



---

[DH home](#) - [Policy and guidance](#) - [Health and social care topics](#) - [Stem cell](#) - [Stem cell key documents](#)  
- [Stem cell general article](#)

---

## Government response to the UK Stem Cell Initiative report and recommendations

**Published:** 2 December 2005

The Government warmly welcomes the report of the UK Stem Cell Initiative Panel, chaired by Sir John Pattison. The report provides a comprehensive overview of the status of stem cell research in the UK and overseas; a clear vision for future endeavour with indicative costs for a strategy to maintain the UK's position as a world leader in basic research. It also provides a 'road map' to translate basic research in stem cells into new therapies to benefit patients.

The Government is particularly pleased that the report has acknowledged the appropriateness of the UK system of regulatory oversight of embryo research and the investment that has been made to date across research funding, infrastructure, people and support for private investment.

In 2004-05 the Government invested around £25m in basic research and associated support such as the UK Stem Cell Bank. The Government accepts the recommendations in the UKSCI report. As a result of taking forward these recommendations, total public sector funding for stem cell research over the two year period 2006-07 and 2007-08 will be up to £100 million, representing additional investment of around £50 million. In particular, the Government will:

- work towards the establishment of a public-private consortium to use stem cells to enhance drug discovery and development (Recommendation 1);
- provide resources to redevelop and maintain the UK Stem Cell Bank (Recommendation 2);
- increase funding to support basic stem cell research and Centres of Excellence, cell production facilities and clinical research in the NHS (Recommendations 3,4,5,7);
- support the joint UK Stem Cell Foundation / Medical Research Council (MRC) initiative to support translational stem cell research and clinical trials (Recommendation 6);
- continue to ensure regulation of stem cell research is flexible and appropriate and makes use of proven expertise such as in the Gene Therapy Advisory Committee (GTAC) to review novel stem cell clinical trials (Recommendation 8), and
- build on the close links established under the UK Stem Cell Initiative to provide effective forums to improve collaboration around research funding, cross-fertilisation between scientists, technical experts and private industry and provide a platform for a sustained programme of public dialogue on stem cell research over the next decade (Recommendations 9-11).

Over the next decade, the Government will take careful note of the recommendations to inform the development of its investment and regulatory strategy in this area in future spending reviews.

The Government is extremely grateful to Sir John Pattison, the members of the UK Stem Cell Initiative Panel, UK scientists and entrepreneurs as well as international advisors for providing such a thorough and considered report and for the vision of improved knowledge about the causes of, and therapies for, devastating diseases and medical conditions.

### Detailed response to specific recommendations

**Recommendation 1: The UK Government should establish a public-private partnership to develop predictive toxicology tools for stem cell lines.**

The Government recognises the importance of this suggestion to establish a public-private consortium to develop a wide range of safe and effective medicines for patients using stem cell technology. We also recognise that such a consortium would undoubtedly extend the stem cell research base within the UK and fortify our global position in this area.

The Technology Programme is already supporting a £1.75m project that is developing a high-throughput screen for small molecule drugs using stem cells. This platform could also be used for toxicology screening. The MRC is supporting research at the MRC Toxicology Unit in Leicester looking at the cellular response to chemicals that will also be relevant to the use of stem cells in predictive toxicology. They have also initiated meetings with pharmaceutical companies to explore the use of stem cells in toxicology and drug development, to discuss possible areas of common interest and possible collaboration.

The Department of Health and DTI will consult widely with the pharmaceutical and biotechnology sectors over the next few months to determine the feasibility of this proposition, reporting in Spring 2006. Should this proposal receive significant support from the private sector, the Government will establish such a consortium with the necessary Government contribution to management and research costs (estimated as up to £0.7m in 2006-07 and £1.3m in 2007-08). DTI will build on its support for collaborative research in stem cell technology through the November 2005 competition of the Technology Programme, and will consider whether further support is justified towards the end of the current projects.

**Recommendation 2: The UK Stem Cell Bank should be consolidated in new permanent facilities adjacent to its current site and its operational and development costs should be secured for the next decade.**

The Government recognises the importance of the UK Stem Cell Bank to provide a world-leading resource of well-characterised and ethically sourced stem cell lines. The MRC will therefore invest between £5m and £6m to redevelop the Stem Cell Bank, and has committed £1m per annum over 2006-07 and 2007-08 towards its operational costs. The Biotechnology and Biological Sciences Research Council (BBSRC) has committed £0.2m per annum over the same period.

