

Regenerative Medicine Call for Evidence

In 2005, the UK Government accepted the recommendations and 10-year vision of the Pattison Review and detailed in UK Stem Cell Initiative Report. However, the regenerative medicine environment, particularly the science, has progressed significantly since 2005 and the Government wants to ensure that the sector is supported by appropriate intervention. Any UK regenerative medicine infrastructure must allow for more than one kind of business model and be able to accommodate future changes in the science wherever possible. We must act now to ensure that the UK builds on its successes, and creates a regenerative medicine industry that improves health outcomes, while also creating vital jobs and growth.

For these reasons we would like to gather your perspectives on the opportunities and needs of the area, as well as barriers to progress, from which Government can identify policy gaps. At this stage we are looking for evidence from across the regenerative medicine field, allowing a broad definition of what this encompasses. We would be grateful if you would fill out the sections of the below questionnaire relevant to your interests and expertise.

We will publish a report detailing our findings in the summer which will be used to inform the development of a forward look / roadmap for the sector later in the year.

Please send your submissions to RegenmedOLS@bis.gsi.gov.uk, by the 11th March.

Science and Research

1. What are likely to be the major scientific advances in the stem cell / regenerative medicine area over the next 5 years? Please list up to 3 topic areas, alongside any supporting evidence.
2. What are the major gaps in the science that need to be overcome to enable the translation and therapeutic development of the research?
3. How close are we in the UK and globally to delivering therapeutics in the regenerative medicine field? What, if anything, is holding back progress?
4. In which therapeutic areas is clinical impact most likely in the near (<5 yrs) and longer term (<15 years)?
5. If you collaborate internationally, do you currently undertake research in partnership with groups or companies in i) Europe, ii) N America, iii) Asia iv) more than one of these regions (specify). Do you expect this to change over the coming decade – if so, towards which region?

Translation and Commercialisation of Research

6. What are the strengths and weaknesses of the UK when it comes to the commercialisation of regenerative medicine research? What could be done to improve the situation?
7. What are 3 specific barriers preventing the development and application of stem cell derived tools and technologies, and how might these be overcome?

8. The development of many regenerative medicine therapies will require collaborations across disciplines and with end-users - how can these collaborations be better facilitated to accelerate translation in this area?
9. How can the regulatory uncertainties inherent to many aspects of this field be most effectively mitigated? Are there examples of regulatory practice in other regions of the world that the UK can learn from?
10. What are the key requirements necessary for future investment in UK companies? Is this investment most likely to come from traditional VC, big pharma or other sources?

Getting Regenerative Medicine Therapies into the Clinic

11. Do we have the right infrastructure to deliver clinical trials of new regenerative medicine therapeutics in the UK? If not, what else is required?
12. Does the NHS have the resources (skilled workforce, infrastructure, facilities etc) to support the efficient adoption of new regenerative medicine technologies?
13. What enablers and policy needs are required for the effective translation of Regenerative Medicine technologies to healthcare?
14. Do the recommendations in the AMS report (<http://www.acmedsci.ac.uk/p47prid88.html>) on research regulation address barriers in this area?
15. Do you believe regenerative medicine will be affordable through the NHS on a large scale or will it be a niche market? Can you explain your answer in terms of reimbursement pathways, and any supporting evidence?