

The Government Response to “*Bioscience 2015*”, the Report by the Bioscience Innovation and Growth Team

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Introduction

In January 2003, Lord Sainsbury, Parliamentary Under Secretary of State for Science and Innovation, and Lord Hunt, then a Minister at the Department of Health, launched the Bioscience Innovation and Growth Team (BIGT), in partnership with the BioIndustry Association. Its mandate was to formulate a strategic approach to the future of the UK's bioscience industry.

The terms of reference were:

1. To identify and clarify the issues that are critical to the future competitiveness of the UK biosciences sector (focusing on healthcare)
2. To identify any barriers that could significantly affect the future competitiveness of the UK biosciences sector, and to make recommendations on what action should be taken to overcome these barriers

Sir David Cooksey, Chairman of Advent Venture Partners, agreed to chair the BIGT Steering Group. Over 70 leading figures from the bioscience industry, financial institutions, universities, research bodies and Government agreed to assist in the project.

The BIGT report was published in November 2003.

This document comprises a Ministerial letter to Sir David Cooksey, which is an integral part of the response, and the response paper itself. The paper provides a reply to each sub-recommendation as set out in the BIGT report; a list of the BIGT recommendations is also attached as an annex for ease of reference.

Sir David Cooksey
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Dear Sir David –

**The Government Response to the
Bioscience Innovation and Growth Team Report**

We would like to take this opportunity to thank you again for chairing the Bioscience Innovation and Growth Team (BIGT), whose report the Government warmly welcomed at its launch on 12 November 2003. All the recommendations addressed to Government departments and agencies have been given serious consideration and this letter constitutes a formal response to the Report.

As you know, the BIGT brought together major stakeholders working in medical biotechnology to identify the key issues that will shape the future of the bioscience healthcare industry and how the UK can best respond to these challenges.

From the Government's point of view, the medical bioscience industry is vitally important to the UK's economy in terms of both jobs and wealth creation. Our aim of encouraging the translation of science into economic activity was recently set out in the consultation document "*Science and Innovation: working towards a 10 year investment framework*", published by HM Treasury on 16 March 2004. This document included an expressed commitment to increase spending on NHS R&D, as requested in the BIGT Report.

Further to this, the Chancellor of the Exchequer announced in his Budget speech on 17 March 2004: "*Today the Government is also announcing a ten year framework for medical science. Our health budget is not just what we spend on the National Health Service but on medical research that is bringing new treatments and cures. Modelled on the successful National Cancer Research Institute, our ten year plan will fund specialist research institutes for other diseases; a new national clinical research network that brings private and public sectors and medical charities together; and I can confirm that the combined budget for medical research and research and development within the NHS will rise and by 2008 approach £1.2 billion a year.*"

On 22 March 2004, the Secretary of State for Health set out further details of the substantial increase to NHS R&D funding over the next 4 years in his speech on the Budget debate: *"Our experience with the National Cancer Research Institute taught us that the real power to solve some of our outstanding health problems comes from the Government's investing in collaboration and in partnership. I can report today that I am making available an additional £25 million in each of the next four years, over and above the inflation-linked increases that have already been agreed, to secure the necessary development of our medical research here in this country... which represents the largest sustained increase in NHS research and development funding ever announced... It is not simply a matter of retaining our place at the forefront of research and development in this country—although I am proud of that, too—but of saving the lives of our fellow citizens. The Government therefore wishes to make Britain the best place in the world bar none for research, development and innovation. I want to ensure that the NHS contribution to medical research is one of the centrepieces of that ambition."*

The Secretary of State also called for the creation of the UK Clinical Research Collaboration (UKCRC): *"Alongside investment we shall also introduce reform. Accordingly, the Government has decided to create a new United Kingdom clinical research collaboration involving the NHS, patients, the Medical Research Council, the Wellcome Trust, the medical charities and industry... I should like them to promote the following elements in particular: the development of a clinical research infrastructure embedded in the NHS; an expansion of United Kingdom clinical research, including clinical trials; an extensive and sustained increase in the research work force, and the development and spread of best practice for statutory regulations."*

The Department of Health is taking forward the work on the Collaboration initially focusing on research into the treatment and cure of four major diseases - Alzheimer's, stroke, diabetes and mental health as well as developing new medicines for children. This work will fully involve research bodies, industry, the NHS and Government in the way envisaged in the BIGT Report.

It is clear that the Government shares the BIGT analysis that patients, the NHS and the medical biotech companies all stand to gain from an increase in clinical research and clinical trials in the UK. Many of the other recommendations made in the BIGT report and addressed to Government have also been wholeheartedly accepted and work is underway to implement them. Details are set out in the attached paper.

We will continue to progress activities across Government to support the development of the medical bioscience sector in the UK, and will meet

biannually with the Chairman of the Bioscience Leadership Council, Sir Richard Sykes, as the implementation of the BIGT recommendations progresses.

Yours sincerely

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Parliamentary Under-Secretary
of State
Department of Health

DAVID SAINSBURY
Parliamentary Under-Secretary
of State for Science and Innovation
Department of Trade and Industry

Recommendation 1 – *Build a mutually advantageous collaboration between the NHS and Industry for patient benefit*

The Government responded to this recommendation by setting up the Research for Patient Benefit Working Party (RPBWP), under the Chairmanship of Professor Sir John Pattison, Director of Research and Development at the Department of Health (DH). The remit of the RPBWP was to consider both this recommendation and the recent Academy of Medical Sciences report, "*Strengthening Clinical Research*".

The Working Party, which included experts from industry, clinicians, patient representatives and the research community, established a strong consensus around a common vision of the future for the NHS: "*Developing clinical research, through investment in a widely-applicable clinical infrastructure, with an appropriate workforce capability, and with better regulation.*"

Their final report, submitted to Lords Sainsbury and Warner before Easter, contains specific elements relating to the above recommendation.

