NATIONAL AUDIT OFFICE

Delivering the Commercialisation of Public Sector Science

REPORT BY THE COMPTROLLER AND AUDITOR GENERAL
HC 580 Session 2001-2002: 8 February 2002

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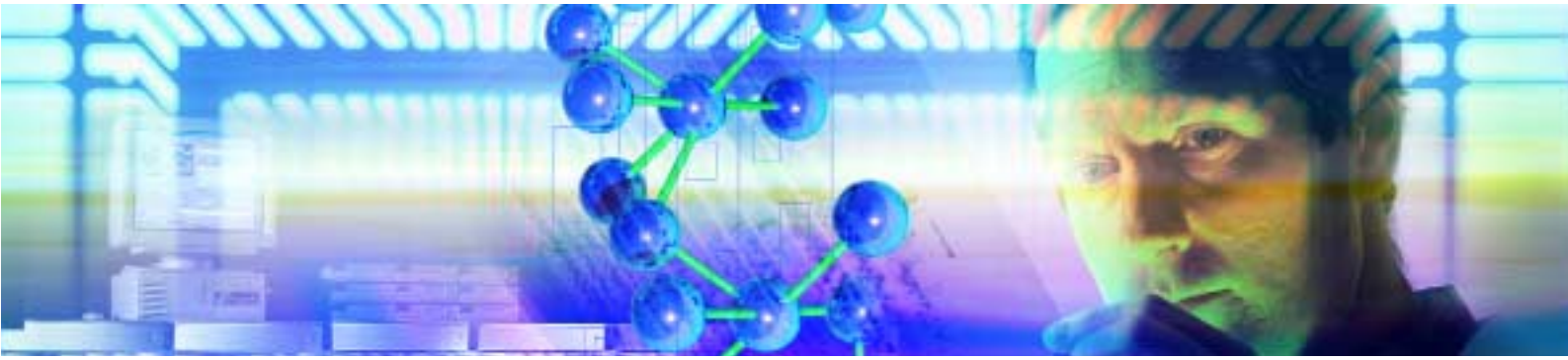

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John Bourn
Comptroller and Auditor General

National Audit Office
25 January 2002

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This report can be found on the National Audit Office web site at www.nao.gov.uk

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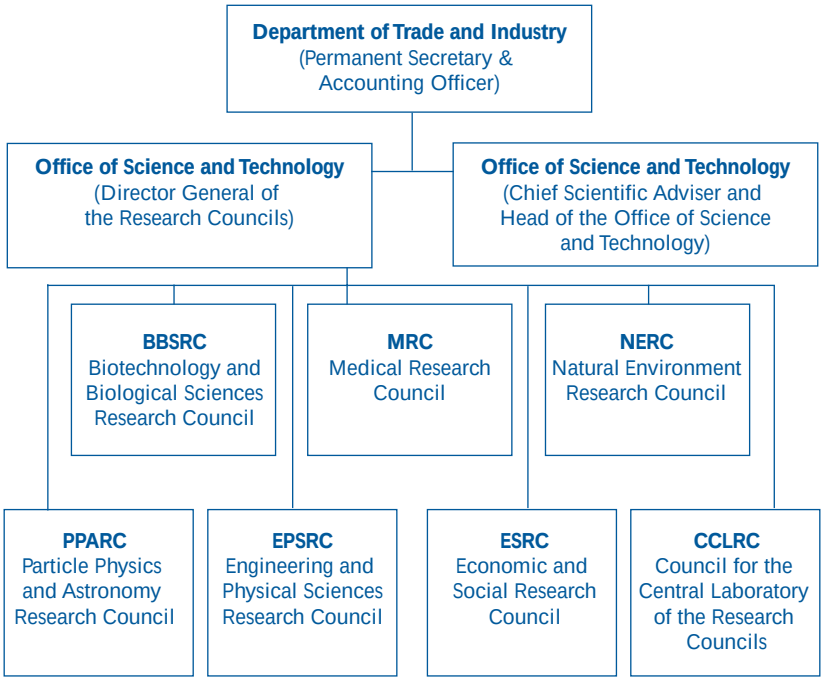
Executive Summary

The Government is encouraging Research Establishments to realise the economic benefits of their research through commercial arrangements with the private sector

1 The Government invests heavily in science - across all government departments some £7 billion is devoted annually to scientific research and development spending. Over £500 million of this in 1999-2000 funded research and research facilities in 83 Public Sector Research Establishments ("Research Establishments"), 59 of which are grouped together under seven Research Councils. The Councils are Non-Departmental Public Bodies brigaded under the Office of Science and Technology, which is part of the Department of Trade and Industry (the "Department") **(see Figure 1)**. The Research Councils cover broad scientific streams and provide funding and strategic direction for their Research Establishments along the lines illustrated by **Figure 2**.

1 The relationships between the DTI and its Research Establishments



Source: Department of Trade and Industry

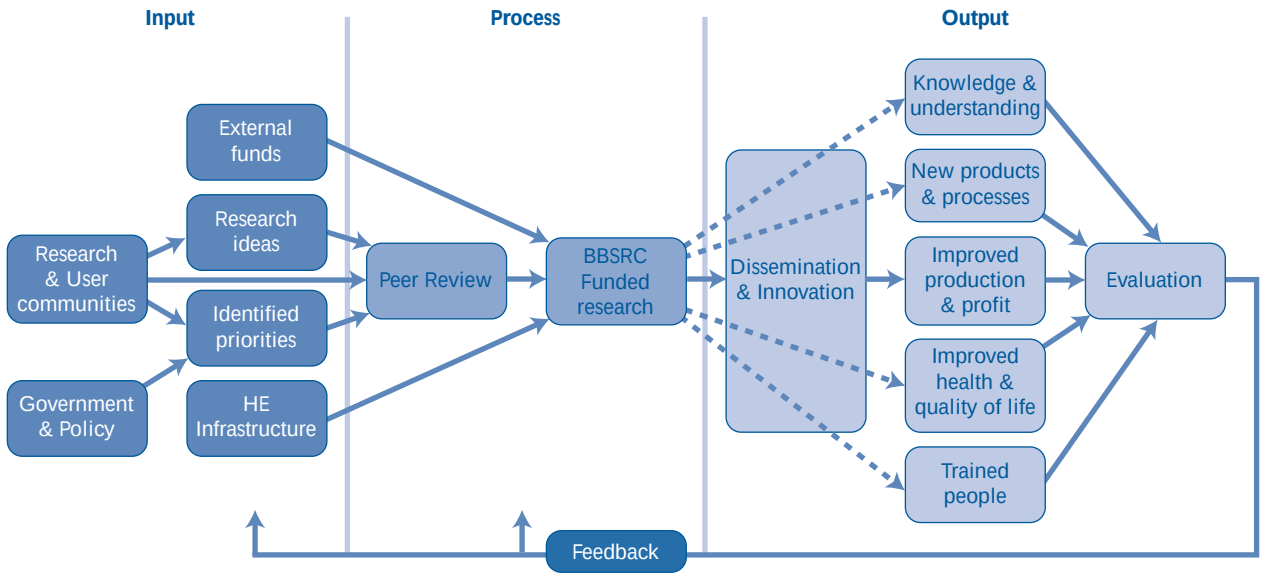
2 The vital core role of the Research Establishments, and the scientists who staff them, is to conduct research in support of the public interest including:

- achieving advances in science, which receives the majority of funding;
- informing government policy-making through the provision of comprehensive scientific data and independent advice;
- training the next generation of research scientists; and
- assisting public sector bodies carry out their statutory or regulatory functions.

3 Many of the Research Establishments are internationally acknowledged centres of excellence in their field. The Medical Research Council claims thirteen Nobel prize winners since 1952, ten of them scientists from the Medical Research Council Laboratory of Molecular Biology, world leaders in research on the structure of biological systems relevant to human disease. Many perform critical advisory roles, such as the Institute for Animal Health, which has played a major role in combating the recent outbreak of Foot and Mouth Disease, including extensive testing and analysis.

4 Although the United Kingdom has a strong record in innovation, it is widely considered to have been less successful in capturing the economic benefits of scientific advances. The ability to capture such benefits - in particular the creation of novel products and processes - could have a significant impact on the competitiveness and growth of the UK economy. For this reason, without wanting to compromise the Research Establishments' core scientific role, the Government is keen to encourage them, in co-operation with the private sector, to apply the outputs of publicly funded scientific research to stimulate economic and social benefits, such as job creation, increased prosperity and enhanced quality of life. This is termed "commercialisation". We describe different forms of commercialisation of research outputs in **Figure 5** (page 15). An early example of successful commercialisation of research is Celltech, a biotechnology company created in 1980 which employed total staff of 1,803 in the year to 31 December 2000, including some 1,150 research and marketing staff in the United Kingdom and abroad. This was built on science originating in Medical Research Council laboratories.

2 A Research Council Grant Support Cycle



Source: The Biotechnology and Biological Sciences Research Council Strategic Plan 1999-2004

The National Audit Office has considered whether the Research Establishments can meet the challenges of commercialisation

5 We have stated publicly that we encourage worthwhile and well thought through innovation in the public sector, for example that we "support well managed risk taking intended to result in tangible benefits for taxpayers" (Para 8, Executive Summary 'Supporting Innovation: Managing Risk in Government Departments' HC864 99/00). In line with this we have examined the capacity of the Research Establishments to meet the challenges arising from increasing commercialisation to deliver the potential economic and social benefits for the nation. Our methodology is described in detail in Appendix 1 - in brief, we considered:

- the key importance of building an enabling culture, capable of encouraging and stimulating effective commercialisation;
- whether Research Establishments are identifying and putting in place the capabilities required; and
- how Research Establishments can best realise the potential benefits of commercialisation.

