

ANNUAL REPORT

Progress against the
recommendations in 'Review
and Refresh of Bioscience
2015'

26 JANUARY 2010

Introduction

Government's approach to the bioscience sector has long been one of industrial activism. In 2003 Government launched the Bioscience Innovation and Growth Team (a coalition of industry, public sector groups and Government Departments) in partnership with the BioIndustry Association (BIA). This set out a vision to create a diverse and sustainable UK bioscience sector by 2015, culminating in the "Bioscience 2015" (BIGT) strategy.

In spring 2008, Government asked the Bioscience Innovation and Growth Team, under the Chair of Sir David Cooksey, to carry out an independent review of 'Bioscience 2015'. This review would look at progress in achieving the 'Bioscience 2015' vision. It would also identify new ideas and proposals that could positively affect the future competitiveness of the UK bioscience sector. A 'Review and Refresh of Bioscience 2015, a Report to Government by the Bioscience Innovation and Growth Team' (BIGTR2) was published on 22 January 2009. It made 23 key recommendations to drive forward the bioscience sector.

In April 2009 Government's New Industry New Jobs (NINJ) strategy identified the Life Sciences industry as one of the priority industries for the future of the UK economy. Embedding this, Government's May 2009 response to BIGTR2 set out a number of new policy initiatives for the bioscience sector. This annual report provides an update on the implementation of those actions, confirming good progress against all of Government's commitments.

Following the Prime Minister's Summit with the Life Sciences industry in January 2009, the Office for Life Sciences (OLS) was created to bring added pace and momentum to Government action on Life Sciences. Its creation signalled the Government's commitment to maintaining the UK's position as a world leader. The OLS was tasked with developing a package of measures to sustain a thriving and integrated UK Life Sciences industry now and in the future. These were set out in the *Life Sciences Blueprint*, published in July 2009. A delivery update, *Life Sciences 2010: Delivering the Blueprint* is published alongside this document.

Around a third of the BIGTR2 recommendations have been taken forward by the OLS. Progress on those items is detailed in *Life Sciences 2010*. Further information can be found at <http://www.dius.gov.uk/ols>.

More broadly, Government has fully recognised the particular issues faced by the bioscience sector, not least access to finance, and the challenge this poses to the future of highly innovative and world-leading research and development. In June 2009 Government created a £150 million UK Innovation Investment Fund (UKIIF) with a £25 million minimum investment committed to Life Sciences (although the expectation is that substantially more will be invested). The UKIIF will target small growing businesses, start ups and spin outs, including pre-profit and pre-revenue stages of development. Rapid progress has been made in establishing the Fund and leveraging additional funding. UKIIF will ensure that venture capital is available by early 2010 to invest in innovative UK businesses in key industries such as Life Sciences. Government's objective was to raise investment that matched its £150 million investment at first closing. This target has been exceeded; the investment has already leveraged £175 million in additional money.

As a further major policy initiative, in December 2009 the Pre-Budget Report announced the introduction of a "Patent Box" applying a reduced rate of Corporation Tax (CT) to income from patents from April 2013, to strengthen the incentives to invest in innovative industries and ensure the UK remains an attractive location for innovation.

The Government has also invested in two major new bioincubators: £11.7 million into a £37 million facility in Stevenage and £12 million into a £24 million facility in Edinburgh. These bioincubators will help stimulate growth and keep Britain among the best places in the world to start and grow a business.

Finally, BIS, DH and UKTI have created a new Bioscience and Health Technology Database providing reliable data on medical biotechnology, medical technology and industrial biotechnology companies in the UK. This is a crucial step forward. It will enable Government to measure and evaluate the UK Life Sciences environment and to characterise the success of the industry. It will be an important policy making tool. A report “Strength and Opportunity: the landscape of medical technology, medical biotechnology and industrial biotechnology enterprises in the UK” was published in December 2009 which highlights the key information in the database.

The annual report below follows the structure of ‘Review and Refresh of Bioscience 2015’. To accompany the progress updates, the report highlights the substance and context of the BIGTR2 recommendations and the commitments Government made against them.

Chapter 1: Stocktake of Bioscience 2015

This chapter in BIGTR2 provided an overview of the UK's current position relative to the original Bioscience 2015 (BIGT) report. It also made a number of new recommendations to reflect the current UK environment and the delivery mechanisms that are now in place.

1. SUSTAIN RESEARCH CAPABILITY PROGRAMME

Clinical trials are a central component of the UK clinical research environment. Bioscience 2015 identified the need to improve the health research environment through NHS and industry collaboration. BIGTR2 then noted the major programme of work that had been underway since 2004 aimed at getting trials up and running more quickly through the streamlining of research administration. It commented that this work was essential to improving the cost-effectiveness of the UK clinical research environment for industry.

Against this, BIGTR2 noted "In what has the potential to become a unique selling point for the UK, the NIHR/ NHS Connecting for Health Research Capability Programme has been initiated to provide the necessary infrastructure to federate and facilitate access to high quality NHS electronic patient record data for use in research."

BIGTR2 recommended that "The good progress in establishing the Research Capability Programme in England should be sustained and every effort taken to ensure that the services delivered via its Health Research Support Services and equivalents in the Devolved Administrations meet the needs of the sector. Funding bodies should work together to maximise the preparedness of the research community and industry to use it."

In response, Government made the following commitments:

1 (i) - The National Institute for Health Research (NIHR) / NHS Connecting for Health's Research Capability Programme would prepare a full business case for investment in a Health Research Support Service (HRSS) which will help improve the quality, speed and efficiency of research processes.

Government has continued efforts to improve the health research environment. Preparation of an Outline Business Case for investment in a Health Research Support Service was completed in December 2009. Its objective is to create a connected NHS, with access to information to improve the safety and quality of patient care. It is envisaged that this will create new opportunities to improve the health of the nation. The business case is now subject to HM Treasury approval, and procurement for the services is being prepared. The full business case will be ready for Ministers to consider in July 2010.

1 (ii) - Public and charity funders would develop a Strategic Framework for Health Informatics in support of Health Research. The Framework would enable the transitioning of Research and Development (R&D) Departments in England to become National Institute for Health Research (NIHR) Research Support Services.

This commitment has been taken forward as part of OLS' work. Good progress has been made to develop a Strategic Framework for Health Informatics in support of Health Research. A full delivery update is provided in *Life Sciences 2010: Delivering the Blueprint* - Chapter 2, Section 6: E-health records – Exploiting the UK's position as a world leader in health informatics.

2. INCENTIVISE CLINICIANS

BIGTR2 noted that Sir David Cooksey's Review of UK Health Research Funding identified key gaps in translational research in the UK. BIGTR2 recommended that "Funding partners should work together under the umbrella of OSCHR to incentivise clinicians to become clinician scientists following a research degree e.g. PhD route to ensure sufficient supply for industry and academia. The numbers of successful clinician PhDs awarded should be published annually."

Against this Government committed:

2 (i) - Office for Strategic Coordination of Health Research (OSCHR) partners to report to OSCHR in May 2009 on their work on human capital. This work was to identify what partners still need to do to establish a skilled and highly motivated research workforce with sufficient capacity and capability across the full range of medical research to meet the needs of the NHS, academia and industry.