- 1.1. The RPBWP Report suggested that a UK Clinical Research Collaboration (UKCRC) should be established and the Secretary of State for Health, Dr John Reid, declared the Government's plan to implement this recommendation, in his speech during the health budget debate on 22 March 2004: "*Accordingly, the Government has decided to create a new United Kingdom clinical research collaboration involving the NHS, patients, the Medical Research Council, the Wellcome Trust, the medical charities and industry. The purpose is to create a partnership to oversee the effect and efficient translation of scientific advances into patient care. I should like them to promote the following elements in particular: the development of a clinical research infrastructure embedded in the NHS; an expansion of United Kingdom clinical research, including clinical trials; an extensive and sustained increase in the research work force; and the development and spread of best practice for statutory regulations.*"

As recommended in the RPBWP's final report, the UKCRC has been established as a partnership between Government, the voluntary sector, patients and industry, with a similar membership to the RPBWP in the first instance. It will have a small, dedicated core team headed by a Chief Executive and this team will be located in one of the non-government partners. One of the roles of the UKCRC will be to help develop the common elements of the research networks and oversee their development (see 1.1.1). Several subgroups will also be established to look at particular issues such as career structure, incentives within the NHS and regulation.

1.1.1 The RPBWP recommended that in addition to the already established cancer networks, others should be established for mental health, medicines for children, Alzheimer's disease, stroke and diabetes. These were suggested as the early priorities with additional networks to follow. These first research networks will operate in a coordinated fashion, employing a common management structure with common processes and protocols, and a shared data capture system.

There was a general consensus within the RPBWP that more clinical research facilities were required and it is proposed that the UKCRC oversees collaboration between research funders to create and sustain such facilities.

1.1.2 and 1.3 The RPBWP acknowledged that in order to take maximum advantage of NHS infrastructure developments there would need to be additional project, programme and clinical trials funding from the Medical Research Council (MRC), charities and industry.

The Chancellor of the Exchequer announced in his Budget speech on 17 March 2004 that funds for R&D spend within the NHS would increase over the next four years: *"I can confirm that the combined budget for medical research and research and development within the NHS will rise and by 2008 approach £1.2 billion a year."*

In his speech on the Budget debate on 22 March 2004, the Secretary of State for Health detailed this further, announcing that the DH will increase NHS R&D funding by £100 million by 2008: *"[The Government is] making available an additional £25 million in each of the next four years, over and above the inflation-linked increases that have already been agreed, to secure the necessary development of our medical research here in this country... which represents the largest sustained increase in NHS research and development funding ever announced."*

This increase will provide a stronger platform for growth in Government investment in medical research. In the Budget statement, the Chancellor also acknowledged the important role charity and industry has in funding research within the NHS, and these groups will have an important role in the UKCRC.

The Government has not yet made decisions about future allocations to the MRC or any of the other Research Councils. Allocations to the Research Councils will be announced later in the year, following the announcement in July of the 2004 Spending Review.

1.2.1 The RPBWP Report picks up the point made by the BIGT of the need to provide incentives to clinicians and managers to pursue clinical research, and set up an NHS subgroup to look at this issue in more detail. This group has made a good start but, as was highlighted in the RPBWP final report, more work needs to be done on this important area. The RPBWP

also recommended that a specific UKCRC subgroup be established to take this forward, including consideration of “innovation scorecards”.

- 1.2.2 The RPBWP Report highlights the importance of the human resource capacity and acknowledges the wide range of research training schemes that cover a variety of subject areas and professions. However this coverage is not comprehensive, and the RPBWP suggests that more needs to be done to coordinate existing and new capacity development schemes. It has been agreed that a subgroup of the UKCRC will be established under the leadership of Dr Mark Walport to feed into the DH’s Modernising Medical Careers project (MMC) that is currently underway within the NHS.

Additionally, the new Consultant Clinical Academic Contract in England agreed in October 2003 addresses a key concern of the University sector regarding pay parity between academic and substantive NHS consultants, removing the economic disincentive to clinical academic careers. The DH will therefore transfer £15 million in 2004-5 and £17.8 million in 2005-6 to the Department for Education and Skills to fund the additional costs incurred by Universities employing Clinical Academics. Integrated job planning will play a key to ensuring the success of these new arrangements.

- 1.2.3 The first meeting of the UKCRC took place on 29 April 2004. The terms of reference and governance of the UKCRC were discussed at that meeting and will be agreed at the next.

The level of commitment to and interest in the work of the RPBWP has revealed an eagerness to proceed with the aforementioned and indicates a willingness to make changes to implement the BIGT report and other related recommendations.

Recommendation 2 – Create a public and regulatory environment supportive of innovation

- 2.1.1 Regulations implementing the EU Clinical Trials Directive came into force on 1st May 2004. Industry concerns were taken into account prior to implementation, and the UK regulations are proportionate and practical. With flexibility on applying the principles of Good Clinical Practice and short time scales for securing Clinical Trial Authorisation for of Phase 1 trials, the Government firmly believes that the UK will retain its global lead as a location for clinical research in terms of quality, speed and cost.

2.1.2 The UK has helped to shape the EU review of pharmaceutical legislation that has now been completed. Proposals for an accelerated assessment procedure, conditional authorisations and harmonisation of compassionate use procedures have been agreed. It is expected that these proposals will be implemented by end-2005 and should have a positive impact on patients gaining early access to medicines. The Government believes that these proposals will meet the objectives behind the BIGT recommendations.

The Research for Patient Benefit Working Party (RPBWP) recommended that the UK Clinical Research Collaboration (UKCRC) should set in train a detailed analysis of the cumulative effects of existing regulations with a view to streamlining the overall requirements. The Department of Health (DH) is ready to work with others on practical issues of compliance that inhibit the conduct of research, and looks forward to the opportunity offered by the UKCRC to continue the collaborative work started in initiatives such as the Pharmaceutical Industry Competitiveness Task Force and the DH/Medical Research Council joint project on publicly funded clinical trials with medicines.