**Recommendation 3: The Research Councils should monitor the emergence of Centres of Excellence in stem cell research, designate them as such and strengthen them with core funding.**

The MRC has already designated two Centres of Excellence in Stem Cell Research and is considering proposals for a third. Others will be considered as part of the regular five yearly reviews of Institutes and Grants. BBSRC also invests in existing Centres and clusters and is actively inviting larger, longer-term, multidisciplinary grant applications from researchers including those involved in stem cell research.

**Recommendation 4: Research Councils and private sector funding bodies should support the development of stem cell therapy production units at UK Centres of Excellence in stem cell research.**

The Government fully recognises the need to develop facilities for the production of stem cells. The Report acknowledges the additional investment, totalling £4.2m in 2005-06 for the NHS Blood and Transplant Authority to support the storage and use of bone marrow and peripheral blood stem cells which we continue to support.

DTI is also anticipating the need for developments in stem cell technology for research and clinical applications through the Technology Programme. Regenerative Medicine Technologies is a priority in the Autumn 2005 Technology Programme competition with an indicative budget of £10m of DTI funding. Additional funding may come from the Research Councils and a proportion of the costs of each project will come from the industrial participants. There are a number of technical focus areas for the competition that are directly relevant to stem cell technology and to underpinning and related technologies such as advanced biomaterials for tissue scaffolds. The proposed research may include early stage clinical trials. Bioprocessing of tissue engineering products was a focus area in the Spring 2005 competition. This is in addition to the earlier stem cell technology projects now underway from the Spring 2004 Technology Programme competition, which will receive an estimated £1.6m and £1.2m from their overall grants in 2006-07 and 2007-08, respectively. Measurement standards are also important in the development of all new technology areas, DTI's Measurements for Emerging Technologies programme has two projects looking at metrological issues in support of stem cell research. The projects will receive £1.2m of DTI funding over the life of the current programme (2005-2008).

BBSRC has recently launched the Bioprocessing Industry Research Club (BRIC) call with a BBSRC budget of

£8.7m. While not all projects will directly involve stem cells, they could provide vital underpinning work to the future scale-up of stem cell culture and distribution.

**Recommendation 5: The Government and Research Councils should strengthen the levels of funding for basic stem cell research over the next decade.**

The Research Councils are aiming to increase their commitment to basic research in stem cells, including centres of excellence, to reach at least £24m by 2007-08. The precise figures will depend on the quality of applications submitted to the Research Councils.

**Recommendation 6: The Government should provide funding for clinical and translational stem cell research over the next decade at a level matching that raised by the UK Stem Cell Foundation (UKSCF), up to a maximum of £10M per annum, and administer it via a UKSCF/Medical Research Council collaboration.**

The MRC and the Stem Cell Foundation have set up a joint mechanism for the scientific evaluation of clinical and translational proposals and are currently considering a proposal worth £2m. In 2006-07 and 2007-08 they will consider additional proposals as they arise and contribute up to £1m per annum to joint projects with the Foundation. If this proves to be a successful way forward, the Government will seek to extend the collaboration to enable the MRC to jointly fund translational and clinical stem cell research projects with the UK Stem Cell Foundation.

In addition, Scottish Enterprise has established a Stem Cell Translational Investment Fund of £5m for collaborative projects in Scotland with other organisations including the UK Stem Cell Foundation.

**Recommendation 7: The Department of Health must ensure that the promised increase in R&D resources is forthcoming and furthermore, that the full NHS costs of stem cell clinical research trials within the NHS are supported with extra funding from each Spending Review over the next decade to match the increase in research grants and activity.**

The Government fully intends to meet its commitment to provide an additional £100 million for NHS R&D compared with 2003-04 levels. This new investment is underpinning the activities of the UK Clinical Research Collaboration (UKCRC) and the Government will ensure that the excellent work begun by the UKCRC continues to transform the clinical research environment in the UK.

It is also the Government's intention to meet eligible service support costs of clinical stem cell research within the NHS. Additional funding beyond the current Spending Review period will need to be considered in future Spending Reviews alongside other priorities.