Recognising the importance of this, OSCHR Partners (the public funders of health research in the UK¹) undertook a UK fellowships survey. This was completed in May 2009 and was the first comprehensive analysis of research fellowships supported by the major UK research funding organisations. It is published at <http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC006501>. This survey, which OSCHR Partners intend to repeat periodically, fed into their human capital work. This work concluded that: (i) Partners already have well developed and coordinated strategic approaches towards meeting the human capital needs of the NHS, academia and industry, and work closely with stakeholders; (ii) many of the current challenges were organisational and cultural rather than reflecting a lack of suitable funding schemes; and (iii) considerable progress had been achieved in recent years, such as introducing the integrated academic training pathway for doctors and dentists. The OSCHR Board endorsed the review's conclusions and further noted that similar pathways are being created for other health professions. It also noted that specific schemes exist for underpinning methodological disciplines in short supply.

Government also noted that:

2 (ii) - Funders of medical research were working together to get better information about trainee numbers and clinical research pathways, including annual data on the numbers of successful clinician PhDs.

Total numbers of PhD training fellowships awarded by major funders to clinicians can be found in the OSCHR Partners' survey referred to above. Demand for National Institute for Health Research (NIHR) doctoral (PhD) research fellowships increased in 2009, compared to 2008, and the total number of recommended awards more than doubled.

The mix of clinical specialties attracting research training support through the integrated academic pathway for clinical trainees (academic clinical fellowships and clinical lectureships) will be reviewed in 2010 with a view to completing the review by November 2010. The objective of this review will be to examine the extent to which the pattern of take-up of the existing allocation of fellowships and lectureships is likely to deliver the breadth of clinical research capacity that an innovative health service will require. The review will look, in

¹ the Medical Research Council; the National Institute for Health Research (for England); the Chief Scientist's Office (for Scotland); the Wales Office of R&D for Health and Social Care; and the Health and Social Care R&D Office of Northern Ireland.

particular, at whether there are vulnerable clinical specialties that need specific support in the next round of allocations.

Planning continues for a long-term study of career choices that trainee clinical academics make. The study would involve OSCHR Partners and other major funders of clinical research training. It would help funders determine the extent to which their research training schemes are meeting the career needs of trainee clinicians. The study is currently expected to commence in Autumn 2010.

3. MAXIMISING AWARENESS OF OPPORTUNITIES

BIGTR2 noted a lack of real incentives for establishing R&D and clinical trials in the NHS. It recommended that “A targeted communication and marketing exercise is needed to maximise awareness of the opportunities offered to industry by the new infrastructure, funding and collaboration put in place since Bioscience 2015 was published. This could be done as part of the UK Life Science Marketing Strategy.”

Against this, Government noted:

3 (i) - that a series of events would roll out a five-year UK Life Sciences marketing strategy including, as resources allowed, country communication plans in target markets.

Under the guidance of the UK Life Sciences Marketing Strategy Board, and working alongside the OLS and the Department of Health, UK Trade and Investment (UKTI) has increased marketing activities over the past six months to further build the reputation and brand of UK Life Sciences overseas. A full delivery update, including information on the activities that have already been undertaken, is provided *Life Sciences 2010: Delivering the Blueprint* - Chapter 2, Section 11: Marketing UK Life Sciences.

4. INCLUDE PARTICIPATING IN RESEARCH IN THE NHS OPERATING FRAMEWORK

BIGTR2 commented that “the global pharmaceutical industry has traditionally seen the UK as a leading location for its clinical trials, but this position has been under increasing competitive threat in recent years, with the proportion of UK patients in global trials falling from 6% to 2%. The key factor for research sponsors, particularly those in the commercial sector, is the speed of trial approval and patient recruitment.”

BIGTR2 noted that “Participation in research has been included in the NHS Operating Framework” and recommended that it “should be accounted for via the annual Quality Accounts submitted by NHS Healthcare Providers with the aim of doubling the current number of people enrolled in clinical trials and large scale evaluations conducted in the UK by 2012 across the full spectrum of clinical trials including biologics.”

Against this, Government’s BIGTR2 response noted that:

4 (i) DH would:

- **work with the NHS to require that providers who conduct research include the number of patients recruited in the previous year to clinical research in the annual Quality Accounts, and;**
- **write to the Service to ask Trusts to:**

- Ø set goals for research in their organisation;
- Ø publish the average time it takes for the local research approval process to be completed, and;
- Ø ensure that they use the National Institute for Health Research (NIHR) Coordinated System for gaining NHS permission and that they do not develop unnecessary additional activities or bureaucracies locally.

The Director of Research and Development at the Department of Health (Professor Dame Sally Davies) and the Department of Health's Director General of NHS Finance, Performance and Operations (David Flory) wrote to the Chief Executives of NHS Trusts, Mental Health Trusts, Ambulance Trusts, Foundation Trusts, Primary Care Trusts (PCTs), Strategic Health Authorities (SHAs), and Special Health Authorities on 9 July 2009 drawing their "attention to recent policy statements and operational requirements regarding research in the NHS" relating to each of the above mentioned areas.

In addition, a number of measures have been taken to address the fact that in recent years the UK has lost ground internationally as a valued location in which to undertake clinical trials for later-phase drugs and medical technologies. A delivery update is provided in *Life Sciences 2010: Delivering the Blueprint* - Chapter 2, Section 2: Improving the UK environment for undertaking clinical trials.

5. LEADERSHIP ON EU CLINICAL TRIALS

BIGTR2 noted that the EU Clinical Trials Directive, which became UK law in May 2004, "was meant to provide an attractive environment for the approval and conduct of clinical trials, whilst ensuring that the rights, safety and well-being of trial subjects are protected. The Directive aimed to simplify and harmonise the rules governing clinical trials in the EU. However, differences in the way the Directive has been interpreted and implemented between Member States have led to a lack of harmonisation which has adversely impacted on the ability of companies to carry out trials, with SMEs, which do not have the resources to cope with the administrative burden, being especially affected."

BIGTR2 recommended that "The UK Government should take a leadership role within Europe to ensure that revisions to improve the EU Clinical Trials Directive reinforce the UK's attractiveness as a prime location for clinical trials and to reflect the better regulation aspects of Government."

Government's response noted:

5 (i) that MHRA continues to lead on behalf of Government on discussions in EU committees dedicated to improving the Clinical Trials Directive.

On 8 October 2009 the European Commission published a consultation document 'Assessment of the Functioning of the "Clinical Trials Directive"' seeking views, by 8 January 2010, on a range of questions on the current functioning of the Directive. MHRA led for Government on a UK response to the consultation, welcoming the consultation as an opportunity to put forward proposals for improving regulation of clinical trials for the future. MHRA developed the UK response (available at <http://www.mhra.gov.uk/Howweregulate/Medicines/Licensingofmedicines/Clinicaltrials/ImplementationoftheClinicalTrialsDirectiveintheUK/index.htm>) to the consultation in discussion with BIS, industry, the NHS and academia. Recognising the importance of improving the clinical trials environment for both the UK and Europe's ongoing competitiveness in the face of

increasing global competition, MHRA will continue to work closely with, and seek to influence, the European Commission as policy in this area moves forward.