2.1.3 Good working relationships between industry, researchers and regulators are important in ensuring that patients and the NHS gain speedy access to new treatments and novel medicines. To improve even further on this relationship the Medicines and Healthcare products Regulatory Agency (MHRA) is currently consulting on reforming the structure of its advisory committees. This, together with improved scientific advice procedures, will provide industry with easier access, including the possibility of more informal contacts to discuss novel products. The MHRA has produced a consultation paper, "*Review of the Advisory Bodies Structure Laid Down in the Medicines Act 1968*", on the establishment of therapeutic advisory groups as a suitable early forum for collaboration. It is also carrying out a review of industry interactions to identify gaps and build on best practice and is setting up a communications strategy to ensure the Agency is reaching stakeholders.

The Government believes that this approach will enable industry and regulators to consider together the development of appropriate guidance for completely new types of medicines (e.g. combined diagnostics and drugs, novel drug delivery mechanisms) and ensure that new products are rapidly brought to market to the benefit of industry, patients and the NHS.

Following a wide stakeholder consultation, on 3 May 2004 the National Institute of Clinical Excellence published updated documentation describing its technology appraisal methods and the associated appeal process. Enhancements include an improved pre-appraisal scoping of the topic; more time for consultation on appraisal documents; a more detailed description of methods of evaluating clinical and economic evidence, incorporating the use of a reference case; and more

information on how appraisal committees determine the cost-effectiveness of technologies. The Institute consulted with a wide range of stakeholders, including industry, on these enhancements and its appraisal process remains an important model for technology appraisals internationally.

- 2.2.1 The Government is addressing the issue of animal rights extremism and is determined to protect individuals from intimidation and attacks. The Government is considering the proposals for a single piece of legislation as a matter of urgency. Officials have discussed the draft legislation with stakeholders and a formal response will be made shortly. A number of measures, both legislative and operational, have already been taken to tackle criminal activities by animal rights extremists.
- 2.2.2 The Government wholeheartedly supports the work of the Coalition for Medical Progress and officials have regular contact with the CMP Director.
- 2.2.1 Recognising the value of a risk assessment forum to monitor and assess emerging issues and identify areas of potential regulation, the Government is working with the BioIndustry Association (BIA) and the Bioscience Leadership Council to create the Bioscience Futures Forum (BFF). The BFF will include senior-level representatives from industry, government, academia, health professionals, ethicists, scientists, patient groups, and others. The timetable, key roles, and secretariat for the BFF are yet to be decided. The Forum will have two major roles – horizon scanning and issue management. These activities need to be complementary to, and supportive of, existing councils and committees examining science and technology. The focus will be to anticipate future impacts of emerging bioscience innovation in order to inform more robust long-term planning; determining actions in the short- to medium-term to influence actual events and developments in a constructive manner; and facilitating the understanding, acceptance and take-up of innovative policies and applications of novel technology while being sensitive to the social, ethical and multi-cultural influences on public perception and opinion.
- 2.2.1 and 2.3.3 The Government recognises the importance of the work that UK industry does in shaping opinion in Europe through working directly with European institutions and other national associations. The Department of Trade and Industry has supported this work and will continue to do so on a case-by-case basis.

Recommendation 3 – Ensure sufficient and appropriate funding is available

- 3.1.1 The recommendation about changing pre-emption guidelines is mainly directed at the Association of British Insurers (ABI) and the National Association of Pension Funds (NAPF), as the guidelines in question exist largely at their instigation.

The Government recognises the importance of the bioscience industry having access to the capital it requires to innovate, invest and grow, as well as the need to maintain appropriate protections for shareholders.

The issue of possible changes to the pre-emption guidelines is primarily one for companies and their shareholders. There is only limited backing for change from other sectors (mainly electronics). To secure the support of shareholders for any changes to the pre-emption guidelines—either generally or for specific industry sectors – would require more evidence of the benefits to shareholders of allowing greater financial flexibility.

The Government will continue to look for ways forward with the BioIndustry Association and representatives of institutional investors.

- 3.1.2 The Government views the proposal on extending the scope of the Corporate Venturing Scheme (CVS) as sector based and analogous to loss buying, which UK tax policy does not generally favour. Corporation Tax (CT) losses can only be moved between *group* companies in the year in which they arise. A provision that allowed the use of CT losses made by one company against the profits of another company outside the group is potentially enormously attractive, so it would have to be tightly drawn, inevitably fairly complex and policed to prevent exploitation (particularly if there was any scope for using accumulated losses). Careful analysis of investor behaviour would need to be done to ensure such a measure did not incentivise investment decisions based on the availability of tax losses, rather than the potential mutual benefits that the CVS is aimed at fostering.

While sympathetic in principle to this idea, Ministers would require a great deal more evidence that it would deliver in practice, as initial analysis indicates that it might not help the companies intended. The larger companies that the BIGT mentions are simply outside the CVS and, as the recommendation points out, there is already a facility for small and medium-sized enterprises (SMEs) to “monetise” their R&D tax losses. While the SME definition is not precisely the same as the CVS “gross asset test”, SMEs make up over 95 per cent of the CVS constituency. Any facility to enable SMEs to “monetise” losses within the CVS may not be welcomed by these companies as they might come under pressure to “surrender” their losses to large corporate shareholders against their wishes rather than claim R&D tax credits.

Any change specifically provided for one sector, in this case the bioscience sector, would be a case of aid to those companies, which could bring it into conflict with European State aid rules and be difficult to accommodate within the CVS as essentially it is a different relief.

The Government continues to monitor the CVS and would welcome substantive evidence of the behavioural changes that a measure of this nature would bring about.

3.1.3 The Government considers that the aim of allowing non-SME companies to “cash in” tax losses associated with R&D is best considered via a ring-fenced mechanism such as the one discussed in Recommendation 3.1.2, although there are still problems with such an approach (as set out above). State aid considerations would preclude sector-specific or size-specific measures of the kind envisioned in the BIGT Report, and the value judgements required to limit costs (e.g. that a firm is loss-making “solely because of the need for substantial investment to validate new product development”) are at odds with the aims of R&D tax credits, which are to give users certainty of a tax rebate on qualifying R&D costs.

