readiness Levels (TRLs) one and two are not typically ready for commercial development. Technologies need to be advanced and de-risked and clinical needs, potential products and markets defined more clearly to make them attractive for investment and subsequent product development at TRL 5 by industry.

Example of Technology Readiness Levels (TRL) using in medical device development

This call for funding is targeted at academia and is focussed on developing and supporting closer collaboration with the medical technology industry. The call will support projects that demonstrate close and tangible links with industry, with the commercial organisations involved in both defining the clinical and market opportunity and the development and progression of the proposals and technologies. The call has been developed with the aim of accelerating and enhancing innovation in regenerative medical devices and medical devices with enhanced regenerative functions. Successfully funded projects will need to meet the selection criteria and demonstrate significant commercial potential.

These funds will be allocated to proof of concept (PoC) university projects with an academic lead to support research and knowledge already funded and created at TRLs 1 and 2 in order to advance it through TRLs 3 and 4, to improve its readiness and attractiveness for future investment and further product development by industry at TRL 5 and beyond. The IKC (funded by EPSRC) is unable to fund projects directly within industry. However potential industrial partners interested in developing collaborations with academia/research institutions which may then be eligible to receive funding are encouraged to contact the IKC or their existing partner universities to discuss opportunities for involvement and collaboration development.

Successful projects will need to be able to demonstrate from the outset that the knowledge and technologies to be advanced have a well-defined and achievable end point and are related to future

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product developments and translation pathways which have a clear commercial objective. Submissions must also show how they will identify, address and remove technical uncertainty and risk. Industry involvement is essential. For the purpose of this call the term Industry Partner includes private sector industry and not-for profit organisations involved in the development, commercialisation and marketing of medical device products.

Award Scope

Up to 6 IKC Proof of Concept awards costed at full economic costs up to £100K (80% FEC will be award funded) (for information about full economic costing [FEC] please see the Research Council guidance at http://www.rcuk.ac.uk/documents/documents/fecfaq-pdf/), and of a duration of up to 24 months, are available through this call to fund projects which fit with the award scope. Larger bids *may* be considered where there is a very clear and justified need.

Specialist Areas

Projects must align with one or more of the following specialist areas:

- **Directly implanted regenerative devices** including scaffolds, biomaterials and devices which deliver tissue repair and regeneration. These could address unmet clinical need in, for example, wound repair, cardiovascular repair, musculoskeletal tissue repair, maxillofacial reconstruction, dental reconstruction, surgery and the demands of the ageing population. Devices may incorporate minimally manipulated autologous stem cells with scaffolds. Embryonic and allogeneic stem cells are excluded, as is the use of autologous adult stem cells which have been expanded in vitro or otherwise significantly manipulated.

- **Enabling technologies for regenerative device development** including strategically-aligned enhanced simulation methods for design, development and pre-clinical evaluation of devices, providing evidence of safety and efficacy at the pre-clinical stage, thus reducing the requirements within phase 1 and 2 clinical trials and reducing the risk, cost and time in product development.

- **Companion technologies for regenerative device development** including aspects of advanced imaging and diagnostics to determine the disease state of the patient and the patient response to treatment. These will address advanced diagnostics for stratified and personalised interventions and technologies to enhance precision of surgical delivery.

- **Implantable medical devices with enhanced regenerative functions** includes conventional medical devices with added regenerative features or capabilities that address unmet clinical needs in wound repair, cardiovascular repair, musculoskeletal tissue repair, maxillofacial reconstruction, dental reconstruction, surgery and the demands of the ageing population.

Special Guidance for Combination Devices

Combination devices are those medical devices that combine two technologies, such as a scaffold with a drug or an implant with a bioactive, such a bone cement with an antimicrobial agent. For the combination product to be classified as a Class III medical device the primary function of the product must '*not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means but which may be assisted in its function by such means'.*

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For the purposes of this funding call combination devices will only fall within scope of the call if the active agent has history of clinical use and approved for use in humans. Projects involving Investigational New Drugs (IND) will not be funded due to the significant risk and medicinal regulatory route.

Applicants with technologies that fall within this definition of combination device will also need to consider and justify commercial access to the active agent, freedom to operate and manufacturing of the active. The IKC highly recommend that the project team liaise and collaborate with the authorised manufacturer(s) of the active.

Eligibility criteria

This call is open to institutions eligible to Research Council funding, including all UK Higher Education Institutions and eligible research institutions (for more information see - http://www.rcuk.ac.uk/funding/eligibilityforrcs/).