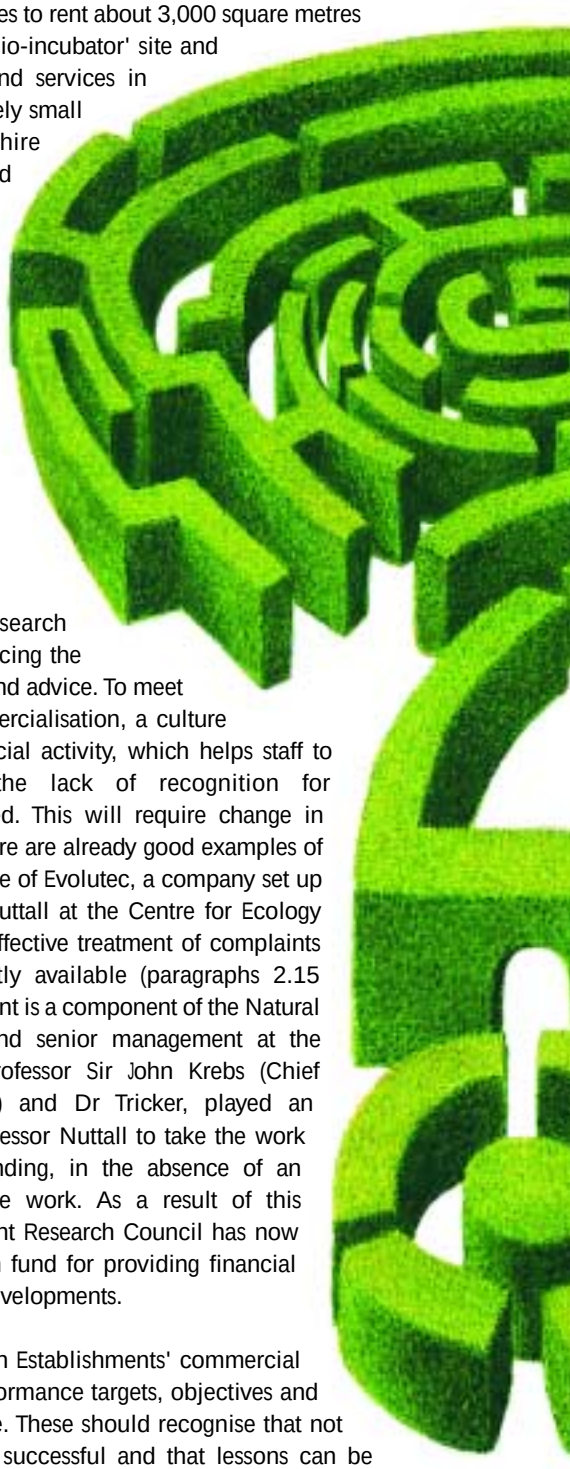
6 We focused our investigation on the 53 Research Establishments within three Research Councils for which the Department for Trade & Industry has responsibility - the Biotechnology and Biological Sciences Research Council, the Medical Research Council and the Natural Environment Research Council. This is because these Research Councils have differing potential for commercialisation so that the collective experience of their Research Establishments is likely to be of relevance to the others. Together, the Research Establishments covered by these three Research Councils received funding of about £443 million in 1999-2000. This study has been carried out in parallel with another National Audit Office report that considers the commercialisation of research sponsored by the Department for the Environment, Food and Rural Affairs which is expected to be published later in 2002.

With committed leadership, Research Establishments can meet the challenges of commercialisation

7 Our examination has shown that where there has been committed and effective leadership at both senior and middle management level there has been significant progress in constructing commercialisation deals with the private sector. Leadership has been a major factor in the fostering of a culture that promotes commercialisation - a prerequisite for success - and has built the capabilities needed to support this culture, without compromising the core public service role in scientific research.

8 The Medical Research Council has been particularly successful in building on intellectual property arising in its Research Establishments (which it calls units). Active leadership from senior staff in the Medical Research Council led to the creation of Medical Research Council Technology Ltd (Medical Research Council Technology) which has been allocated sufficient resources to lead the commercialisation research outputs for all Medical Research Council units. The Medical Research Council was also instrumental in the creation of MVM Limited, a venture capital company managed by individuals from the private sector. This has two funds which invest in early stage life science companies, the first, UK Medical Ventures Fund, raised £40 million in 1998 and the second fund raised a similar amount in October 2001.

9 Other Research Establishments have also demonstrated leadership by obtaining funds to develop commercialisation activity. The Biotechnology and Biological Sciences Research Council sponsored Babraham Institute, for example, competitively obtained a £250,000 grant from the Department to refurbish laboratory and support facilities appropriate for use by early stage companies. This attracted 19 fledgling companies to rent about 3,000 square metres of space at their suitably named 'Bio-incubator' site and generated £680,000 from rents and services in 2000-01. Implementing this relatively small initiative provided funds to hire qualified people and helped to build an effective framework for commercialisation activity. This has since led on to a larger public private partnership project, with similar aims, at the Babraham site.

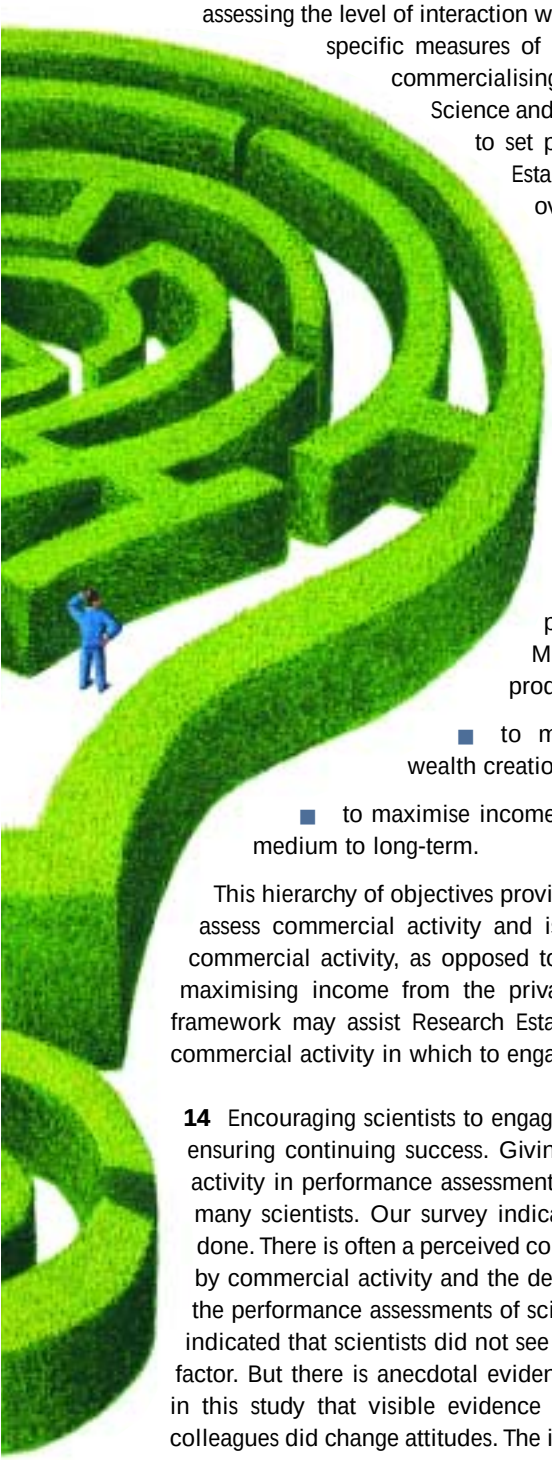


Without enabling cultures, effective commercialisation is not possible

10 The traditional focus in Research Establishments is, rightly, on producing the highest quality scientific research and advice. To meet the increasing emphasis on commercialisation, a culture that is also supportive of commercial activity, which helps staff to overcome barriers, such as the lack of recognition for commercialisation work, is needed. This will require change in many Research Establishments. There are already good examples of such support as in our case example of Evolutec, a company set up to exploit research by Professor Nuttall at the Centre for Ecology and Hydrology to develop more effective treatment of complaints such as asthma than are currently available (paragraphs 2.15 and 4.3). This Research Establishment is a component of the Natural Environment Research Council and senior management at the Research Council, particularly Professor Sir John Krebs (Chief Executive until September 1999) and Dr Tricker, played an important role in encouraging Professor Nuttall to take the work forward and in finding some funding, in the absence of an established budget for early stage work. As a result of this experience the Natural Environment Research Council has now established a £500,000 innovation fund for providing financial support from the centre for such developments.

11 Effective accountability of Research Establishments' commercial performance through relevant performance targets, objectives and review will also encourage change. These should recognise that not all commercial initiatives can be successful and that lessons can be learned from studying successes and failures. The Government has set a high level target to 'increase the level of exploitation of technological knowledge derived from the science and engineering base, as demonstrated by a significant rise in the proportion of innovating business citing such sources.'

12 The Office of Science and Technology is revising the performance indicators that apply to Research Councils to reflect this high level target. These indicators currently include measures such as the level of income received from the private sector, the number and value of collaborative or co-funded research projects and the number of co-publications with industry. Such broad measures are of use in assessing the level of interaction with the private sector although they are not specific measures of Research Establishments' performance in commercialising their research outputs. The Office of Science and Technology would like Research Councils to set performance indicators for their Research Establishments which are consistent with their overall targets. It emphasises, however, that its role is to influence targets rather than to set them.