3.1.4 R&D tax credits, like all tax, work on the basis of an individual company’s tax circumstances only and the Government has maintained this principle in revising the definition of R&D for tax purposes. This means that whether or not work is R&D does not fundamentally depend on whether the work is intended to form part of an R&D project conducted by a larger company, and hence whether work by a Chief Research Officer or other sub-contractor is eligible for R&D tax credits must be judged on the fundamental criteria for R&D. However the definition of R&D has been amended so that it should be easier for a sub-contractor to show R&D in its own right: that an advance in knowledge or capability in a field of science or technology is being sought, and that the sub-contractor’s work directly contributes to achieving that advance. Evidence that work by a sub-contractor contributes to a larger R&D project can be taken into account by tax inspectors in determining whether the sub-contractor is doing R&D (for example, that systematic testing is being done in pursuit of a new or appreciably improved pharmaceutical product). This will be reflected in guidance on the revised definition, which the Inland Revenue is committed to introducing by the time of the Pre-Budget Report 2004.

Bioprocessing work too must constitute R&D in its own right to attract R&D tax credits. The revised definition of R&D which came into effect on 1 April 2004 makes it clear that process development work is R&D if an advance in knowledge or capability in a field of science or technology is being sought, and that the work directly contributes to achieving that advance. Developing new or appreciably improved biomanufacturing processes would therefore typically constitute R&D for tax purposes.

3.1.5 Cash benefits for later stage bioscience companies are inevitably subject to European State aids rules. If they exceed the *de minimis* threshold and unless they are linked to specific investment projects, they are generally not possible. If the R&D tax credit scheme were changed to offer extra benefit to a small group of innovative companies, as the recommendation suggests, this would be a clear operating aid to those companies, which would be disallowed by the European Commission and therefore illegal.

The Government does not, in any case, support the “picking of industrial or sectoral winners” for specific, unconditional financial support; rather it seeks to identify market failures in order to address the causative factors across the board. The Government’s view is that support for later stage bioscience companies is best supplied through funding for the science base; support of knowledge transfer and collaborative R&D through the new DTI Technology Strategy Fund; building NHS capacity for clinical trials; and generic incentives such as the R&D tax credit.

The Government does run award programmes through its Research Councils for support of entrepreneurs arising out of the research base (the BBSRC Young Entrepreneurs Scheme being an obvious example). In these cases, intervention is justified by the market failures surrounding the process of transforming publicly funded science and technology into business, but these failures do not apply to later stage companies, which are already well established.

3.1.6 The question of whether there should be a consolidated, pan-European technology exchange led by the London Stock Exchange is one for the markets to determine. The role of Government here is to remove the obstacles to integration and allow the markets to operate at maximum efficiency. However, the UK Government strongly supports the integration of European capital markets and has led pressure within Europe to remove the obstacles to liquidity throughout the European Union. It will continue to press for removal of artificial barriers to capital flows and balanced regulation in the EU.

3.2.1 The Government's investment in funding Higher Education Institutions (HEIs) to increase their knowledge transfer activity and levels of business interaction continues to rise and will be worth £100 million a year by 2005-06. A significant share of this funding has been directed towards building the capacity and skills within universities, enabling them to interact successfully with the business and the wider community. Recommendations from a number of reports including the Lambert Review, concerning future Government investment in “third leg” activity, are currently being considered and a full Government response will be published this summer.

3.2.2 The Government has consolidated the funding for University Challenge (UC) and Science Enterprise Challenge (SEC) into the Higher Education Innovation Fund (HEIF) to create a single stream of funding for HEIs. This was done in order to reduce the bureaucratic demands on the higher education sector and to create the flexibility for HEIs to direct available resources to the areas of knowledge transfer activity that maximises the strengths and opportunities of individual institutions. The increased funding for the HEIF will ensure that successful activity previously funded under the UC and SEC can continue to be supported through the HEIF. The Government will report to the Bioscience Leadership Council on the percentage of calls dedicated to “proof-of-concept” and seed funding.

3.3.1 The DTI promotion of European funding sources to UK bioscience companies is being strengthened through the new coordinated National Contact Point support service. The DTI and Medical Research Council (MRC) are jointly hosting an event on 16 June 2004 to provide research organisations and businesses with details on the €540 million call for proposals for EU Framework Programme 6, which is under the priority of Life Sciences, Genomics and Biotechnology for Health.

Additional resources have been allocated to support promotion of life science for health opportunities and priorities here reflect industry and academe needs as set out in the BIGT Report and the Bioscience Unit’s survey work. For example, two additional specialists have been engaged to help broker collaborations and track bids. The DTI is also working more closely with the MRC to ensure that there is a focus on UK strengths and national needs for the future of bioscience.

3.3.2 In October 2003 the European Investment Bank committed half a billion euros for the European Investment Fund (EIF) to invest in funds in high-technology companies and it is expected that bioscience companies will be a major beneficiary of this. The EIF investment rules have also been changed to allow investments in later stage entrepreneurial companies. The Government very much supports the principle of EC funding of fewer but better qualified companies, and believes that companies with strong business models and robust patent portfolios will attract investment and go on to create a consolidated industry that will continue to compete on a global scale.

Recommendation 4 – Building a strong bioprocessing sub-sector within UK bioscience

The Government recognises the importance of a strong bioprocessing sub-sector to the UK. There have been a number of very positive developments over the last few years, including the commencement of construction on the £30 million National Biomanufacturing Centre in Speke, Merseyside, which is being built with Regional Development Agency and DTI funding.