6. FOLLOW ON IN BIOPROCESSING

The original Bioscience 2015 vision was to achieve a network of bioprocessing centres of excellence across the UK. BIGTR2 noted that “the long-term vision was the creation of a number of multidisciplinary academic centres with critical mass for training and research.” It recognised the creation of the Bioprocessing Research Industry Club (BRIC) to help eliminate current bottlenecks in development of bio-therapeutics and contribute to the development of a strong bioprocessing community in the UK.

BIGTR2 recommended “Relevant Research Councils and Knowledge Transfer Networks [KTNs] along with the Technology Strategy Board [TSB] and industry should build on the success of the Bioprocessing Research Industry Club [BRIC] to develop a set of follow-on activities. New funding must be in place for distribution in 2009 and onwards to build capacity for multidisciplinary bioprocessing research and training to 2015. The growth in capacity should make the emergence of new centres of excellence possible, and be sufficient to meet the needs of academic and industry recruitment. The Technology Strategy Board should continue to provide financial support to the provision of a Knowledge Transfer Network at least at the current level that will deliver the bio-processing agenda set out in Bioscience 2015 beyond 2009.”

Against this, in its BIGTR2 response:

6 (i) - Government noted that an independent panel would report and make recommendations by summer 2009 regarding the Biotechnology and Biological Sciences Research Council (BBSRC) evaluation of the early impact of the Bioprocessing Research Industry Club (BRIC). The Club Steering Group and others would then consider whether there should be follow-on activities and what form these should take – taking into account the outcomes of the evaluation, BIGTR2 recommendations, as well as the needs of industry and the impact of the economic downturn. Initial recommendations would be developed by a BBSRC-led Working Group in consultation with the BRIC Steering Group and wider Club membership.

Bioprocessing continues to be a high-skill knowledge-based activity vital for driving speed, efficiency and cost effectiveness in the development and production of advanced biopharmaceuticals. Government has continued to take steps to help the sector attract more talent and to contribute to the development of a strong bioprocessing UK community.

In July 2009 a ‘Report of the Bioprocessing Research Industry Club (BRIC) Working Group on Future Activities for BRIC’ was published. The report is available at www.bbsrc.ac.uk/business/collaborative_research/industry_clubs/bric/bric_working_group_report.pdf. The report recommended the continuation of BRIC with future activities focused on:

- Ø supporting further research;
- Ø supporting the translation of research funded through BRIC; and
- Ø meeting skills needs.

In response to this report the Biotechnology and Biological Sciences Research Council (BBSRC) has agreed to provide further funding of up to £7 million and the Engineering and Physical Sciences Research Council (EPSRC) has agreed to provide £3 million providing companies continue to provide support for the club. The newly formed HealthTech and

Medicines Knowledge Transfer Network (HTM-KTN) will continue to be involved in the management of the club just as bioProcessUK KTN was prior to its amalgamation into this HTM-KTN.

Further, in September 2009 a Review Panel of experts published an 'Evaluation of the Bioprocessing Research Industry Club'. This report is available at http://www.bbsrc.ac.uk/organisation/policies/reviews/funded_science/0909_bric_evaluation_report.pdf. The evaluation found BRIC to be an effective and timely scheme that is achieving its objectives and is on track to deliver future impact. The report nonetheless makes a number of recommendations (the full list can be found in the report) including:

- Ø Research Councils should build on the success of BRIC by funding a successor scheme;
- Ø A BRIC successor scheme should refine its network to encourage greater participation from industry and academics from other disciplines;
- Ø Research Councils should publicise the success of BRIC to a wide audience;
- Ø Research Councils should consider funding studentships that are directly aligned to BRIC grants.

An implementation plan for the next phase of BRIC has been developed. A workshop was held in December 2009 to consider the future focus of calls for research proposals. From this workshop, priority research areas for the next phase of BRIC are being developed. It is anticipated that the first call for research projects will be launched in Spring. BRIC is also considering, for example, how PhD studentships can be embedded within the next phase of BRIC. A sub-group has been set up to develop plans for this area.

6 (ii) - Government committed that the Technology Strategy Board's (TSB) Knowledge Transfer Networks (KTNs) would receive appropriate funding.

The Technology Strategy Board (TSB) is completing the optimisation process for the Knowledge Transfer Networks (KTNs). Within the medicines and healthcare technologies area, BioProcessUK KTN and the Health Technologies KTN have been merged; the newly formed HealthTech and Medicines KTN (HTM-KTN) commenced operations in August 2009. A new KTN business plan was submitted to the TSB and the key priorities (including support for bioprocessing and new Bioprocessing Research Industry Club (BRIC) activities) agreed with the TSB. Appropriate funding was given to maintain bioprocessing knowledge exchange activity and to broaden this to encourage TSB priorities such as in Regenerative Medicine.

6 (iii) - Government committed that the Technology Strategy Board (TSB) would look to re-focus the work of the Knowledge Transfer Networks (KTNs) to align them more closely with the innovation priorities it has identified.

The Technology Strategy Board (TSB) is developing a number of priority areas within the medicines and Healthcare areas. These include the newly launched 'Detection and Identification of Infectious Agents' Innovation platform, the Regenerative Medicine programme and ongoing work to develop a case for supporting stratified medicine. The HealthTech and Medicines Knowledge Transfer Network (HTM-KTN) plays a key role in the development of these activities. It is tasked with developing and supporting areas of knowledge transfer and exchange. A number of KTNs also have a role to play in the medicines and healthcare areas (e.g. Chemistry Innovation KTN, Nano KTN, Materials KTN etc); the HTM-KTN is responsible for ensuring co-ordination amongst the 'community of KTNs'.

6 (iv) - Government committed that the Technology Strategy Board (TSB) should increase the support the Knowledge Transfer Networks (KTNs) give to international activities.

The Knowledge Transfer Network (KTN) International Fund (£500,000 per annum) has been established – the first tranche was issued at end 2009. The fund was set up to encourage international networking activities that offer direct value to the business community that the network is aiming to represent and support. It is envisaged that innovative projects will emerge that promote cross-boundary knowledge exchange and collaboration, the benefit of these activities lying primarily with the businesses in the network.

6 (v) - Government committed that a new combined Knowledge Transfer Network (KTN) would be asked to put together a business plan in which bioprocessing would be a key activity as well as regenerative medicine and manufacturing operational excellence.

The new HealthTech and Medicines Knowledge Transfer Network (HTM-KTN) includes bioprocessing and operational excellence in its business plan. It will continue the activities of bioProcessUK as a distinct priority area under its structure. This will include continuing to support new BRIC activities once these have been agreed by the Biotechnology and Biological Sciences Research Council (BBSRC) and the Engineering and Physical Sciences Research Council (EPSRC). In addition the knowledge transfer and exchange needs in the field of regenerative medicine are being developed to support the Technology Strategy Board's (TSB) £18 million Regenerative Medicine programme of activity, announced in the Office for Life Sciences (OLS) Blueprint in July 2009 and launched in September 2009.