13 Medical Research Council Technology has prioritised its objectives for commercial activity in the light of the policy aim of capturing economic and social benefits and the mission of the Medical Research Council:

- to choose the most suitable commercial arrangement and the partner(s) judged most likely to develop Medical Research Council technology into products and services useful to society;
- to maximise the contribution to national wealth creation and UK industrial competitiveness; and
- to maximise income to the Medical Research Council in the medium to long-term.

This hierarchy of objectives provides a clear context for decision makers to assess commercial activity and is likely to stimulate long term types of commercial activity, as opposed to potential short term objectives such as maximising income from the private sector. The establishment of such a framework may assist Research Establishments in deciding on the forms of commercial activity in which to engage.

14 Encouraging scientists to engage actively in commercialisation is vital to ensuring continuing success. Giving adequate weight to commercialisation activity in performance assessments is likely to be an effective incentive for many scientists. Our survey indicated, however, that this is frequently not done. There is often a perceived conflict between the confidentiality required by commercial activity and the desire to publish research results, on which the performance assessments of scientists are largely based. Our survey also indicated that scientists did not see financial incentives as a main motivating factor. But there is anecdotal evidence from many of those who participated in this study that visible evidence of the positive impact of incentives on colleagues did change attitudes. The impact of the awards to inventors schemes and the scope for staff to act as company founders were thought to be particularly important. A recent innovative example comes from the Human Reproductive Science Unit where a number of scientists have been given the opportunity to take equity stakes in a spin out company specialising in women's health **(Figure 8)** and this, in conjunction with the input of market knowledge from the private sector, is linked to an upsurge in commercial activity. It appears, therefore, that scientists' involvement can be stimulated and rewarded through the provision of fair and effective incentives.

15 Scientists do not generally have business training and cannot be expected routinely to display or to acquire the full range of commercial skills required to commercialise their research. Our work points to the benefits of offering incentives to scarce professional commercial staff who also have a key role to play in successful commercialisation activity. They bring to bear business and intellectual property management knowledge allied to the commercial experience to assess opportunities realistically and to negotiate successfully.

16 As scientists become involved in commercial ventures, conflicts of interest may emerge. The Office of Science and Technology has produced guidance on managing these conflicts of interest (which is available on their website www.dti.gov.uk/ost). All the Research Establishments we have studied have developed procedures to register, assess and monitor potential conflicts. After such scrutiny, some commercial activities may only be taken forward after the development of specific measures to manage risks relating to such conflicts. The arrangements rely on transparency and oversight from senior management who do not stand to benefit. The concerns voiced by scientists responding to our survey suggest that they attach importance to having access to an impartial procedure for challenging specific commercial activities.

Effective commercialisation requires supporting capabilities

17 All Research Establishments have some scope for commercialisation and seek to ensure that commercial ideas are identified. The extent depends largely on the nature of an individual Research Establishment's science and the level of demand from the market sector in which it operates. Research Establishments sponsored by the Medical Research Council operate in the human healthcare market sector with significant external demand in the United Kingdom and internationally. In contrast, for example, the Biotechnology and Biological Sciences Research Council sponsored Silsoe Research Institute has traditionally operated in the agricultural engineering sector, where demand in the United Kingdom appears low, following problems in that industry. Most Research Establishments do not carry out assessments of prospective world-wide industry demand and do not generally have enough staff to follow a proactive industrial strategy.

18 There are examples of successful commercialisations from research developed following demand from industry (technology pull) and from Research Establishments, themselves, deciding to take development forward (technology push). But there are indications that technology push projects have a comparatively lower success rate, encounter difficulties in raising development finance, and require more confidence in the science, resources, effort and time from commercialisation specialists and the scientists. The Office of Science and Technology and the Treasury consider that technology push projects can usefully play a part in a portfolio, bearing these factors in mind.

19 The three Research Councils have chosen to apply different degrees of centralisation to their commercialisation activities, which they explain as due to differences in mission and the scope of the opportunity. Our examination has shown that different approaches can work, when allied to commitment. Developing a portfolio will help Research Establishments to diversify risk, explore options, and possibly increase the number of successful projects. There are two distinct portfolios that Research Establishments could aim to develop: where practical, a related body of intellectual property or know-how which they could manage actively; and if this is achieved, a portfolio of commercialisation projects based on different routes to market and incorporating different types of partnership with the private sector.

20 Research Establishments can maximise a portfolio of commercial activity either individually or, even though they are often in competition for grant funding, by working together across organisational boundaries to establish a critical mass of opportunities (paragraph 3.10). To facilitate this, the Baker Report recommended that intellectual property should be delegated to Research Establishments. The Babraham Institute, for example, building on past success, manages actively its own relatively modest amount of intellectual property (paragraph 4.16). In the case of the Medical Research Council intellectual property is managed centrally on behalf of its 40 component units, many of which are small, realising the advantage of critical mass in the Bio-medical sector; in contrast the Biotechnology and Biological Sciences Research Council is decentralised, partly because its eight institutes are all large and operate in distinct market sectors. As funding for research programmes often comes from more than one source, pooling intellectual property could involve a number of different parties that have different intellectual property policies. Co-ordination of these policies is important to ensure that there is clarity about which policy applies and who will lead for commercialisation purposes.

21 Adequate finance is needed to resource commercialisation including patenting, funding additional scientific work to demonstrate commercial potential, remunerating professional commercial staff, and obtaining external advice. Once a portfolio of commercial deals is in place, it may provide an income stream which can be recycled to produce a continuing flow of opportunities. The Medical Research Council income has grown from £150,000 in 1986-87 to some £7 million in 1999-2000 and £17.9 million in 2000-01. Other bodies are at an earlier stage and may need external resources to help to kick-start the process.

22 Tackling this initial shortfall in resources is important if the commercial potential of Research Establishments' scientific output is to be realised. The Government has recognised the need to provide additional finance through a £10 million competition held in 2001, called the PSRE Fund competition. Up to half this fund was planned to build commercial capabilities in eligible bodies, with the balance intended for pre-seed funding, that is funding to demonstrate to potential partners the link between an invention or a range of intellectual property and the proposed new products or services. The potential scale of commercial activity, and the limited extent of existing finance, is indicated by the fact that bids for the fund exceeded the £10 million on offer, even though Partnerships UK told us that some likely bidders were discouraged by what they considered the modest amount proposed. On the basis of a 50:50 split, the PSRE Fund has been over-subscribed by 11:5 for capability building and 13:5 for seed funding. The Office of Science and Technology guidelines for seed funding suggests that investments are made over a three year period and requests that funds be managed in a way that ensure a good prospect of continued existence in the long term. Given the length of time taken for commercialisation work to yield a return, venture capitalists commented that this appears a difficult, and quite possibly unrealistic, objective. The Office of Science and Technology will, however, monitor the financial position of the seed fund, allocated £4 million funding after the PSRE Fund competition, with a view to understanding the prospects for the emerging portfolio of investments.

23 The Government also encourages Research Establishments to explore other sources of finance such as those available from Regional Development Agencies and the University Challenge scheme, which "enables universities to establish seed funds to assist the transformation of good research into good business", with the Government providing some £40 million in two rounds by the end of 2001 alongside an equivalent sum from charities and university sources. Research Establishments can apply for University Challenge funding as part of a university bid. Information on Research Establishments' success in obtaining funding from these sources, including successful University Challenge bids, and how it is spent is not easily available. The Office of Science and Technology monitors funding committed to particular projects through the annual reporting process and makes summary information available at the aggregate level, but not at the detailed level.

Realising the potential benefits of commercialisation

24 The Research Establishments we studied, as a group, have developed the full range of commercialisation opportunities, from free dissemination of information to venture capital financed spin out companies. These developments offer significant potential benefits to the economy and to society

as well as to the Research Establishments themselves. Since the Treasury agreed in 1999 that Research Councils and Research Establishments could retain the financial benefits of their commercial activity and share this between them in whatever proportion they agree, commercialisation receipts have been used not only to sustain further commercialisation activity but also for extra scientific research. Our parallel report on research funded by the Department for the Environment, Food and Rural Affairs examines a notable example at the Biotechnology and Biological Sciences Research Council sponsored Roslin Institute, where nuclear transfer technology, pioneered by cloning Dolly the sheep, generated such receipts. The Biotechnology and Biological Sciences Research Council also anticipates that, if it is brought to market successfully, the Roslin Institute will earn substantial future royalties from a cystic fibrosis treatment currently undergoing clinical trials.

25 As suggested in paragraph 13, these benefits are most likely to be realised if a Research Establishment has a strategy for its intellectual property and know-how which focuses on a clear set of desired outcomes. Thorough risk management procedures, although not formally undertaken at present, are also important. A key determinant of the value obtained from commercialisation deals is the worth of the intellectual property that the Research Establishment is committing. By providing a range of intellectual property, as in the case of the Human Reproductive Science Unit **(Figure 15)**, Research Establishments can make a venture more attractive to the private sector. Assessing the worth of intellectual property is difficult, and precise valuation is unrealistic. A systematic categorisation, for example, into therapeutic area, market potential, competition, cost of manufacture (if knowable), complexity of development and time to market, can, however, inform the comparative assessment of projects in a portfolio.

26 In the sample of Research Establishments we examined, we have not investigated specific deals in detail, but the Research Establishments appear to be reducing their potential exposure by taking little management or financial risk and allowing these risks to be managed by the private sector. This is a sensible way to start. We also found that Research Establishments are seeking to protect the public interest from non-financial risks, such as developing intellectual property in a way that impacts adversely on the achievement of their core pure science goals, through ad hoc arrangements.