- 4.1.1 The Government values the recommendation to build up a network of bioprocessing centres of excellence to focus on graduate training, leading edge research and collaborations with leading UK-based companies. The first stage of the implementation of this recommendation is that the DTI will support the creation of managed networks in medical bioprocessing under the first call of the new DTI Technology Programme. Collaborative research and development projects in stem cell technology and a single national network in stem cell technology will also be supported. We aim to work closely with the Research Councils and Regional Development Agencies in the delivery of the managed networks and the collaborative R&D. The new DTI Technology Strategy Board, with external industry membership, will be established by August 2004, and we expect future calls for proposals, as well as the new DTI Technology Strategy to reflect the importance of the area of medical bioscience.

The Biotechnology and Biological Sciences Research Council (BBSRC) and the Engineering and Physical Sciences Research Council (EPSRC) welcome the BIGT Report and recognise the importance of bioprocessing in the UK. The EPSRC currently supports several related centres of excellence including the industry driven Innovative Manufacturing Research Centre at UCL and the Pro-Bio Faraday Partnership based in northwest England. The BBSRC, EPSRC and Medical Research Council also jointly sponsor the £9.6 million Tissue Engineering Interdisciplinary Research Collaboration at Liverpool and Manchester Universities. The EPSRC intends to work with other stakeholders, in particular the BBSRC, to take forward the BIGT recommendations relating to centres of excellence. The Council also remains receptive to industry-led consortia that wish to enter into a partnership arrangement.

- 4.1.2 The BBSRC is keen to explore how the cutting edge skills of the bioscience research community can be brought to bear on processing issues. It has appointed a Working Party comprising industrial and academic researchers to examine in detail the best way of achieving this aim. The EPSRC and DTI are also engaged in the Party's discussions. The

Working Party will explore this recommendation in depth and the BBSRC Strategy Board will consider its conclusions in July 2004.

4.1.3 Support for new bioprocessing centres under the DTI Technology Strategy will be helpful in building the skills base. Skills requirements for bioprocessing are actively being considered by the Sector Skills Council for Science, Engineering and Manufacturing Technologies (SEMTEA) and will form part of its proposed national bioscience skills accreditation framework.

The EPSRC-sponsored Engineering Doctorate Centres at UCL and Birmingham both have a strong presence in this field, and are supplying highly skilled research engineers. In order to further develop and nurture this field the EPSRC has supported four research networks.

4.2.1 Through the DTI and UK Trade & Investment, the Government has committed specialist resource, both in-house and external, to identify and respond to specific inward investment enquiries from the sector, including bioprocessing. This includes specialist organisations within a national network of regional bodies, the establishment of sector specialist teams in key target markets such as the US, and the appointment of individuals from industry and within Whitehall.

4.2.2 UK Trade & Investment are committing resources to ratchet up the coordinated promotion of inward investment, including in biosciences. This includes a new approach to client presentations, better supporting IT, more targeted marketing, deeper analysis of regional sector selling points and a new approach to pinpointing specific science and technology activity in the UK. Traditional efforts such as attendance at key events like BIO2004 are continuing concomitantly.

4.3.1 and 4.3.2 The BIA has identified and employed an individual for the post of Bioprocessing Industry Development Director, and its Manufacturing Advisory Committee has also decided to schedule its first National Bioprocessing Forum to take place later this year. The Government welcomes these developments which have both been funded by the DTI.

Recommendation 5 – Develop, attract and retain a high quality scientific and managerial talent base

5.1 and 5.2 The Government is supporting the work of SEMTA, the Sector Skills Council for this area. The DTI and the Department for Education and Skills (DfES) are actively engaged with the SEMTA Bioscience Group and on groups working to develop a national accreditation framework for bioscience – including technicians, graduates and PhDs. This work is very much in alignment with the recommendations made in the BIGT Report.

5.1.1 The Government welcomes the BIGT recommendation to support interdisciplinary education in the bioscience sector. As part of its deliberations, the Research for Patient Benefit Party has looked at the issue of human resources (see 1.2.2) and a subgroup of the UK Clinical Research Collaboration will carry this on; the Government will work with this group, and continue to work with SEMTA, in addressing this area.

5.1.2 As discussed in the BIGT Report, there are already a number of Government initiatives underway to support science graduates and postgraduates wishing to undertake business school education, such as the “Investing in Innovation” scheme instituted following the Roberts Review “*SET for Success*”. The DfES has highlighted the importance of, and is encouraging, interdisciplinary collaboration within and across institutions. The Government will look to complement existing funding and support, whilst minimising the creation of additional initiatives.

5.2.1 The Government appreciates the excellent contributions made by industry to generate interest and excitement in the physical sciences, such as the Salters’ Chemistry Club from the Salters’ Institute, Pfizer’s Academic Liaison Programme and Science Across the World run by the Association of Science Education in partnership with GSK. The Government has also overseen a number of useful developments addressing the issue of science teaching and profile-raising in schools since the publication of the Roberts Review; for instance, there is the joint DTI/DfES initiative Science and Engineering Ambassadors Scheme which provides role models in science or engineering to work in schools, both to support teachers and encourage more young people to consider careers in these fields.

There are now 121 science specialist colleges which focus on the curriculum areas of science and mathematics, raising standards of achievement in science and maths across the full ability range.

Science is a priority curriculum area – and for many students, exposure to advanced level study helps them in considering the high-tech

industries and related degree pathways that the BIGT Report focuses on. The decision that the DfES Standards Unit will focus on improving teaching and learning in post-16 science education was informed in part by the findings of the Roberts Review.

5.2.2 The Government welcomes the recommendation to increase the programmes and initiatives that provide interdisciplinary training at post-graduate level, which is in line with the Roberts Review. The Research Councils already fund “discipline hopping” schemes, which provide short-term support to pump prime new collaborations between Engineers and Physical Scientists with Life Scientists in the aim of fostering long-term interaction.

The Office of Science and Technology is looking at how best to provide more flexibility in PhD funding and extension to allow the time necessary for the completion of interdisciplinary aspects.

5.2.3 There are already a number of Research Council programmes being run to provide opportunities for business exposure to science and engineering students at university, such as the Biotechnology Young Entrepreneurs Scheme (BBSRC) and CASE (BBSRC, EPSRC). The feasibility of building on this in terms of other programmes, such as Knowledge Transfer Partnerships (formerly the TCS programme), will be examined in order to make small and medium sized entities more aware of this area.