**Recommendation 8: The Government should continue to ensure that regulation of stem cell research is risk-based and proportionate and does not stifle the development of the full range of safe and effective new cell therapies for the benefit of patients. In particular,**

- (i) the Department of Health should establish a specialised research ethics committee for stem cell clinical research;**
- (ii) the Government should clarify the regulatory requirements for the use of animals and animal cells in human stem cell research; &**
- (iii) for the in vitro use of embryonic stem cell lines, researchers should be registered with, and submit an annual research summary report to, the UK Stem Cell Bank.**

The Department of Health has overall responsibility in this policy area and will continue to ensure that regulation of stem cell research is flexible, proportionate, accountable, consistent, transparent and targeted. They will work closely with the DTI, Medicines and Healthcare products Regulatory Agency (MHRA), patient groups, the public and the commercial sector to maintain the best possible environment for stem cell research and to facilitate the development of safe and effective therapies for patients. The Department of Health will also continue to work with our European partners to ensure that current and future EU regulatory measures are based on sound science and help to deliver the targets set out in the EU Strategy for the Life Sciences and Biotechnology.

As part of its broader review of the Human Fertilisation and Embryology Act 1990, the Government invited views on whether the law should permit the creation of human-animal hybrid or chimera embryos for research purposes only (subject to a limit of 14 days culture in vitro after which the embryos would have to be destroyed). This followed a recommendation of the House of Commons Science and Technology Committee, that new legislation should define the nature of hybrids and chimeras, make their creation legal

for research purposes, and prohibit their implantation in a woman.

The Home Office is responsible for providing guidance on the application of the Animal (Scientific Procedures) Act to experimental and other scientific uses of animals in work involving human and animal stem cells. The intention is to ensure that researchers are clear about their duties and responsibilities and that unnecessary delay is avoided. The Home Office is also committed to working with relevant stakeholders via the improved collaborative mechanisms described below.

### **Ethical oversight**

The Government has taken careful note of the Report's recommendation for a specialist research ethics committee to consider stem cell clinical trials of embryonic stem cells and other pioneering trials of stem cells introduced into different organs or locations. The report notes that the House of Lords Select Committee Report on Stem Cells recommended extending the remit of the Gene Therapy Advisory Committee (GTAC), but eventually recommended a separate research ethics committee. Whilst the Government shares the desire to ensure patients safety, we do not anticipate a large number of novel clinical trials involving stem cells in the next two to three years. Therefore, for the time being we believe that the expertise developed by GTAC over the last decade would lend itself to the specialist ethics review of stem cell trials in the manner recommended by the Report. Some stem cell clinical trials will already fall under GTAC's remit, and the Government will therefore ask them to undertake the ethical oversight of other relevant stem cell clinical trials and to act as a source of expert advice to researchers and other research ethics committees. The appropriate route for ethical oversight will be kept under review. In particular, the Department of Health is making further improvements in the NHS ethical review process and foresees a smaller number of better-trained research ethics committees. Increasingly, the experience derived by GTAC's review of these clinical trials will be valuable to researchers and other NHS research ethics committees.

**Recommendation 9: The UK Clinical Research Collaboration should help to**  
**(i) coordinate organisations supporting stem cell research, including all of the relevant Research Councils and the UK Stem Cell Foundation and**  
**(ii) ensure that the National Health Service is optimally engaged in this area.**

**Recommendation 10: The Government should allocate additional funding to establish The UK Stem Cell Cooperative, to maximise the cross-fertilisation between those involved in the sub-disciplines of UK stem cell research.**

The Government recognises the importance of co-ordination between funders, researchers, charities, the private sector and Government Departments. The UK Clinical Research Collaboration is a model for how this should work. The UK Stem Cell Initiative has proved to be an effective means of engaging a wide cross section of those active in stem cell research and we propose that these links should continue and be strengthened to help to implement the recommendations and deliver the vision in the report. The MRC will lead discussions on how best to take this forward, possibly through a revitalised Stem Cell Funders Forum. They will consult a wide range of stakeholders including existing stem cell networks and wider UKSCI partners.

The Research Councils are also supporting workshops and conferences to encourage the sharing of ideas and scientific collaborations. The recent joint BBSRC/EPSRC initiative in Stem Cell Science and Engineering required formal collaboration between stem cell biologists and engineers and/or physical scientists. Sixteen new collaborative projects have been funded under this initiative, with a total funding commitment of approximately £6m.

**Recommendation 11: The Research Councils, charitable funding bodies, and Government Departments should develop a sustained and coordinated programme of public dialogue on stem cell research over the next decade.**

The Government accepts this recommendation. Government Departments will work with the private charity sector to develop a sustained programme of public dialogue on stem cell research. We will use our dialogue with the public to inform our policy work on any further development of the regulatory system of oversight of UK stem cell research. We believe that it will be vital for the public to have confidence in stem cell research if we are to see the successful development of stem cell therapy. The Research Councils and the Office for Science and Technology's Sciencewise programme will take this recommendation forward.

### **Related Links**

[UK Stem Cell Initiative \(opens new window\)](#)