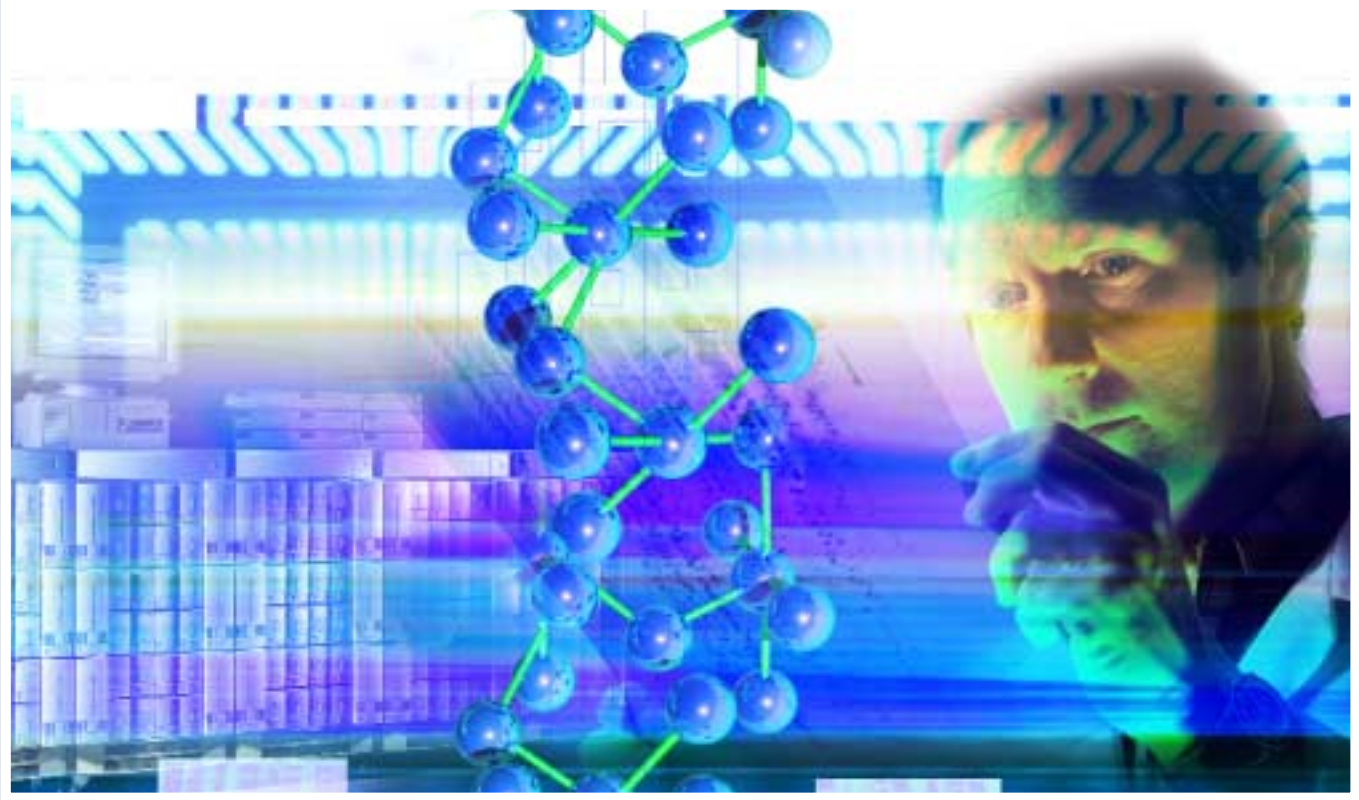
27 We have examined "The Radiocommunications Agency's joint venture with CMG" (HC21 December 2000) in detail. This innovative joint venture was entered into partly to help the Radiocommunications Agency exploit its technical expertise. Although the Radiocommunications Agency has a very different role to that of a Research Establishment, there are some useful general lessons. We praised the Radiocommunications Agency for identifying the key elements of a successful partnership and incorporating them in the joint venture, while at the same time negotiating a contractual framework that meant that satisfactory delivery was not solely dependent on a collaborative relationship. Partnerships UK published detailed guidance on setting up joint venture companies in December 2001. In constructing partnership deals, Research Establishments will benefit from a considered choice of partner, where possible, and a cohesive negotiating strategy that keeps the scientists well-informed and fully motivated, alongside their commercial colleagues, to take forward the scientific aspect of commercial development.

Recommendations

Recommendation	Aim	Responsibility
(A) For the Department, the Office of Science and Technology, and Research Councils: Review performance indicators including recognition of the diversity of research and hence of the performance indicators required. **(paragraphs 2.8 and 2.9)**	To agree performance indicators with Research Councils that strengthen accountability, taking into account the goal of improving UK competitiveness, and to review relevance of existing targets, some qualitative, for Research Establishments.	Director General of the Research Councils and Research Council Chief Executives.
(B) For the Research Councils: B.1 Research Councils should hold annual operational reviews, dealing with commercialisation, with all Research Establishments. **(paragraph 2.13)**	To review the progress of commercialisation efforts at frequent intervals.	Research Council Chief Executives.
B.2 Research Councils should establish guidelines, on an exception basis, for Research Establishments to take advice on conflicts of interest and to consider forming an independent science advisory board to advise them on novel cases. **(paragraph 2.30)**	To provide, when appropriate, external advice on conflicts of interest	Research Councils and Establishment Chief Executives.
B3 Research Councils should define major deals, or what would constitute novel deals, for oversight purposes, including guidelines for taking expert advice. **(paragraph 4.13)**	To ensure that they are kept informed and consulted when appropriate.	Research Councils and Establishment Chief Executives.
(C) For Research Establishments: C1 Chief Executives (in the case of the Medical Research Council the head of Medical Research Council Technology) should review the scale of the commercial opportunity annually and submit a plan for their establishment explaining any major constraints. **(paragraph 2.13)**	To review scope for commercialisation and budget accordingly	Research Establishment Chief Executives
C2 Research Establishments should review and set minimum levels of training in commercialisation **(paragraphs 2.16, 2.23 and 2.24)**	To define and make obligatory an appropriate level of training for scientists and for team leaders	Research Council Chief Executives

Recommendations

Recommendation	Aim	Responsibility
C3 Scientific staff and research appraisals should give 'kudos' for effective participation in commercial exploitation, including timely patent applications. **(paragraph 2.17)**	To encourage early identification of opportunities for commercialisation.	Line Managers, starting from the Chief Executive Officer and including the guidance that he gives to Peer Review Panels.
C4 Research Establishments should budget time, down to research team leader level, for market assessment of the commercial opportunities of research projects. **(paragraph 2.25)**	To identify and assess, from a commercial perspective, whether current research has potential commercial applications.	Commercialisation Officers, Technology Transfer Officers and Team Leaders
C5 Each Research Council should review its budget for 'proof of principle' funding, i.e. funding work to demonstrate the commercial promise of an initial scientific discovery. **(paragraph 3.25)**	To improve the prospects for commercialisation by funding the gap between scientific discovery and an initial proposal to prospective private sector partners.	Research Council Chief Executives
C6 Research Establishments should analyse the potential of their intellectual property in a systematic way. **(paragraph 4.18)**	To manage patent costs effectively and to help estimate approximate differences of potential value between projects.	Commercialisation Officers and Technology Transfer Officers



Part 1 Introduction

1.1 Scientific research in the public sector is carried out by a number of bodies, including Public Sector Research Establishments (Research Establishments), and is funded by several government departments. Overall responsibility for science policy rests with the Department for Trade and Industry (the Department). **Figure 3** shows the relationships between the various parties involved in the commercialisation of public sector science and this section explains the roles of each party. It also sets out the background and findings of a Report commissioned by the Government from John Baker, then Chairman of Medeva plc (the Baker Report) into realising the economic potential of the Research Establishments which was published in August 1999.

The Department for Trade and Industry has responsibility for science policy

1.2 Promoting innovation is a key strategic objective for the Department and it pursues this objective in part through a science and innovation strategy which seeks to:

- promote standards of international excellence in basic science; and
- maximise the contribution of science and technology findings and research outputs to the economic development of the United Kingdom and the quality of lives.

1.3 The Office of Science and Technology is part of the Department and provides the central focus for the consideration of science, engineering and technology issues across government. It has responsibility for the science budget and for the work of the Research Councils. As such it is responsible for quinquennial reviews of the Research Councils. The Director General of the Research Councils in the Office of Science and Technology has responsibility for advising the Secretary of State on the resources needed by the Research Councils and on the distribution of the science budget between them. He also advises Ministers on the performance of the Research Councils.

The Research Councils are providers of funding and strategic direction

1.4 There are seven Research Councils principally funded by and responsible to the Office of Science and Technology. They are responsible for funding and managing scientific research in their broad area of expertise throughout the United Kingdom. Each Research Council is a non-departmental public body headed by a Chief Executive. They have three main activities:

- funding research by universities and scientists outside the public sector;
- funding research in the Research Establishments; and
- supporting research students in Universities and Research Establishments.