5.2.4 The Government will work with the industry to maximise the contribution the Centres of Vocational Excellence (CoVEs) make in meeting the industry's skills needs through the continued development of existing CoVEs and the possible creation of new CoVEs. The Government will also encourage and support the CoVEs to develop strategic links with the industry through representation on high-level groups and, at the same time, encourage and support CoVEs to continue to be innovative in developing and delivering vocational training and actively sharing good practice and networking with other providers.

5.3.1 The Government believes that raising the approved Company Share Option Plan (CSOP) limit from £30,000 to £100,000 is unlikely to encourage much greater use of share options. Only a relatively small proportion of employees are actually granted the full £30,000 under the CSOP and those that are tend to be on high incomes and so also receive options that are subject to tax and National Insurance Contributions (NICs). Therefore, increasing the limit would not be cost effective for the Government because it would benefit mostly those who receive more

than £30,000 of options already as companies could replace their taxed options with tax and NICs advantaged ones.

Disposal of shares at option exercise is not always only to meet tax and NIC liabilities. Maintaining significant shareholdings in one company entails specific risk and so a diversified portfolio of assets can be more important to the individual.

The CSOP is only one of four tax and NICs advantaged employee share/share options schemes. Companies can use the Share Incentive Plan, Save as You Earn and Enterprise Management Incentive (EMI), in addition to the CSOP. Increasing the CSOP limit to the same as that for the EMI would reduce the targeting effect of the EMI and weaken its policy objective of helping smaller companies recruit and retain skilled staff.

5.3.2 Wide-ranging consultation on the Enterprise Management Incentive (EMI) agreed that £100,000 was very generous and substantial relative to a small company's share capital and sufficient to entice key employees.

If unexercised EMI options were allowed to drop out of the calculation of the £100,000 limit after 3 years, this could lead to employees holding more than £100,000 unexercised EMI options at anyone time. This would impact on the £3 million limit of shares under the EMI option allowed in a company or group, leaving employers less flexibility to use EMI options to attract and retain other workers.

The EMI has proved very popular and exceeded government expectations with over 4,500 companies granting some 70,000 EMI options since its introduction in 2000. The majority of EMI option grants are at less than £25,000 and only a small percentage of employees hold EMI options at the £100,000 limit. Given this it is not clear a problem exists around the £100,000 maximum in a 3 year period and further evidence would be needed to show the proposal would enable the EMI to be used by companies more successfully.

The Government will continue to monitor the EMI and welcome evidence put forward by business to support changes that will enhance its operation and incentive effect.

5.3.3 The £8,000 tax-free ceiling on relocation expenses has remained unchanged for many years and although the Inland Revenue has had a number of representations seeking an increase, it does not feel it would be appropriate to do so.

The level of relief is intended to reflect a reasonable amount for the Exchequer to contribute towards relief on the financial assistance some employers give to their employees to help them relocate. In setting the level of relief they have to bear in mind the fact that there are many employees who have to move for work related reasons, who do not

receive assistance from their employer, and so receive no help from the tax system.

A higher level of relief available to employees who receive financial assistance towards the cost of relocation from their employers would increase the disparity in the tax treatment afforded to those who receive assistance from their employer and those who do not. Also the tax system has to be fair to everyone so any change in the rules governing relocation expenses would affect everyone who receives help in relocating because of their job. The cost of doing so would be considerable.

The recommendation asks for all reasonable relocation expenses to be tax deductible and so save money for the employer. These costs are – by and large – already tax deductible. The revenue costs incurred by an employer in relocating staff will generally be allowable in computing the employers' profits for tax purposes. From the employee's perspective, the rules currently exempt the first £8,000 of certain relocation expenses, paid for or reimbursed by the employer from tax and National Insurance Contributions. The employee, not the employer, is taxable on any of those expenses over and above the £8,000 limit, although the employer will be liable to pay Class 1A National Insurance Contributions on the excess.

Recommendation 6 – *Making it happen: Create the Bioscience Leadership Council*

- 6.1 Ministers invited Sir Richard Sykes, Rector of Imperial College, to chair the Bioscience Leadership Council (BLC), which had its second meeting in April 2004. The Council is charged with monitoring the implementation of all the BIGT recommendations - prioritising them with the aid of the BIA - and the Government looks forward to continuing to work with it. The BLC will report to Government biannually, and Ministers will meet with Sir Richard in the summer to discuss further the progress on the BIGT.

The Bioscience Innovation and Growth Team Report

Below is a list of the sub-recommendations in the Bioscience Innovation and Growth Team (BIGT) report.

For further information on this contact the Director of Biotechnology Industry Business Relations, DTI Bioscience Unit, on +44 (0) 20 7215 4190