The IKC is unable to directly fund Industry/commercial organisations. However this call aims to stimulate and strengthen interaction and collaboration between HEIs/RIs and industry. Projects must be led by the HEI/RI but also show significant involvement and partnership with industry. Industry wishing to partner with academic and research institutions should proactively develop consortiums; the IKC is available to support identification and introduction of potential academic partners through its strong links with a large number of universities around the UK.

Projects must be able to demonstrate:

1. Fit with the Specialist Areas outlined above.
2. Industry partnership.
3. Clear achievable project outputs with a well-defined product concept that has defined commercial application.
4. Clear demonstration of how technical uncertainty and risk will be identified, addressed and removed.
5. The technology under development will have attained Technology Readiness Level (TRL) 5 by the end of the project funding.
6. Clear benefit in harnessing the research and development strengths of the University Partner(s) and, where possible, partnership with NHS hospital trusts.
7. Leadership by an academic with a good track record in the selected technology.
8. Direct industrial contribution and/or company involvement.
9. Clinical need and/or benefit.
10. Evidence that the Medical Technologies IKC can add value, including an indication of how the involvement of the Medical Technologies IKC in the development of the project is expected to add value beyond the provision of funding.

What can be funded?

Support for innovation through Proof of Concept awards that provide:

1. Funding for staff in academia and research institutions to undertake specific activities to accelerate the commercial opportunity.
2. Support for legal and professional costs including commercial business plan development and assessment of market size and reach.

3. Support for demonstration of 'proof of technical concept', preclinical safety and efficacy up to early clinical evaluation.
4. Support for prototype development, manufacturing cost assessment and other key aspects required as part of validating a commercial investment decision.
5. Support to engage with additional commercial and investment partners that may have the capacity and potential to support taking the product to market.

What will not be funded?

1. Support for intellectual property protection, exploitation or freedom to operate reviews. It is envisaged that as the respective institutions and/or their partners will own the IP generated through this process, that they will provide the required IP support as part of the co-investment process.

Application Process

This call will open on **12th September 2016**. Funds will be allocated up to a maximum of 6 PoC projects during 2016/17. Projects are normally expected to have a full economic costed grant value of up to £100K with 80% of the FEC value being funded by the POC award from the EPSRC Medical Technologies IKC, which follows current RCUK funding procedures. However, larger bids may be considered where there is a very clear and justified need. The start date for projects is flexible but must be completed by 1st January 2020

There will be a three-stage application process:

Stage 1 – Submission of EOI
In order to prioritise how and where the investment can be most productively used, all projects will be mapped through a simple EOI system that tracks the nature of the project, the lead academic, industry partner(s), the value of investments in the project and where the activity currently sits in terms of Technology Readiness Level, clinical partners involved and the likelihood of success to commercialisation. A workshop will be held as part of the EOI application process. **Stage 1 will be structured in 3 waves with the first wave submission deadline closing on 30th November at 5.00 pm.** Wave 2 will close on 31st January 2017 and the final wave on 31st March 2017. The Medical Technologies IKC project team will be available to answer questions during this stage.

Stage 2 - IKC PoC Full Application Co-Development Phase
EOIs will be assessed against the criteria listed above to select those that offer significant commercial potential and address technical uncertainty and risk that can be further developed through an IKC Proof of Concept award. Successful applicants will be invited to meet with the IKC team to develop the IKC PoC Full Application proposal. It is expected this development phase will involve support and involvement of the industry partner(s) with support from IKC Technology Innovation Managers.

Stage 3 – Full Proposal Review and Approval
Upon completion of the full proposal and with mutual agreement of all parties, full applications will be assessed by an IKC POC Review Panel, which will include independent members with expertise in translation, innovation and commercialisation of medical technologies. Three review panel meetings will take place in 2017 at the end of quarter 1, 2 and 3. During these meetings applicants will be requested to briefly present on their proposal and will then take questions from the panel. This will give the applicants the opportunity to clarify and further elaborate and aspect of the proposal. Following successful approval the IKC team will work with successful applicants throughout the life of the project to ensure it delivers to time and on budget.

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Key Dates

Expression of Interest call opens	12th September 2016
Expression of Interest workshop (venue - Leeds)	12th October 2016
Expression of Interest proposals submission deadline - wave 1	5pm 30th November, 2016
Expression of Interest proposals submission deadline - wave 2	5pm 31st January, 2017
Expression of Interest proposals submission deadline - wave 3	5pm 31st March, 2017
First Full Application Review panel meeting	(tbc) end March 2017
Second Full Application Review panel meeting	(tbc) end June 2017
Final Full Application Review panel meeting	(tbc) end Sept 2017
Applicants informed of outcome	1 week after panel review meeting

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