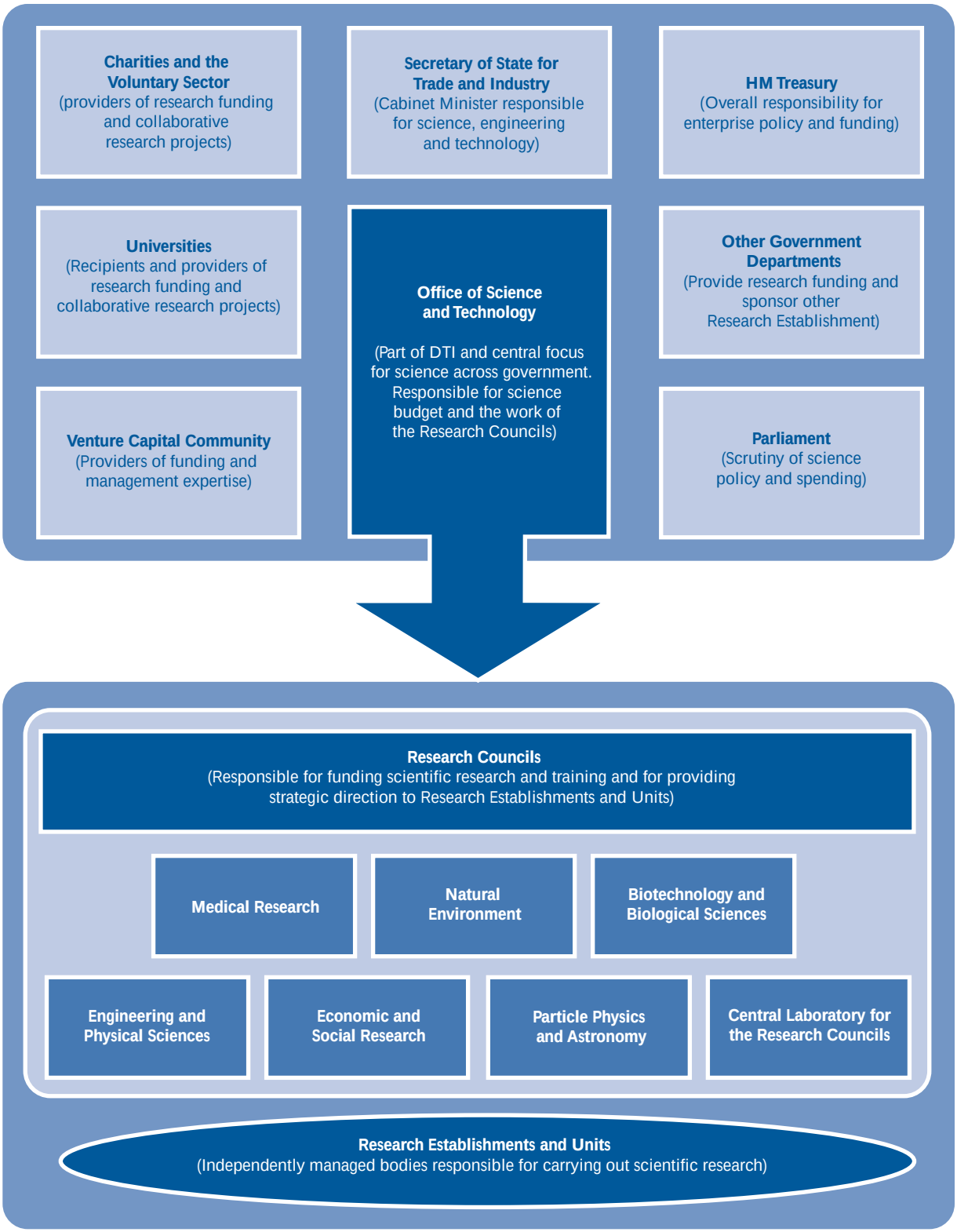
The Research Councils provide strategic direction and the majority of funding for their Research Establishments and their mission statements are set out in paragraph 1.15 below. Funding is allocated following an assessment of the quality of Research Establishment's current research and their forward research programmes.

1.5 Research Establishments are bodies that carry out research in specific areas of science and are either part of government departments or grouped together under Research Councils that cover broad scientific streams. They may have a number of alternative sources of research funding including commissioned or joint research for industry, the charitable and voluntary sectors and universities. Some Research Establishments also perform consultancy work applying their knowledge to specific problems.

1.6 The first priority for each Research Establishment is to conduct research in pursuit of various government objectives including:

- achieving advances in science, which receives the majority of funding;

3 Key Stakeholders in Commercialising Public Sector



The organisational structure of the research community

- informing government policy-making through the provision of independent advice;
- training the next generation of research scientists; and
- assisting public sector bodies carry out their statutory or regulatory functions.

Research Establishments have some commercialisation experience

1.7 Without wanting to compromise the Research Establishments' core scientific role, the Government is keen to encourage them to apply, in co-operation with the private sector, the outputs of publicly funded scientific research to stimulate economic and social benefits, such as job creation, increased prosperity and enhanced quality of life **(Figure 4)**. This is termed "commercialisation" and when applied to publicly funded research is by its nature opportunistic.

4 The Government objectives for commercialisation of research

The Government wishes knowledge transfer and collaboration with industry to become part of the core mission of both public sector research establishments and universities, so that investment generates the maximum benefits in the form of jobs and prosperity for the nation.

"The ability to capture the economic benefits of science and technology - in particular the creation of novel products and processes - is a crucial determinant of competitiveness and growth in a globalising economy. Key mechanisms for creating economic value from research include wide dissemination of knowledge through the economy, and the transfer of trained people from science labs to industry. But there is increasing recognition - in government, academe and the private sector - of the need for science and industry to work closer together to forge more direct routes, including commercial routes, for exploiting the outputs of research. "

Source: The Government's Response to the Baker Report

Commercialisation is not a new activity for Research Councils and their Research Establishments, although the priority afforded it has increased following the introduction in 1999 of the Government's Wider Markets Initiative to encourage public bodies to make better commercial use of public assets. In this report we mainly focus on forms of commercialisation listed at 4 to 6 below **(Figure 5)** because these forms tend to involve more challenges for Research Establishments. Research Councils encourage Research Establishments to work with industry in other ways such as contracted research to exploit know-how and expertise some of which may lead to further economic benefits that are difficult to quantify. To encourage such activity, the Biotechnology and Biological Sciences Research Council, for example, sets targets for industrial income over a four year period and takes account of this within its four yearly reviews of performance. The Biotechnology and Biological Sciences Research Council's research and consultancy income from industry aggregates some £14 million per year.

5 Forms of commercialisation of research outputs

The following would not include general industrial funding of a research activity before any identified research outputs have been generated

1. Free or 'at cost' dissemination of research outputs
2. Sale of services, data and software to the business sector
3. Collaboration with industry to solve problems
4. Licensing of technology and royalty provisions
5. Joint venture agreement to exploit research outputs
6. Start Up or Spin Out company

Source: The Baker Report

1.8 A number of successful companies and products have been founded in the past on the basis of public sector science including publicly quoted companies such as Celltech and Cambridge Antibody Technology (see paragraph 4.5) and PPL Therapeutics (see paragraph 4.6), which were built on science originating in the laboratories of the Medical Research Council and the Biotechnology and Biological Sciences Research Council respectively. Celltech was founded in 1980, with the National Enterprise Board as its major shareholder, in order to create the first biotechnology company in the UK. Initially the company had a broad research remit but later concentrated on the discovery, development and manufacture of novel therapeutic products. The company implemented a strategy of collaborating with pharmaceutical companies on development programmes. These collaborations assisted the financial strategy of the company and introduced the development and commercial expertise of the partners. Celltech Group was listed on the London Stock Exchange in 1993 at a price of 250p per share, raising $30 million of new funds, and has since grown to become an international group employing 1,803 staff (year to 31 December 2000) including over 600 research and development staff and 550 sales and marketing staff.

1.9 The Biotechnology and Biological Sciences Research Council Research Establishments, which it calls institutes, had income of some £2.7 million in 2000/01 from sales of equity in spin-out companies, licensing and royalties. On a similar basis the Medical Research Council had income running at an annual average of some £12 million to September 2001, and the Natural Environment Research Council has annual licensing and other commercial consultancy income, including income from the sale of data related products, totalling £2.45 million.

The Baker Report "Creating Knowledge, Creating Wealth"

1.10 The Baker report was commissioned in 1999 by Treasury and DTI Ministers to investigate the commercialisation of research in the Research Establishments and to make recommendations for increasing the rate at which their research is commercialised successfully, consistent with other government objectives for the Research Establishments. The report noted that knowledge transfer through commercialisation is a difficult and complex process, and made a number of recommendations including those set out in **Figure 6** below:

6 Key Baker Report recommendations

- **Give Research Establishments more control of intellectual property and financial freedoms** "The departmental Research Establishments should be put at greater arm's length from Government departments. Ministers should consider how this should best be done for each of these Research Establishments, with the presumption in favour of a move to less central control."
- **Manage incentives for research establishment staff** "Bars on certain forms of direct participation by serving Government scientists in the commercial exploitation of their research - in particular receiving equity or share options - should be removed. Personal gain should not be outlawed; rather it should be permitted subject to having proper systems in place for ensuring the probity of the proposed commercialisation arrangements."
- **Ensure access to commercial expertise** "Sponsors of Research Establishments should encourage the development of networks among Research Establishments for the sharing of best practice in knowledge transfer, to promote synergies", including across Departments, and to support them in "gaining access to relevant expertise".

Source: The Baker Report

1.11 The Government broadly accepted Baker's recommendations, including decentralising ownership of intellectual property, making changes to the civil service rules affecting government scientists, and providing funds to help bridge the gap in finance for seed investments. The parties we interviewed in preparing this report considered that the challenge now is for all the Research Councils and Research Establishments to expand their existing commercialisation portfolio and to build the capabilities to ensure that commercialisation is sustainable.