BIGT RECOMMENDATION 1

Critical challenge	Main recommendations	Sub-recommendations
<p>1. Build a mutually advantageous collaboration between the NHS and industry for patient benefit.</p>	<p>1.1 Create a National Clinical Trials Agency (NCTA) to support excellence in clinical trials and clinical research within the NHS.</p> <p>1.2 Create incentives and career structures within the NHS and academic medicine to promote clinical investigation.</p> <p>1.3 Increase the total funds for R&D within the NHS, initially stepwise over five years, from their current level of 0.9% of total spending (~£560 million) to 1.5%</p>	<p>The NCTA should be an arm's length body, sponsored by the Department of Health (DH), working in collaboration with Research Councils UK. The NCTA would require £5 million of new money in its first year to supplement £45 million from existing sources (NTRAC, NCRN, MRC and HTA). The NCTA and funding would scale up over the initial five years to reach £200m per year (£150m in new money). A successful NCTA will provide benefits for patients, better quality and more effective clinical trials for industry, and will generate further income for the NHS.</p> <p>To raise the level of professionalism in the NHS surrounding clinical trials, the NCTA will focus on two main activities:</p> <p>1.1.1 Develop the infrastructure required to support professional, efficient clinical trials. Specifically:</p> <ul style="list-style-type: none"> • Create a national network that will audit clinical trials capacity; establish 5-10 infrastructure offices to advise on clinical trial set up, conduct and regulation, develop national costing models and provide essential training (e.g. to research nurses). • Build business cases for, and fund further investments in critical physical and human infrastructure e.g. the MRC clinical trials unit should form part of the NCTA. An initial pilot could include dedicated facilities for Phase I/II trials, translational clinical research networks along NCRN and NTRAC lines for respiratory, neuroscience, cardiovascular, musculoskeletal, and paediatrics. <p>1.1.2 Fund a portfolio of clinical research programmes and projects. In the medium term, the NCTA would fund clinical research including hypothesis-driven, pragmatic, and longitudinal studies. At least some portion of this portfolio should focus on enabling NHS-academic-industry collaboration, and create vehicles for public-private partnership.</p> <p>1.2.1 Develop an innovation scorecard for NHS Trusts.</p> <p>1.2.2 Create two new cadres of clinical researchers by funding 4-5 year fellowships with programme management support: clinical investigators and clinically trained scientists.</p> <p>1.2.3 Monitor and celebrate progress by upgrading the functionality of the NHS Research Register Register (NRR) and developing a communications strategy for the NHS R&D programme (e.g. reporting annually to highlight major achievements), ensuring that progress of this type is highly regarded by the RAE.</p>

BIGT RECOMMENDATION 2

Critical challenge	Main recommendations	Sub-recommendations
<p>2. Create a public and regulatory environment supportive of innovation.</p>	<p>2.1 Improve regulatory support for the development, approval and use of innovative medicines in the UK.</p> <p>2.2 Defend the responsible, regulated use of animals in medical research through two measures.</p> <p>2.3 Adopt a proactive approach to bioscience regulation and reputation management, actively shaping the UK and EU regulatory environments of the future.</p>	<p>2.1.1 Implement the EU Clinical Trials Directive in a manner consistent with the aim of achieving global leadership in clinical research.</p> <p>2.1.2 Introduce a system for provisional licensing of drugs in the UK and EU, along the lines of an adapted version of the French Autorisations Temporaires d'Utilisation (ATU) de cohort system. This will make promising treatments available to patients where a genuine public health need exists, often before the completion of Phase III clinical trials. In addition, the UK should support the draft EU legislation that recommends creation of a European conditional marketing approval, a fast-track procedure, and harmonisation of compassionate use regulations.</p> <p>2.1.3 Create a collaborative relationship between NICE, the EU and UK drug approval regulators and the bioscience and biopharmaceutical industry, to ensure that approval times for approved medicines/therapies are competitive with the USA.</p> <p>2.2.1 Introduce new, specific legislation to deal with animal extremism against those conducting legitimate medical research, and associated organisations and service providers.</p> <p>2.2.2 Support the work of the Coalition for Medical Progress in encouraging informed public debate on animal research, and seek to optimise the involvement of patient groups in this work.</p> <p>2.3.1 Create a Bioscience Risk Assessment Forum (BRAAF) under the auspices of the Bioscience Leadership Council (BLC) to monitor and assess emerging issues, develop issue management strategies, and anticipate areas where regulation will be needed.</p> <p>2.3.2 Create an ongoing programme of activity to shape opinion in Europe.</p> <p>2.3.3 Create alliances across EU member states to support the biosciences industry, on an issue-by-issue basis.</p>

BIGT RECOMMENDATION 3

Critical challenge	Main recommendations	Sub-recommendations
3. Ensure sufficient and appropriate funding is available.	<p>3.1 Support measures to improve the liquidity of emerging bioscience companies in order to advance self-sustainability.</p> <p>3.2 Invest in the 'bridge' between idea generation and commercial financing, providing the infrastructure and funding to create more high quality, commercially exploitable projects from the academic, research and hospital sectors.</p> <p>3.3 Improve UK bioscience companies access to EU funding sources.</p>	<p>3.1.1 Support amendment of the Pre-emption Guidelines to permit UK-listed life science companies to issue up to at least 20% of their share capital on a non-pre-emptive basis during a rolling three-year period.</p> <p>3.1.2 Extend the scope of the current Corporate Venturing Scheme (CVS) regulation to allow investor companies to utilise a tax loss asset received from the investee company in lieu of/in addition to an equity stake. This measure will enable large bioscience companies to monetise their tax loss assets and provide an incentive to engage in partnerships (for example, with pharmaceutical companies) that will improve the chances of successful product commercialisation.</p> <p>3.1.3 Explore the possibilities for extending the payable R&D tax credit to loss-making bioscience companies with up to 1,000 employees.</p> <p>3.1.4 Ensure that the R&D tax credit applies equally to R&D work contracted out or kept in house, and that innovative manufacturing design work for bioprocessing is covered by the tax credit.</p> <p>3.1.5 Establish a Bioscience Innovation Awards scheme for 10 later stage Human Health bioscience companies, providing cash benefit (e.g. through amplified R&D tax credits).</p> <p>3.1.6 Strongly support efforts to create a more accessible and liquid European capital market for technology companies, through harmonisation of listing rules and through a, LSE-led, consolidated pan-European technology exchange.</p> <p>3.2.1 Strengthen Technology Transfer Offices (TTOs) through a series of measures, including £20 million 'top-up' funding programme to build skills and facilities at leading TTOs; consolidation of existing small TTO's; new performance metrics emphasising value created rather than number of spin-outs generated; and an "Entrepreneurs-In-Residence" scheme to increase commercial input to promising projects at an early stage.</p> <p>3.2.2 Ensure the new Higher Education Innovation Fund (HEIF) and the Public Sector Research Exploitation Fund (PSRE) provide adequate priority funding to accommodate: <ul style="list-style-type: none"> • Technology Validation Programmes to provide 'proof-of-concept' funding. • Seed Funding to enable supported projects and companies to create the technology and commercial case required for qualifying as 'investment ready vehicles'. </p> <p>3.3.1 Establish a 'Bioscience Framework Access Office' (BFAO) to: <ul style="list-style-type: none"> • Improve UK bioscience companies' access to the EU Framework sources of funding (e.g. FP6). • Actively aid Government to shape specifications and access criteria for EU Framework FW7 funding to maximise opportunities for UK bioscience companies. • Extend role over time to become a single point of contact to facilitate access for bioscience companies seeking public funding to the variety of schemes and funding sources available. </p> <p>3.3.2 Support the EC Biotech Finance Forum's recommendations on creating a 'fund-of-funds' to support European bioscience companies and lobby the EC to make money available for such a fund.</p>