7. ANNUAL PROGRESS REPORT

BIGTR2 found that “the lack of reliable statistics characterising the medical biotechnology sector within the UK was an impediment to understanding how the sector had changed since publication of the [Bioscience 2015] report in 2003.” It recommended that “BERR [now BIS] should ensure the provision of good quality evidence in order to accurately assess the state of the sector, working together with industry to ensure the capture and tracking of an agreed set of metrics that will assist in determining the extent to which the sector is growing and prospering moving forward.”

BIGTR2 also recommended that “The BIA, ABPI and BERR [now BIS] should produce a short annual report on progress and challenges against the recommendations in this report; this should be presented to the Ministers with responsibility for bioscience within BERR, DH and DIUS [now BIS].”

Against this Government's BIGTR2 response noted that:

7 (i) - BERR (now BIS), UKTI and DH had commissioned a database covering the medical biotechnology, industrial biotechnology and medical technology sectors for improved industry metrics.

An analysis and commentary document entitled “Strength and Opportunity: the landscape of medical technology, medical biotechnology and industrial biotechnology enterprises in the UK” was published in December 2009. This report analyses the information contained in the Bioscience and Health Technology Database, supplemented by information from other sources, and shows the real strength in these sectors across the UK. Over 3,500 companies have been

identified, spread across the regions and Devolved Administrations, employing approximately 78,000 people and generating a turnover of around £15 billion per annum.

The Database will be accessible by nominated users from the three sponsoring Government Departments, BIS, UKTI and DH. It will ensure Government has a reliable source of data from which it can track and measure progress within the Life Sciences industry.

7 (ii) - UKTI would use some information from the Bioscience and Health Technology Database to promote the UK's medical biotechnology, medical technology and industrial biotechnology industries as part of its Life Sciences Marketing Strategy via a publicly accessible website.

The first transfer of data to UKTI took place in January 2010. UKTI will shortly begin the process of contacting the companies on the database to invite them to be part of the Life Sciences Marketing website. A high uptake would lead to a comprehensive publicly accessible database of UK medical biotechnology, medical technology and industrial biotechnology companies.

7 (iii) – BERR (now BIS) would lead on producing an annual report on progress and challenges against the BIGTR2 recommendations.

This document provides that annual report.

Chapter 2: A new Vision and Business Model

This BIGTR2 chapter reviewed “how the bioscience sector has performed since the publication of Bioscience 2015..... how finance and investment trends have affected companies in the sector..... [and reviewed] the Bioscience 2015 vision:

‘To create a diverse, self-sustaining bioscience sector, with a core of large, profitable, world-class companies.’”

It explored “whether this [vision] is still relevant and achievable – and, if not, what a new vision should look like and in the light of this suggest ideas for a new business model appropriate for the future environment.” It also examined “how investors’ behaviours have affected the business model of bioscience.”

It also explored “a new vision which would better enable the sector to drive forward to the longer term goal described in the Bioscience 2015 report:

“Creating a diverse self-sustaining bioscience sector which supports, on a sustainable basis, high value-added employment, thereby leading to increased wealth creation and improved health in the UK.”

8. ATTRACTING OVERSEAS INTEREST

BIGTR2 noted difficulties for bioscience companies in acquiring appropriate levels of seed funding and raising equity funds via the public market as investors had become increasingly sceptical over the rate of return offered by such investments. Fewer investors meant less liquidity. It noted that “Listing high quality overseas companies from the established (e.g. Switzerland) and emerging markets (in particular India, China and others) on the LSE could benefit UK bioscience and boost confidence.”

BIGTR2 recommended that UKTI should:

- Use its life sciences marketing strategy to focus on attracting high quality overseas companies to list on the London Stock Exchange, persuading overseas funds, including Sovereign Wealth Funds, to invest in the UK and also assisting UK companies to gain investment from foreign funds by holding road shows for non-UK investors both in the UK and abroad; and
- Boost its resources in the Global Entrepreneurs Programme and encourage closer relationships with Angel Networks (for example the BIA BioAngels). By doing this UKTI could also enhance the bioscience investment opportunities that it presents to US funds.

Against this, Government committed that:

8 (i) - With regard to the Finance Workstream of the UKTI Life Sciences Marketing Strategy, UKTI would develop a plan to take forward research to identify corporate venture contacts, analyse their portfolios and through a series of interviews, identify measures which would encourage further UK activity.

8 (ii) - The UKTI Global Entrepreneur Programme Life Sciences strategy would introduce initiatives aimed at fund raising; further mentoring/advisor opportunities; introducing technologies/businesses to the UK; and helping to develop UK science.

8 (iii) - Further, UKTI would continue to develop close relations with Angel Networks.

As noted previously in this annual report, UKTI has increased marketing activities over the past 6 months to further build the reputation and brand of UK Life Sciences overseas. A delivery update is provided in *Life Sciences 2010: Delivering the Blueprint* - Chapter 2, Section 11: Marketing UK Life Sciences - Attracting additional investment into the UK.

9. EXTEND TAX CREDITS

BIGTR2 recommended that supporting innovation through R&D tax relief would help to put the UK ahead of its competitors and enable biotechnology companies to become more attractive to investors. Specifically BIGTR2 recommended Government extend R&D tax credits through:

- **Extension of relief to cover benefits in kind;**
- **Relief on payments to self-employed individuals and high quality management talent at CEO and CSO level;**
- **Remove the PAYE/NI limit on repayable credit;**
- **Extension of the relief to rent costs; and**
- **Extension of the relief to cover IP costs.**

Government's May 2009 response noted that the current reliefs have been strongly endorsed by businesses and there is not currently a case for change, but as with all aspects of tax, the Government will continue to discuss the effectiveness of the R&D tax credit with industry and will keep this under review.

10. EXTEND ENTERPRISE INVESTMENT SCHEME (EIS)

BIGTR2 commented that "Many bioscience companies fail to qualify as valid EIS or Venture Capital Trust (VCT) investments, even though these companies continue to invest in R&D activity despite being loss-making..... If EIS or VCT benefits were extended to cover secondary purchasers then this could lead to help to stimulate the market and potential investors at all stages would be more likely to participate."

BIGTR2 recommended Government should "Extend the applicability of the Enterprise Investment Scheme and Venture Capital Trusts by for example extending their scope to cover SMEs, following the definitions used for R&D tax credits. Extend EIS and VCT scope to cover shares acquired through shareholder to shareholder transaction."

Government's May 2009 response noted that in line with European State Aid Risk Capital guidelines, any further relaxation (i.e. further to the recent legislative change to the Enterprise Investment Scheme (EIS) relating to relaxing the timing rules for employing money raised from an EIS share issue, and applying this relaxation also to the Venture Capital Trust (VCT) and Corporate Venturing Schemes) is not possible at present.

11. ENCOURAGE ENTERPRISE CAPITAL FUND APPLICATIONS

BIGTR2 recommended that “Capital for Enterprise Limited, which delivers Enterprise Capital Funds on behalf of BERR [now BIS], should particularly encourage strong bids from bioscience in future funding rounds in view of its importance to the UK economy and the lack of such bids to date.”

Government committed that:

11 (i) - BERR (now BIS) would task Capital for Enterprise Limited with encouraging bids from the bioscience industry in future rounds for Enterprise Capital Funds (ECFs).