The role of Partnerships UK

1.12 The Government recognised that Research Establishments need advice to help them commercialise their discoveries, and made provision for Partnerships UK to act as a source of assistance. Partnerships UK is a public private partnership that combines private sector expertise with a strong public sector mission to bridge the gap between the public and private sectors. It has a dedicated science and technology commercialisation team to provide advice and help 'on the ground' (paragraph 3.22). In a separate capacity, with safeguards to cover possible conflict with their advisory role, Partnerships UK may consider providing equity funds for investment in public private ventures.

The scope of this report

1.13 We have stated publicly that we encourage worthwhile and well thought through innovation in the public sector, for example that we "support well managed risk taking intended to result in tangible benefits for taxpayers" (Para 8, Executive Summary 'Supporting Innovation: Managing Risk in Government Departments' HC864 99/00). In line with this we have examined how the Research Establishments can meet the challenges arising from increasing commercialisation to deliver the potential economic and social benefits for the nation. Our methodology is described in detail in Appendix 1 and accompanied by a list of parties consulted - in brief, we considered:

- the key importance of building an enabling culture, capable of encouraging and stimulating effective commercialisation;
- whether Research Establishments are identifying and putting in place the capabilities required; and
- how Research Establishments can best realise the potential benefits of commercialisation.

1.14 We focused our investigation on the 53 Research Establishments within three Research Councils for which the Department for Trade & Industry has responsibility. This is because these three Councils have differing potential for commercialisation so that the collective experience of their Research Establishments is likely to be of relevance to the others. Together, these Research Establishments received funding of about £443 million in 1999-2000. The proportion of funding distributed varies between Research Councils and Research Establishments. Generally, the Medical Research Council provides its Research Establishments with a higher direct proportion of funding than either the Biotechnology and Biological Sciences Research Council or the Natural Environment Research Council.

1.15 The purpose of the three Research Councils is explained in **Figure 7** below:

7 The Research Council missions

Research Council	Area of Science	Published Mission
Biotechnology and Biological Sciences Research Council	Biosciences	a) To promote and support high quality basic, strategic and applied research and related postgraduate training relating to the understanding and exploitation of biological systems; b) To advance knowledge and technology, and provide trained scientists and engineers, which meet the needs of users and beneficiaries (including the agriculture, bioprocessing, chemical, healthcare, pharmaceutical and other biotechnicological related industries), thereby contributing to the economic competitiveness of the UK and the quality of life; c) To provide advice, disseminate knowledge, and promote public understanding in the fields of biotechnology and biological sciences.
Medical Research Council	Bio-medical Science	a) To encourage and support high-quality research with the aim of maintaining and improving human health; b) To train skilled people, and to advance and disseminate knowledge and technology with the aim of meeting national needs in terms of health, quality of life and economic competitiveness; c) To promote public engagement with medical research.
Natural Environment Research Council	Environmental Sciences	a) To promote and support, by any means, high quality basic, strategic and applied research, survey, long-term environmental monitoring and related postgraduate training in terrestrial, marine and freshwater biology and Earth, atmospheric, hydrological, oceanographic and polar sciences and Earth observation; b) To advance knowledge and technology, and to provide services and trained scientists and engineers, which meet the needs of users and beneficiaries (including the agricultural, construction, fishing, forestry, hydrocarbons, minerals, process, remote sensing, water and other industries), thereby contributing to the economic competitiveness of the United Kingdom, the effectiveness of public services and policy and the quality of life; c) To provide advice on, disseminate knowledge and promote public understanding of the fields aforesaid.

1.16 This study has been carried out in parallel with another National Audit Office report that considers the commercialisation of research sponsored by the Department for the Environment, Food and Rural Affairs which is expected to be published later in 2002.

Part 2

Effective commercialisation is not possible without an enabling culture

2.1 The core role of Research Establishments is to produce scientific research and advice of the highest quality, often in a public context. Their culture rightly prizes excellent research and is geared to disseminating the results across the scientific community. There is a wide variation in the extent of Research Establishments involvement in and commitment to commercialisation. In Research Establishments sponsored by the Medical Research Council, that have had success in commercialisation, commitment to knowledge transfer from scientists to the wider community - in forms that secure and reinvest economic benefits - has been embedded in the institutional culture. This section considers how an enabling culture that encourages commercialisation, a prerequisite for effective commercialisation, can be developed and enhanced.

Committed leadership is the first step in building a culture that encourages commercialisation

2.2 Leadership by both top and middle management is needed to encourage change of the order hoped for by the Government. Research Councils can give an active lead to their Research Establishments in a number of ways particularly through encouraging a medium to long term planning framework that recognises the risk of failure and consequent losses of sunk costs and time. This is compatible with a continuing focus on delivering high quality science as world class science also goes hand in hand with commercial opportunities. At the Medical Research Council Laboratory of Molecular Biology laboratories , world class research into recombinant antibody technologies, that is genetically engineering antibodies to disease targets, but antibodies which are accepted by the human immune system, has created licensing opportunities resulting in a substantial contribution (some 71 per cent between 1995 and 2000) to overall commercial income for the Medical Research Council. The latter grew from just £150,000 in 1986-87 to £1,550,000 in 1996-97 and £7,6 million in 1999-2000 and £17.9 million in 2000-01.

2.3 The Biotechnology and Biological Sciences Research Council sponsored Babraham Institute ("Babraham") is developing a £50 million Research Campus project. Babraham competitively obtained a £250,000 grant from the Department to refurbish laboratory and support facilities appropriate for use by early stage companies in what proved to be a successful pilot project. Its suitably named 'Bio-incubator' site attracted 19 fledgling companies to rent about 3,000 square metres of space. This activity generated £680,000 from rents and services in 2000-01 helping it to hire qualified people and build a framework for commercialisation activity. The tenants have included three 'spin-out' companies, one based on Babraham research and two based on research sponsored by the Medical Research Council.

2.4 In the Medical Research Council active leadership has come from the Chief Executive of the Research Council, from Council members - including the Chairman - and from other senior staff. Their leadership has led to the creation of Medical Research Council Technology Ltd to manage the commercialisation of research across Medical Research Council Research Establishments (which it calls units). The Medical Research Council has actively supported the ideas of the Chief Executive of Medical Research Council Technology such as the creation of MVM Limited, a venture capital company managed by individuals from the private sector, which has two funds under management investing in start up and early stage life science companies. Both funds are standard venture capital funds structured as English limited partnerships with capital from the private sector. MVM launched the first UK Medical Ventures Fund, a £40 million fund, in 1998. The second fund raised a similar amount in October 2001.

2.5 A degree of active leadership is also evident in the other Research Councils we examined, for example, through the appointment of senior staff to posts with responsibility for commercialisation. A few examples of personal involvement on the part of senior management are shown in the table overleaf, demonstrating that commercialisation is becoming a more central part of the Research Council's mission, and of their Research Establishments:

8 Examples of personal involvement

Research Council	Individual	Action
Biotechnology and Biological Sciences Research Council	Chief Executive	Active role in consideration of reward structure for the sale of technology by the Roslin Institute (detail of which will be covered in the NAO report referenced in paragraph 1.16)
Natural Environment Research Council	Chief Executive and Exploitation Director	Active support to their first spin-out company - Evolutec
Medical Research Council	Chief Executive, Medical Research Council; Chief Executive Medical Research Council Technology; Directors Laboratory of Molecular Biology and National Institute for Medical Research.	Encouragement of upsurge of commercialisation of Laboratory of Molecular Biology research and creation of Medical Research Council Collaborative Centre Mill Hill.

Effective accountability will support a change of culture

2.6 Effective accountability will support culture change if meaningful objectives and targets for commercialisation are put in place and monitored actively. The Office of Science and Technology, Research Councils and Research Establishments need to further develop objectives and targets to provide an effective incentive to encourage commercialisation.

Progress can be measured against relevant performance indicators

2.7 The Government's 2001 Comprehensive Spending Review set an overall target to 'increase the level of exploitation of technological knowledge derived from the science and engineering base, as demonstrated by a significant rise in the proportion of innovating business citing such sources.'

2.8 The Office of Science and Technology is revising the performance indicators that apply to Research Councils to reflect this high level target. These indicators currently include measures such as the level of income received from private sector, the number and value of collaborative or co-funded research projects and the number of co-publications with industry. Such broad measures are of use in assessing the level of interaction with the private sector although they are not specific measures of Research Establishments' performance in commercialising their research outputs. The precise nature of these targets are likely to vary to reflect the differential sophistication of research in different industrial sectors.

2.9 In revising these performance indicators, the Office of Science and Technology is developing targets for the Research Councils that encompass, as far as possible, all the routes to commercialisation. It emphasises, however, that its role is to influence targets rather than setting them. The intention is that targets should then be set for Research Establishments, as part of their overall set of performance indicators, which are consistent with those for the Research Councils.

Research Establishments and their senior management should have objectives for commercialisation to which they attach weight

2.10 The three Research Councils examined in this study recognise that commercialisation forms part of their mission. Commercialisation is explicit in the Medical Research Council mission. Our survey of a range of scientists in different Research Establishments also indicates that individual scientists are aware of the technology transfer element of their Research Establishments' mission.

2.11 Medical Research Council Technology has prioritised its objectives for commercial activity to reflect the policy aims of capturing economic and social benefits and the mission of the Medical Research Council:

- to choose the most suitable commercial arrangement and the partner(s) judged most likely to develop Medical Research Council technology into products and services useful to society;
- to maximise the contribution to national wealth creation and UK industrial competitiveness; and
- to maximise income to the Medical Research Council in the medium to long-term.