BIGT RECOMMENDATION 4

Critical challenge	Main recommendations	Sub-recommendations
<p>4. Build a strong bioprocessing sub-sector within UK bioscience.</p>	<p>4.1 Build a network of bioprocessing Centres of Excellence across the UK.</p> <p>4.2 Attract significant inward investment in bioprocessing assets.</p> <p>4.3 Foster bioprocessing community development.</p>	<p>4.1.1 Establish Centres of Excellence across the UK in leading HEIs, with strong leadership from international 'heavyweights' (directors should be supported by three other academics and 6-8 post-doctoral researchers), a clear mission, and secure funding. The Centres of Excellence will focus on an ambitious, three-pronged mission:</p> <ul style="list-style-type: none"> • Deliver graduate training designed to create interest and interdisciplinary awareness, and expertise in bioprocessing. • Develop leading edge research resulting in strong IP positions in emerging areas of bioprocessing. • Build collaboration with leading UK-based companies to ensure real-life experience. <p>Secure funding will be vital. BIGT recommends £5 million per year in total from research councils, for eight years, with matching investment from host HEIs and/or RDAs.</p> <p>4.1.2 Focus the research agenda of Centres of Excellence around 'next horizon' bioprocess-related technology areas, where the UK has an existing foothold and the potential to develop global IP leadership positions.</p> <p>4.1.3 Develop training programmes and agendas in Centres of Excellence and expand training options across the UK to build skill levels among the existing bioprocessing workforce.</p> <p>4.2.1 Contract a specialist company to identify and respond to potential inward investors and liaise with a bioprocessing dedicated individual appointed to InvestUK.</p> <p>4.2.2 Develop a more coordinated approach for facilitating the evaluation of potential foreign inward investors.</p> <p>4.3.1 Sponsor a Bioprocessing Industry Development Director.</p> <p>4.3.2 Develop an agenda-setting programme of industry events, including a focal point annual National Bioprocessing Forum.</p>

BIGT RECOMMENDATION 5

Critical challenge	Main recommendations	Sub-recommendations
5. Develop, attract, and retain a high quality scientific and managerial talent base.	<p>5.1 Initiate two new programmes to support dual, interdisciplinary education essential to the bioscience sector.</p> <p>5.2 Support and extend existing initiatives to broaden and deepen interdisciplinary education and training</p> <p>5.3 Enhance incentives to existing talent by removing targeted barriers.</p>	<p>5.1.1 Create a programme to fund combined Bachelor of Medicine Mb-PhD qualifications (like the US MEdPhD qualification), with 30 studentships at selected HEIs, rising to 100 in equilibrium.</p> <p>5.1.2 Introduce a programme to fund post-PhD scientists and engineers undertaking formal business education ranging from modular courses to full MBAs.</p> <p>5.2.1 Encourage interest and excitement in the biosciences and their relation to the physical sciences from a young age through:</p> <ul style="list-style-type: none"> • An Interdisciplinary Education Scheme • Further support of bioscience focused science centres. <p>5.2.2 Increase programmes and initiatives that provide interdisciplinary training at the post graduate level (i.e. Masters and Doctoral) such as:</p> <ul style="list-style-type: none"> • Encourage Research Councils to increase support for doctoral training in key interdisciplinary fields (e.g. the EPSRC scheme for four year PhD training in Interface Interdisciplinary Centres) • Encourage the establishment of competitive schemes for prestigious, well supported interdisciplinary Masters courses in priority fields. <p>5.2.3 Extend and support the provision of business exposure opportunities (e.g. Biotechnology Young Entrepreneurs Scheme (YES)) amongst science and engineering students at university, and encourage greater involvement.</p> <p>5.2.4 Encourage the pharmaceutical and bioscience industries and SEMTA to drive sector specific vocational training of technical staff.</p> <p>5.3.1 Extend Approved Share Option limit from £30,000 to £100,000.</p> <p>5.3.2 Amend the calculation of the £100,000 limit on Executive Management Incentive Scheme (EMI) option grants to remove anomalies around unexercised options.</p> <p>5.3.3 Abolish the £8,000 tax-free ceiling on relocation expenses and instead make all reasonable relocation expenses tax deductible.</p>

RECOMMENDATION 6

Critical challenge	Main recommendations	Sub-recommendations
<p>6. Making it happen: Create the Bioscience Leadership Council</p>	<p>6.1 Create the Bioscience Leadership Council to oversee implementation of the BIGT recommendations and continue the sector-wide dialogue.</p>	<p>The BLC should be composed of six industry representatives and six non-industry stakeholders (e.g., from the NHS/academia), reporting annually to Ministers. The Council has a vital role to play to:</p> <ul style="list-style-type: none"> • Facilitate Government and industry cooperation. • Proactively drive implementation of the measures recommended by the BIGT. • Monitor their effectiveness. • Provide a forum to discuss issues management. • Enhance the probability of success for a world-leading bioscience industry developing in the UK. <p>The BLC will be supported by a secretariat, who's first task will be to amplify and finalise the implementation plan for the BIGT recommendations, and achieve agreement from all interested parties on their respective roles. Working Groups of the Council may be convened to assist in the implementation of particular recommendations (e.g. NCTA).</p>