Capital for Enterprise continues to encourage Enterprise Capital Fund (ECF) proposals from across all sectors of the economy, including from funds targeting the Life Sciences. BIS is monitoring both the number and outcome of bids.

12. INCENTIVES FOR BIG PHARMA

BIGTR2 noted that “Successful emerging bioscience businesses need skilled management and appropriate funding and there are opportunities to encourage both of these based on a model of ‘big pharma’/biotechnology dependency.....There is a real need to encourage pharmaceutical companies to invest in the early stages of biotechnology company development in the UK.” BIGTR2 commented that this would benefit ‘big pharma’ “because the more biotechnology companies there are, the more possibilities become available to replenish drug development pipelines.”

BIGTR2 recommended Government should “create incentives for big pharmaceutical companies to invest in UK biotechnology, and to spin-out assets in the UK to create new companies, through development of the tax incentives”.

Against this, Government committed:

12 (i) - in Budget 2009 to consider evidence for changes to the way the tax system encourages innovative activity and the relative attractiveness of the UK to global firms as they make decisions on where to locate their R&D and other innovation activities, setting out its assessment and approach in the Pre-Budget Report.

To strengthen the incentives to invest in innovative industries and ensure the UK remains an attractive location for innovation, in December 2009 the Pre-Budget Report announced that Government will introduce a “Patent Box”. Further detail is provided in *Life Sciences 2010: Delivering the Blueprint* - Chapter 2, Section 10: Incentivising innovative activity and investment.

Government has also provided support to stimulate investment in UK biotechnology. Government has committed Strategic Investment Funding (SIF) to two major Life Sciences projects:

- (i) £11.7m is being invested to create the first purpose-built open innovation campus for drug discovery and development. This will be located alongside the GSK R&D Headquarters in Stevenage. The project comprises a biocubator and accelerator building which will allow early stage companies to be co-located with a major pharmaceutical company to create an innovation hub. The SIF funding has leveraged

further funding from GSK, the Technology Strategy Board (TSB), EEDA and the Wellcome Trust.

- (ii) £12m of SIF Funding has also been allocated to build a bioincubator on the Edinburgh BioQuarter site. This funding has been matched by Scottish Enterprise. This building will be at the heart of a strong incubation environment and provide the facilities for business development to thrive.

These projects will provide an essential step towards the BIGTR2 vision of creating "a diverse and self-sustaining biotech sector which supports, on a sustainable basis, high value-added employment, leading to an increase in health and well-being in the UK."

Chapter 3: Exploiting the Knowledge Base and increasing uptake

Chapter 3 of BIGTR2 examines why “the rate of progress of translation and development of the UK sector’s ideas has slowed substantially [and].....new ideas for improving the processes driving uptake of innovative medicines and therapies.”

13. REDESIGN REGULATION

BIGTR2 noted that “more could be done to adapt drug development to meet current needs and the rapidly advancing science and to benefit SMEs. We realise that drugs are developed for global markets and must meet the requirements of global regulators. The UK should take a lead in re-designing the early development pathway for medicines and promoting the adoption of this with key partners such as the [US Food and Drug Administration] FDA and [the European Medicines Agency] EMEA.”

BIGTR2 recommended that “The Ministerial Industry Strategy Group [MISG] should build on existing work to develop a vision for the future evolution of global biopharmaceutical regulation, taking into account initiatives which are already underway in the major regulatory jurisdictions. MHRA should work with its EU and international counterparts to develop and promote the vision.”

Against this, Government committed that:

13 (i) - A working group of industry and Government representatives would consider possible changes to the wider legal and regulatory framework to support earlier access to medicines through a system of conditional licensing so that the UK can influence future change to the European system. The working group would report to the MISG.

A Ministerial Industry Strategy Group (MISG) initiative run by senior industry and Government personnel to explore the feasibility of an earlier access programme in the UK is well advanced. A proposed framework for an Earlier Access Scheme was considered by MISG at its 25 November 2009 meeting. MISG endorsed the framework; its view was that such a scheme would offer significant benefit to patients suffering from life threatening or seriously debilitating conditions for which medicines are being developed but cannot yet be made available as licensed treatments. Whilst access to such medicines will, at least in most cases, be at the end of the formal development stage, the scheme could still provide potentially life-saving treatments around one year earlier than at present.

The framework is available at

<http://www.mhra.gov.uk/Howweregulate/Medicines/MISGNewTechnologiesAdvisoryPanel/Earlieraccesstonewmedicinesintheuk/index.htm>. Broadly, the following eligibility criteria for the programme have been proposed:

- It will cover new medicines that will treat, diagnose or prevent life threatening, chronic or seriously debilitating conditions without adequate treatment options;
- Data will be required that indicates that the benefit:risk profile of the medicine is positive and that it is likely to offer advantages over any existing treatment options;
- The scheme will be available for medicines that have completed Phase III trials but in exceptional circumstances an earlier authorisation may be possible (based on Phase II data) if information available merits it.

The following principles have been proposed in relation to the scheme:

- Industry has freedom of pricing for medicines supplied under the earlier access scheme;
- The scheme does not involve any NICE appraisal;
- There would be no central mandate for funding as applies to NICE approved products;
- No additional funding is available for earlier access medicines;
- A UK wide exit strategy which is specific to each medicine (i.e. funding of earlier access patients once the medicine has been licensed) should be stated upfront.

MHRA will develop a complete scheme for implementation by end 2010. MHRA will keep industry informed as the detail of the scheme is developed. It expects to publish a 12 week public consultation on the proposal by end January 2010.

Supplementing this, in October 2009 BIS began work on a scoping study to identify potential barriers to the global drug discovery and approval process. The study is looking to broadly identify both the regulatory and non-regulatory barriers in major trading blocks (the United States, the European Union and Japan). It is detailing specific national requirements, drawing out peculiarities in schemes and indicating those requirements that may be adding excessive cost or time to the process whilst providing little benefit. The study has recently concluded and areas for further work and action will be agreed shortly.

14. STRATIFIED MEDICINE

BIGTR2 noted that “The UK already has many of the components in place for a stratified disease strategy as a result of historical strengths and current levels of research interest, both public and private, in relevant bioscience and bioinformatic tools. We believe the UK is well placed to lead in this area and to demonstrate how the model could be re-engineered into one that puts disease and patient information right at the centre. Unfortunately, being well placed is not enough. If Government and industry are to aspire to having a robust and globally competitive biotechnology industry, then we need to take action now.”

BIGTR2 recommended “A stratified disease strategy should be created and executed by Government through a multi-organisation integrated programme. This should involve BIA, ABPI, OSCHR, TSB, NIHR, MRC, industry, academia and other relevant organisations. The strategy should set out common therapeutic goals, building on areas of UK competitive strength and lead to: enhanced patient outcome; accelerated uptake of medicines; and better value through more effective targeting.”

Against this, Government noted:

14 (i) - that stratified medicine is considered a priority area for activity, particularly for the Medical Research Council (MRC) and the Technology Strategy Board (TSB) who it noted would work closely together. The MRC would coordinate activities on behalf of the Office for Strategic Coordination of Health Research (OSCHR) to ensure coordination and to address research, capacity and methodology issues. Through its Medicines and Healthcare Strategy, the TSB would provide a business-led vision for the sector to drive forward business innovation in the next generation of disease prevention and management, diagnosis and treatment.