This hierarchy of objectives provides a clear context for decision-makers to assess commercial activity and is likely to stimulate long-term types of commercial activity, as opposed to potential short-term objectives such as maximising income from the private sector. The establishment of such a framework may assist Research Establishments in deciding on the forms of commercial activity in which to engage.

2.12 The senior managers of the Research Establishments covered in this study also recognise that commercialisation should form part of their personal objectives. Commercialisation is implicit within the knowledge transfer elements of some individuals' objectives. Explicit recognition of the importance of commercialisation in senior management objectives will give greater impetus to the changes needed to stimulate effective commercialisation.

Frequent review of Research Establishments' commercial performance will stimulate commercialisation

2.13 Some Research Establishments are subject to regular operational reviews of their commercialisation activities. The Board of Medical Research Council Technology reviews its performance on a quarterly basis, and provides an annual report to the Medical Research Council. Medical Research Council Technology is uniquely constituted, however Research Establishments in the Biotechnology and Biological Sciences Research Council also used to be subject to annual reviews of commercial activity. The Biotechnology and Biological Sciences Research Council has recently moved to a system of six-monthly business plan meetings which include links with industry and commercialisation on the agenda. Formal annual reviews of commercial performance, covering the degree of success attained in commercialising existing research outputs, which would not replace ad hoc discussions of aspects of commercialisation, would play a useful role in stimulating and improving performance. Such operational reviews, akin to progress meetings, are likely to be particularly useful in stimulating less active or relatively inexperienced Research Establishments.

2.14 We would not expect Research Establishments to apply a commercial perspective to the progress of their mainstream ongoing research, as in the private sector. The nature of research undertaken in Research Establishments is a matter for the funding bodies who have their own criteria based on the science mission of the Research Councils. Neither should such additional reviews replace any part of the generic reviews of Research Establishments that occur every five years. Commercial performance is not the main subject of these strategy reviews which are designed to assess Research Establishments' performance in delivering their core scientific mission.

Scientists and commercialisation experts need incentives to drive commercialisation forward

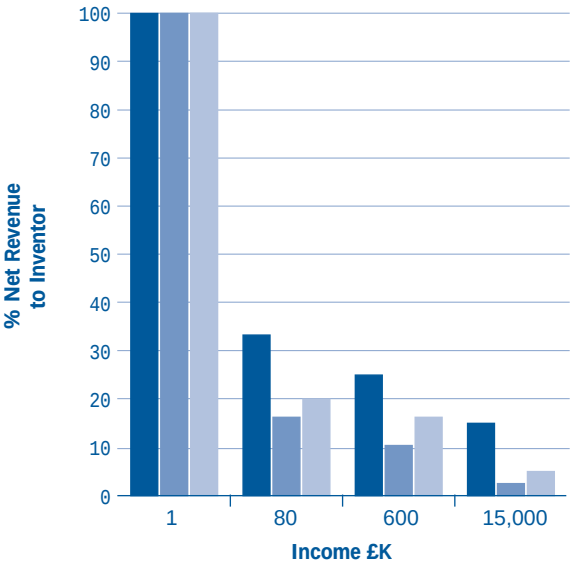
2.15 Our survey indicates that, although scientists know that commercialisation is part of the mission of their Research Establishment and that they have a role in delivering commercialisation, they are less clear about the extent of their role. Our work suggests that scientists are the most likely people to identify the commercial potential of their own research. As an example, the spin out of Evolutec from the Natural Environment Research Council was dependent on the identification by Professor Nuttall at the Centre of Ecology & Hydrology of the commercial potential of her research on the saliva of ticks (see paragraph 4.3). Scientists not only advise on the science during commercial negotiations but also have a continuing role once a commercialisation project is underway, for example, in further developing the research where necessary.

2.16 Energetic commercialisation staff in Research Establishments can provide information and training aimed at ensuring that scientists have a good understanding of their role in the overall commercialisation process. This has been exemplified by Frances Green, the responsible officer, at the Medical Research Council's Mill Hill laboratories, winning praise from our private sector consultants. The Biotechnology and Biological Sciences Research Council also produces a booklet on Intellectual Property, and an Exploitation Guide to inform scientists and others involved in commercialisation. The Natural Environment Research Council also produces a useful handbook for its staff, while staff in the Medical Research Council are encouraged to attend road-shows given by Medical Research Council Technology staff. Although suitable initiatives are under way, a shortage of skills for the provision of hands-on training may prevent the optimal amount being undertaken, and we recommend that Research Establishments should define a training requirement and make it an obligatory standard for scientists leading research teams.

Scientists should be rewarded for their initial intellectual contribution to commercialisation

2.17 Scientists' involvement in commercialisation is vital - both in identifying commercial potential and for developing the science - and their contributions should be adequately recognised in their performance assessments. Our survey indicated that this is frequently not done and that scientists believe that their career path discourages involvement in commercialisation activity. There is often a perceived conflict between the confidentiality required by commercial activity and the desire to publish research results, on which the performance assessments of scientists are largely based.

9 **Awards to Inventors Schemes of Biotechnology and Biological Sciences Research Council, Natural Environment Research Council, Medical Research Council**



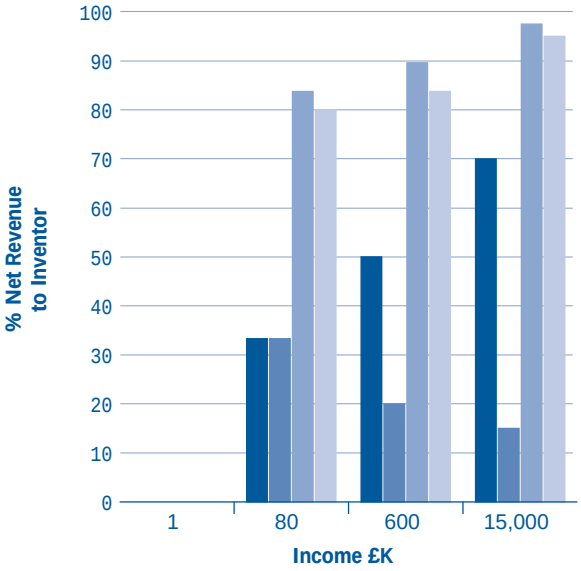
Medical Research Council

Natural Environment Research Council

Biotechnology and Biological Sciences Research Council

NOTES

1. Break points from the Medical Research Council scheme are used (£80,000 then £600,000 and £15 million)
2. Biotechnology and Biological Sciences Research Council rates revised June 2001 and Natural Environment Research Council rates revised November 2001 with discretion up to double the percentage shown. Inventors may receive their percentage based on the gross revenues towards the bottom of the scale (up to £50,000) or throughout the scale for the Medical Research Council.



Medical Research Council Centre

Medical Research Council Unit

Natural Environment Research Council Unit

Biotechnology and Biological Sciences Research Council Unit

NOTES

1. Natural Environment Research Council & Biotechnology and Biological Sciences Research Council do not take any income into the Centre
2. Natural Environment Research Council institute share is the maximum (see note on inventor's share)

Many of those we interviewed consider that this lack of status and recognition is discouraging scientists from involvement in commercial activity, and that insufficient 'kudos' attaches to filing a patent. In general, it appears that the type of science involved in commercialisation - which is generally more about the application and development of research - is not accorded an equivalent status within Research Establishments. Giving adequate recognition to science with a commercial purpose as well as to pure research, for example by enhancing its status in scientists' assessments will encourage scientists' involvement.

2.18 Providing financial incentives both recognises the scientist's unique intellectual contribution and is likely to encourage participation. Scientists responding to our survey said that they are not primarily motivated by the potential to make money for themselves. There is anecdotal evidence from many of those who participated in this study, nevertheless, that visible evidence of the positive impact of incentives on colleagues has changed attitudes. Financial rewards have been welcomed when, as with the spin out of Ardana from the Medical Research Council (see **Figure 15**), they have been applied. The Medical Research Council considers that its income from the licensing of intellectual property began to increase substantially with the introduction of an awards to inventors scheme as part of the Medical Research Council conditions of service and that the number of Medical Research Council Start Up companies was increased after permission was granted for Medical Research Council staff to hold equity stakes in such companies.

2.19 Scientists receive some financial reward for inventions through awards to inventors schemes which operate in all three Research Councils **(Figure 9)**. These transparent and accountable schemes exist to provide financial recognition to all members in a research team whose discoveries lead to financial benefits to their Research Establishment. The 'Rewards to Inventors' schemes are not identical across the Research Councils and differ in the levels of reward from schemes in universities and the private sector. All the schemes follow the principle of giving the scientists a proportion of the receipts received by their Research Establishments.

2.20 The Medical Research Council scheme generally offers the highest levels of return. The Biotechnology and Biological Sciences Research Council paid out over £100,000 in 1998-99 under their previous guidelines and amended their rates on 21 June 2001 by increasing the inventor's share of net receipts between £50,000 and £500,000 to 20 per cent (up from 10 per cent) and retaining a 5 per cent inventor's share of all net receipts above £500,000 (previously halved for receipts above £1,000,000). Following the Baker Report the Natural Environment Research Council has renamed its scheme 'Rewards to Innovators' and increased the levels of reward offered to scientists responsible for innovation. The scheme also gives flexibility to Research Establishments to make the rates for public sector scientists comparable with those offered to university staff working alongside them in collaborative ventures or research projects. The scheme is likely to encourage new ventures because substantial and visible rewards for success are likely to bring about changes in behaviour.