Stratified Medicine is both an increasing challenge to healthcare providers and an opportunity for the UK’s pharmaceutical, diagnostics and devices sectors in the medium-term. The Technology Strategy Board (TSB) and the Medical Research Council (MRC) are working

together with relevant Government Departments and Government agencies (including MHRA, NICE and the NIHR regarding their health technology assessment (HTA)) to develop a holistic UK stratified medicine strategy. This objective is that this strategy will generate the optimal research, regulatory and fiscal environment in which stratified approaches to healthcare can flourish. This includes work to explore the case for developing a new Innovation Platform in Stratified Medicine. If the business case for the Platform is approved by the TSB Governing Board, there will be up to £50m of new investment in the area commencing in the financial year 2010-11.

As part of the preparation for the business case, the TSB and MRC organised a Stakeholder Workshop in November 2009 to identify pathways and solutions to the key issues which emerged at a Forum on Personalised Medicine organised jointly by ABPI and MHRA in October 2009 (a report is available at <http://www.mhra.gov.uk/Howweregulate/Medicines/MISGNewTechnologiesAdvisoryPanel/Forums/CON065590>).

Other options to promote collaboration, engagement and networking between companies, academics and clinicians in the area, particularly in the diagnostics sector, are being taken forward through the TSB's new HealthTech and Medicines Knowledge Transfer Network (HTM-KTN). An industry round table to identify models for collaboration in the development of drugs and diagnostics is planned for early 2010. In addition, proposals for a high-profile meeting to launch the new TSB-MRC investment plans in this area will be developed by summer 2010.

15. REWARD ACADEMIC COLLABORATION

BIGTR2 acknowledged that there are “unprecedented opportunities for the UK university sector to work in collaboration with the bioscience industry..... [but noted that] further incentives are needed to encourage the fastest possible cultural change in the university sector.”

BIGTR2 recommended “The Research Excellence Framework should recognise and reward excellence in both stand-alone research and collaborative research with industrial partners. There are real opportunities for the academic sector to play a greater role in a rapidly changing bioscience industry. In order to realise these opportunities the evaluation framework used by the Funding Councils needs to promote greater collaboration between academia and industry.”

Government's BIGTR2 response noted that:

15 (i) – the next Research Assessment Exercise (RAE) would be done under a new “Research Excellence Framework” and would take account of the impact of research.

Between September and December 2009, the Higher Education Funding Council for England (HEFCE) consulted, on behalf of the 4 UK funding bodies, on its proposals for a new Research Excellence Framework (REF), the successor to the Research Assessment Exercise. This included a proposal that under the REF, for the first time, impact would be an explicit element of the total assessment in order to take better account of the impact that excellent research has on the economy and society. A delivery update is provided in *Life Sciences 2010: Delivering the Blueprint* - Chapter 2, Section 1: Enhancing collaboration in Life Sciences – Supporting the translation of research: The Research Excellence Framework.

16. INDEPENDENT INQUIRY INTO NICE

BIGTR2 noted that “The UK, because of the existence of NICE, is the world leader in Health Technology Appraisals (HTA), and our HTAs have been commended by the World Health Organisation as ‘an important model for technology appraisals internationally’.....Correctly positioned, and resourced, NICE could become a significant UK competitive advantage, providing early health economic assessments for the NHS, allowing companies to understand their likely market (and possible reimbursement) more thoroughly.” BIGTR2 however highlighted delays in the NICE appraisal process; industry views that there had been a lack of transparency in some NICE decisions; and issues with clinicians’ access to drugs.

BIGTR2 recommended – “There should be an independent inquiry to assess NICE’s long term impact on cost, access to, and uptake of, medicines in the UK. There should also be an independent review of the way in which NICE values medicines so that the current economic evaluation is complemented by clinician, patient and research inputs on the value of innovation from their perspectives. A revised NICE should offer health economic data to companies as a way to support the functions of market forecasting, and determining likely revenues within the NHS, as this would incentivise R&D.”
Against this, in Government’s BIGTR2 response:

16 (i) - NICE and Government recognised the importance of promoting innovation in the NHS and agreed with the BIGTR2 Chair, Sir David Cooksey, that the specific issue should be considered further. Professor Sir Ian Kennedy would lead an independent study of value in new innovative health technologies and would report in time for the July 2009 NICE Board meeting.

Sir Ian Kennedy's report into aspects of value and innovation that NICE should take into account in its work was published on 22 July 2009. More information, including on NICE’s 3-month consultation on its response to the Kennedy Report, is provided in *Life Sciences 2010: Delivering the Blueprint* - Chapter 2, Section 3: The National Institute for Health and Clinical Excellence – Supporting the NHS as an innovation champion - NICE methodologies.

17. TRANSLATIONAL SCALE-UP CENTRES FOR REGENERATIVE MEDICINE

BIGTR2 highlighted that the UK is already considered a leader in the field of regenerative medicine (RM) and the steps taken by Government to support the development of therapies based on stem cells. It noted the potential “for the UK to nurture development of this fledging industry, by making investment more attractive”

With the objective of ensuring “that the RM industry can take treatments translated from the lab and develop production techniques in order to commercialise them”, BIGTR2 recommended Government should “Create two cell scale-up centres at research institutions to build capacity and capabilities (skills training and technology) in this specialist area of bio-processing. Centres should work at the interface between the researcher, the manufacturer and the physician. It is also essential that Government should support the delivery of an enhanced industry representation.”

Government committed:

17 (i) - Research Councils including the Medical Research Council (MRC) and the Technology Strategy Board (TSB) to help the UK develop strengths across a range of translational activities needed for effective stem cell therapies.

17 (ii) – the MRC, having supported the development of the Centre for Regenerative Medicine in Edinburgh, to explore further opportunities regarding scale-up for Regenerative Medicine.

17 (iii) - Research Councils to continue to work together to ensure the science base funding is well coordinated.

After Government's May 2009 BIGTR2 response was published, the Office for Life Sciences July 2009 *Blueprint* announced a RegenMed Programme of investment, supported by £18 million from the Technology Strategy Board (TSB) and by £3.5 million jointly from the Engineering and Physical Sciences Research Council (EPSRC), the Biotechnology and Biological Sciences Research Council (BBSRC), and the Medical Research Council (MRC). The Programme is aimed at creating a step-change in the competitiveness of UK regenerative medicine businesses and technology providers and enhancing the ability of UK business to provide global solutions. Work relating to scale-up for regenerative medicine is therefore being focused within the remit of the TSB. The RegenMed Programme was launched in September 2009 and will underpin and enable the best regenerative medicine businesses in the UK to flourish. It will build a connected regenerative medicine community through programmes of work and activities to develop medicines and technology platforms. Capability building in industry is a key element of the programme.

In addition, on 7 January 2010, Government announced investment in a new EPSRC Centre for Regenerative Medicine to be based at Loughborough University. This centre will carry out world-leading research, test and implement ideas in clinical and industrial settings, create next generation platforms for manufacturing regenerative medicines and inform business models, policy and public debate. Investment from EPSRC will total £5.3 million over a five year period beginning in September 2010. Twenty-eight industrial and Government partners will contribute a further £3 million.

Chapter 4: Human Capital

This chapter in BIGTR2 examined issues around effective leadership and management noting that these allow a company to develop the right strategy and will increase the chances of commercial success. BIGTR2 noted that “The quality of the leadership and management team is also an essential element determining investors’ view of the company but SMEs face significant barriers in competing with large companies in attracting the best talent.” However “many bioscience startups in the UK originate from academia. As such the founders are often academics who do not necessarily want to run a company or have all the skills to become the Chief Executive Officer (CEO).”

18. ATTRACTING LEADERS AND MANAGERS

BIGTR2 noted that “A growing number of scientists and top managers leave the UK to work in the US or in the major European bioscience clusters..... encouraging leaders and managers from countries with established and developed bioscience sectors to return to the UK would help strengthen the sector. The UK should also do more to draw in talent from overseas to return in a non-executive role.”

BIGTR2 recommended that “UKTI should use its in-country expertise and life sciences marketing strategy to attract leaders and managers to become re-engaged and provide the benefits of their experience. Such people should be encouraged in both full time positions and as non-executive Directors, mentors, or advisors.”

Against this, Government’s BIGTR2 response noted that:

18 (i) - UKTI was considering options on how to maintain an international network of individuals who could contribute to selling the UK as a place to do business, or who might in the future do business in the UK.

UKTI has developed a model for the network. The central purpose of the network will be to promote the growth of a thriving UK economy by promoting the UK as a springboard for global growth and by helping to build the desire and capability of UK firms to operate internationally. Specific network objectives will be to:

- Improve the UK’s reputation as the international business partner of choice;
- Attract high value foreign direct investment to the UK by communicating the strengths of the UK as a place to do business;
- Help UK businesses internationalise by:
 - Sharing market insight and best practice;
 - Signposting and facilitating key contacts;
 - Identifying/encouraging/generating offers which facilitate exports.

Although UKTI will encourage members to seize every opportunity to promote the UK, UKTI will seek to focus network member activities in priority areas, particularly linked to Government’s New Industry, New Jobs (NINJ) agenda.

In its early days, as UKTI develops its operation, the network will be small (around 100 members worldwide), but it will grow to approximately 1000 members within 2 years. An initial call went out to UKTI international posts and International Trade Directors in the

English regions at the end of the summer requesting nominations for network members. Nominations from the Life Sciences industry were prioritised. Fifteen per cent of initial nominations came from the Life Sciences industry. UKTI has now reviewed all nominations and is making approaches to potential members. The network will launch by March 2010.

UKTI is examining its use of the network and the support it provides for them as part of its wider strategy development.

19. MAXIMISING CAPITAL RECYCLING

BIGTR2 noted that “Setting up a new biotechnology company needs more specific knowledge than is usually found within general (and local) business support services.”

It recommended that “Government and industry should work with the entrepreneurial community to produce an implementation plan identifying the infrastructure and mechanisms needed to make the most of the human and knowledge capital that flows from the restructuring of the UK bioscience industry. As part of this plan an information pack should be produced that shows the path from leaving a pharmaceutical company to successfully running a biotechnology company.”

Government responded that:

19 (i) - BERR (now BIS) was liaising with Trade Associations to consider how they might take forward the provision of an information pack that shows the path from leaving a pharmaceutical company to successfully running a biotechnology company.

The primary area of help needed to successfully run a biotechnology company is access to finance. The BioIndustry Association (BIA) has developed, with the support of the Technology Strategy Board's (TSB) Knowledge Transfer Network (KTN) programme (specifically the Electronics and Photonics KTN), a FundMap which provides navigation to the grants and funding available to businesses in the UK technology sector (including Life Sciences). It aims to provide a definitive online resource for companies, researchers or entrepreneurs seeking advice on funding options, from seed finance to late phase clinical trial funding. European funding options will be added to the FundMap by end February 2010, and US funding options by end 2010. The FundMap is available at <http://www.fundmap.co.uk/bio/>.

Government further noted that:

19 (ii) – the Research Councils would consider proposals to provide support for two-way academic-industry exchanges on a more permanent basis. Funds would be provided to establish new posts over the first one, two or three years while the appointee might be seeking grant funding.

Medical Research Council (MRC)

In response to the recent very rapid changes in the UK and global economies a one-off interim Skills Gap Award scheme was launched in March 2009. The objective was to ensure that high quality scientific or research support skills which currently reside in industry and in areas where it has previously been hard to recruit into UK universities, are retained in the UK, through recruitment to UK universities.

The scheme aimed to provide fast-track start-up funding for appointments relevant to biomedical or biotechnology research which addressed important skills needs in universities.

Under this scheme, the MRC committed more than £2.4 million for appointments ranging from 18 months to 3 years, with the seniority ranging from appointees with a few years of post-doctoral experience to group leader level.

Awards have been spread between eight UK universities and offered over a broad range of scientific areas, including drug discovery, and medicinal chemistry to strengthen a cancer drug discovery programme and develop new therapeutics for infectious diseases.

In addition the MRC runs a strategic appointment scheme which can be used to support researchers moving into academia from industry. The scheme also supports international appointments, bringing international research leaders to the UK.

Furthermore, the MRC has a people-exchange scheme which provides support for individuals who wish to undertake a secondment into industry from academia and vice versa.

The Biotechnology and Biological Sciences Research Council (BBSRC)

BBSRC's Industry Interchange Programme supports the flow of researchers, in either direction, between the science base and industry. It does so through short-term exchanges that provide strategic advantage to the UK science base and industry arising from reciprocal access to facilities, expertise and/or knowledge and an increased understanding of scientific issues of common concern. Awards are typically up to £50,000. Details are available at: www.bbsrc.ac.uk/business/people_information/industry_interchange.html

The Engineering and Physical Sciences Research Council (EPSRC)

EPSRC runs Knowledge Transfer Secondments (KTS) which support the secondment of EPSRC funded staff into organisations that can exploit their research results. KTS funding can also be used to host researchers from industry working on specific projects which build on the results of earlier EPSRC-funded research. Thirteen organisations currently hold grants for KTS, with a total value of £11 million.

Other

Other Research Councils also have schemes in place to promote the exchange of knowledge between academia and industry, for example the Economic and Social Research Council (ESRC), and the Natural Environment Research Council (NERC).

20. IMPLEMENT BIOSCIENCE SECTOR SKILLS AGREEMENT

BIGTR2 recognised Sector Skills Agreement (SSA) as “a key mechanism for articulating industry skills demand and challenging employers and stakeholders to work collaboratively.” It noted the Sector Skills Council for Science, Engineering and Manufacturing Technologies’ (Semta) recently published Bioscience Sector Skills Agreement and the Action Plan setting out the skills and education requirements for the bioscience sector and detailing how this will be done.

It recommended “that the focus of activity should now be on early and tangible implementation of the SSA. As part of this Semta should ensure that a comprehensive list of current regional initiatives is compiled by the end of Q1 2009. This should be circulated widely perhaps via Trade Associations and intermediaries and a mechanism put in to place to annually review and update it. This list should be used to share best practice, assess where there is overlap of initiatives, and measure impact.”

Against this, Government noted:

20 (i) - Semta would circulate their mapping of regional activity regarding the Bioscience Sector Skills Agreement (SSA) via Trade Associations and other stakeholders and would make it available on the Semta website.

Good progress is being made to implement the Bioscience Sector Skills Agreement (SSA) – a 10-year Government and private sector skills plan for the industry. This includes completion of regional activity mapping and publication of this on the Sector Skills Council for Science, Engineering and Manufacturing Technologies (Semta) website and its circulation to members of the Sector Strategy Group (SSG) (including Trade Associations and Industry). The Regional Development Agencies (RDAs) will be able to use this work as they look at the Skills Strategies for each region.

BIS has facilitated strong Semta engagement with the regions, and is helping to ensure there is regional representation, as appropriate, on the SSG.

21. REVIEW SECTOR SKILLS AGREEMENT (SSA) METRICS

BIGTR2 also recommended that “the Semta Bioscience SSA Action Plan should be updated to contain a series of outcome indicators. Implementation of the SSA Action Plan should be reviewed on a quarterly basis by Semta’s Sector Strategy Group (SSG)² (of which BERR [now BIS] is a member) at the SSG Meetings as set out in the Terms of Reference for the Group. The membership of the SSG should be reviewed annually and consist of representatives from both large and small companies.”

Against this, Government noted that:

21 (i) – Semta had agreed that membership of the Sector Strategy Group (SSG) should be reviewed annually and that the SSG should consist of both large and small companies.

The Bioscience Sector Skills Agreement (SSA) metrics are reviewed at Sector Strategy Group (SSG) meetings which take place quarterly. Part of the role of the SSG is to ensure that implementation of the SSA is pushed ahead. Membership of the SSG has been reviewed and the Terms of Reference have been refreshed to ensure appropriate membership for driving forward implementation of the SSA. Membership has been supplemented to include the Industrial Biotechnology Sector. The SSG is now looking to further increase SME membership.

22. PILOT LEADERSHIP PROGRAMME

BIGTR2 considered that a more coherent approach to mentoring and leadership training was necessary. It recommended that “Semta and BIA work with the [Sector Strategy Group] SSG members and other stakeholders to implement the proposal for a Pilot Leadership Programme with pump priming funding from Semta that would enable the BIA to maximise the impact of the programme. Other funding would come from companies themselves. The Scheme should also look at how to draw in the expertise and knowledge of expatriates working in the industry. The pilot should start in 2009 with a pool of at least 12 identified potential leaders in the first year and then climbing to 72 over five years. The process should be reviewed at the end of the second year.”

² Sector Strategy Group – Made up of senior employers, they are principal advisory bodies to the Semta Board providing strategic leadership and driving delivery of the Sector Skills agreement.

Government committed to:

22 (i) - consider how to take forward the Pilot Leadership Programme.

Business and leadership skills continue to be as vital to building a successful small or medium Life Sciences company as the scientific excellence that led to its formation. This commitment has been taken forward by BIS - a delivery update on the industry sponsorship model that has been agreed is provided in *Life Sciences 2010: Delivering the Blueprint* - in Chapter 2, Section 7: Building a sustainable Life Sciences skills base - Life Sciences Business and Leadership Programme.

23. REVIEW IN VIVO SKILLS

BIGTR2 noted that “industry has said that they need good quality scientists who have proven practical capability”. Against this it recommended that “Government should consider how an appropriate supply of graduates with *in vivo* skills should be maintained including whether *in vivo* skills should be included under the strategically important and vulnerable subjects (SIVS) list.”

Government committed:

23 (i):

- **The Medical Research Council (MRC) to expand its PhD studentship *in vivo* funding in 2009**
- **The Biotechnology and Biological Sciences Research Council (BBSRC) to meet the Medical Research Council (MRC) to discuss the provision of additional costs awards on PhD studentships in the *in vivo* area to meet more of the full cost of research training in this area.**
- **The BBSRC, MRC and others to continue to strengthen the UK’s training base and science in *in vivo* areas.**

The Medical Research Council (MRC) has awarded 22 new PhD studentships in *in vivo* sciences to seven universities at a value of £ 1.91 million for 2009 and 2010. Additional support for capacity building in *in vivo* sciences is being provided through initiatives focused on integrative mammalian biology, toxicology and drug safety science. These collectively aim to support over 50 new PhD studentships and two new fellowships over a five year period.

Following discussions between the Biotechnology and Biological Sciences Research Council (BBSRC), MRC and the British Pharmacological Society, a new initiative will be launched in January 2010 to provide BBSRC and MRC studentships with additional funding to cover the high costs of *in vivo* training. In the first funding round, BBSRC and MRC jointly will be making up to 68 awards available, representing total additional funding to this area of £ 1.3 million.

BBSRC and MRC are active members of the OLS Industry and Higher Education Forum, and the In Vivo Task and Finish Group which reports to it. Both Councils are involved in discussions around strengthening of skills at postgraduate level. The funding provided by MRC in 2009 for places on *in vivo* Masters courses will be maintained in 2010 and 2011.

At undergraduate level, the Councils are exploring the creation of undergraduate masters programmes including a fourth year involving significant levels of *in vivo* training and an industry placement.

Furthermore, Government recognised the potential for the UK to do more to build on the successes within the UK's Higher Education and NHS system to ensure the core skills needed to pursue a career in the Life Sciences industry, academia, or the NHS are provided. These skills are in particular mathematics and laboratory practices and key disciplines, such as *in vivo* sciences and clinical pharmacology. In the *Life Sciences Blueprint*, Government committed to establish an Industry and Higher Education Forum to ensure undergraduates and postgraduates undertaking relevant degrees and courses gain the necessary skills and knowledge to pursue a career in Life Sciences. The Forum was established in December 2009; a delivery update is provided in *Life Sciences 2010: Delivering the Blueprint* - Chapter 2, Section 7: Building a sustainable Life Sciences skills base - Establishing the Industry and Higher Education Forum.

23 (ii) – In addition, that in developing the Framework for the future of Higher Education (HE) (for the next 10-15 years) Government would consider how strategic subjects might be designated and supported to best meet the needs of the economy and society in the future.

This commitment was delivered in November 2009 when Government published the *Skills for Growth – The National Skills Strategy* and the *Higher Ambitions Framework*. These documents set out the UK's vision for developing a skilled workforce that is equipped with the necessary skills required to take up employment opportunities in the key industries, such as Life Sciences, which have the potential to drive future growth in the UK economy.

Conclusion

Government action has seen significant added pace and momentum over the last 12 months to transform the operating environment for the UK bioscience sector and the Life Sciences industry more generally. As a key priority industry, Government is taking steps to ensure that this continues in the longer term. The Office for Life Sciences will be strengthened by the direct involvement of teams across Government working with the Life Sciences industry. At Ministerial level, Lord Drayson will maintain responsibility for the Office, working closely with the Secretaries of State for Business, Innovation and Skills, and for Health, who continue to share responsibility for the Life Sciences sectors within Government.