Equity shareholdings can be an appropriate financial incentive to stimulate the successful application of ideas

2.21 The involvement of the originators of a discovery, often called founding scientists, in spin out companies generally increases the chances of success because the scientist's involvement is often necessary to strengthen the commercial case by further developing the science involved. The Government has amended the civil service code to allow scientists to take equity share-holdings within their terms of employment so that they can have a financial interest in the success of the enterprise. Private sector partners encourage scientists to take equity stakes for this reason.

2.22 Scientists' shareholdings are subject to approval by senior management and there is differing emphasis in the approach to equity holdings across the three Research Councils. The Biotechnology and Biological Sciences Research Council and the Natural Environment Research Council allow their staff to invest their own money in start up companies. The Medical Research Council, whose scientists have stakes in some 15 companies, prefers equity to be in the form of consideration for work undertaken for the company, and discourages, on the grounds of the risk involved, direct financial investment by its scientists. Such equity holdings are recorded centrally or in registers of interest (paragraph 2.30).

Commercialisation specialists also need incentives

2.23 Scientists do not generally have business training and cannot be expected routinely to display or to acquire the full range of commercial skills required to commercialise their research. They require support from a professional cadre of commercialisation experts if their ideas are to mature into innovative products or processes. This support exists in some Research Establishments. Plant Bioscience Limited, a technology transfer company specialising in plant and microbial science, jointly owned by the Gatsby Charitable Foundation and the Biotechnology and Biological Sciences Research Council's John Innes Centre, for example has trained staff, often with private sector commercial experience, as does Medical Research Council Technology. Other Research Establishments generally have designated technology transfer officers, who have training on intellectual property rights, but less commercial experience. Partnerships UK can also provide 'on the ground' advice (see paragraph 3.22), but in general there is little commercial expertise within public sector science.

2.24 Commercialisation experts require a full portfolio of business and intellectual property management knowledge allied to the commercial experience to assess opportunities realistically and to negotiate successfully. Such skills are valuable and marketable to private sector companies engaged in similar activities. Commercialisation experts also require significant training or prior experience. Research Establishments and Medical Research Council Technology have suffered from a high turnover of internal specialist staff once trained. To counter this Research Establishments have the flexibility to design appropriate reward packages. The public sector allows pay allowances for specialists such as accountants and others, and public sector staff are often paid modest performance bonuses for success. Medical Research Council Technology is confident that its retention problems have been resolved by the provision of specialist allowances.

Research Establishments can take action to prevent commercial ideas being overlooked or put at risk

2.25 Our survey indicates that most scientists are aware of their role in identifying ideas with commercial potential and that scientists are active in putting their ideas forward in Research Establishments. In some cases a steady flow of ideas with commercial potential has been less forthcoming either because the underlying research offers less scope, or sometimes because it has a lower priority for some Research Establishments. There is a view that the scope may be limited in some Research Establishments sponsored by the Natural Environment Research Council, for example, that collect and maintain data of scientific interest where there is also an expectation that some basic data on the natural environment should be in the public domain. In some such cases, however, scientists in these establishments are frequently engaged in commissioned work based on specialist know-how, and the consultancy

income from such knowledge transfer is important and may cover a fundamental part of establishment costs. There are indications that innovative approaches to commercialising this type of work can be developed, for adding value to the underlying data, or forming marketing joint ventures and strategic alliances. If scientists were provided with a sufficient budget to consider the commercial potential of their research it is possible, therefore, that preconceptions about what is or is not commercialisable might be altered. Providing scientists with sufficient time to consider commercialisation options should therefore be a key issue for heads of Research Establishment when they set budgets.

2.26 Where commercial potential is a possibility, regular assessments of the active research by the leader of each research team and, where possible, by commercialisation specialists, as the best placed people to grasp the implications, will help to confirm whether the commercial idea is practical. Initially until scientists are sufficiently aware of the commercialisation dimension, this could be a major exercise across a Research Establishment and may involve significant up-front resources. Our survey indicates that scientific team leaders are aware of how to obtain initial advice from commercialisation specialists in their Research Establishments. The many and varied demands on the time of commercialisation specialists, however, often mean they cannot be proactive.

2.27 Under current policy, publicly funded research contracts contain provisions to ensure that intellectual property will accrue to the public sector research provider rather than the public sector sponsor. Research Establishments have well developed review procedures for emerging scientific findings although there is no obligation on scientists to patent or exploit their research. Scientists are rightly keen to publish the outcomes of their research as quickly as possible, but there is a risk that this may result in the disclosure of information that may compromise impending patent applications.

2.28 Research Establishments have procedures to avoid this risk crystallising from articles and presentations. In general, these procedures seem to work well for Research Establishment's own staff but sometimes some intellectual property may be placed at risk by pre-emptive publication by other parties such as external academic collaborators. Before the spin out of Prolifix from the Medical Research Council, some intellectual property was published prior to patenting and considerable effort was then required to secure the remaining intellectual property on a basis that provided overall protection.

Conflicting priorities and conflicts of interest that may emerge from commercialisation can be managed

2.29 Responses to our survey indicate that some scientists remain concerned about potential conflicts of interest that may affect themselves as individuals and their Research Establishments as a result of becoming involved in commercialisation. Research Establishments themselves recognise that conflicting priorities may arise for those scientists actively involved in commercialisation projects, for example when scientists' time is unavoidably diverted from core research. Some scientists are also concerned that the confidentiality required for commercial work conflicts with the desire to share research findings openly and puts the impartiality of their advice at risk.

2.30 The Office of Science and Technology has assured us that all Research Establishments have put in place procedures to manage specific examples of conflicts that may arise, based on guidelines they have developed. The procedures are designed to ensure that any potential conflict is registered, considered by senior management in the Research Establishment and that involvement is approved. For example, all equity held by scientists in spin out companies needs to be approved by Research Establishment's management and recorded transparently in a register of interests or centrally held records. The time spent by scientists working for spin out companies is also subject to approval by management. The results of our survey suggested that scientists attach priority to having access to an impartial procedure for challenging specific commercial activities.

2.31 Concern over the diversion of scientists from core research should also recognise that commercialisation requires high quality research to succeed, and for commercialisation to be sustainable Research Establishments must continue to produce such research. Companies founded on research of international standing are more likely to attract substantial funding as demonstrated by the Medical Research Council's Laboratory of Molecular Biology (paragraph 2.2). Research funding and research priorities are not influenced by the prospect of the commercialisation of research outputs. The Treasury has also stated that success in commercialisation will not result in reductions in core research funding, so that an individual Research Establishment need not be concerned about becoming financially dependent on commercialisation income.

Research Establishments can seek out good practice

2.32 Not all commercialisation activity will be successful but good practice lessons can be learned from any project, including where early difficulties have been overcome. As already mentioned, the Natural Environment Research Council has developed an Innovation Fund to provide a source of early funding following initial difficulties experienced prior to the spin out of Evolutec (paragraph 4.3). It is important that the Research Councils should continue to disseminate lessons learned, as the Office of Science and Technology has done, for example, through a successful series of seminars launched in early 2001 covering all aspects of commercialisation.

2.33 The Baker Report included lessons for Research Establishments that were accepted by the Government (Appendix 2). The Office of Science and Technology has disseminated a number of pieces of relevant guidance on such matters as managing conflicts of interest and staff incentives. Partnerships UK, as mentioned in paragraph 1.12, is a public private partnership formed to increase public sector access to private sector resources. Among its goals, on behalf of the Treasury, is the facilitation of the exploitation of intellectual property arising from public sector research (paragraph 3.14). Partnerships UK published detailed guidance on setting up joint venture companies in December 2001. The Research Councils have also developed and disseminated guidance, including handbooks on Intellectual Property produced by the Biotechnology and Biological Sciences Research Council and Natural Environment Research Council. This report also aims to contribute useful information on good practice.

2.34 The Office of Science and Technology sponsors a formal cross Research Council commercialisation group and responses to our survey of scientists show that informal networks also exist. These networks can incorporate universities and the private sector - as happens, for example, with the Biotechnology Partnership Ltd. at the Babraham Institute. This is a joint venture with the universities of East Anglia and Newcastle under the Department's Biotechnology Exploitation Platform Challenge that has been established to promote the aggregation and exploitation of related technologies and intellectual property from the three partner institutions. Such networks can be based on regional or scientific ties, and four other Biotechnology and Biological Sciences Research Council institutes are covered by similar arrangements. Support, including funding, for these networks where they exist and encouragement for their creation where they do not is likely to be an effective way of sharing ideas and good practice and helping to develop a culture that nurtures commercialisation.

Part 3

Successful commercialisation requires supporting capabilities

3.1 All Research Establishments have some scope for commercialisation. The extent of this scope depends on factors such as the nature of the science pursued by the Research Establishment and the level of demand from the market sector in which it operates. Flexibility of approach is therefore important, and different models for commercialisation exist across the three Research Councils. All the approaches require Research Councils and Research Establishments to put capabilities including finance, skilled personnel and appropriate risk management processes, in place. The chosen approach and level of investment in building capabilities should reflect a thorough assessment of the scope for commercialisation in the specific Research Establishments. This section considers the capabilities that Research Establishments need to put in place.

All Research Establishments have some scope for commercial activity

3.2 The nature of a Research Establishment's science affects the scale and type of commercial opportunities available. At first sight, the science of some, such as the British Antarctic Survey, provide reduced scope for spin out companies based on patentable intellectual property, nevertheless opportunities still exist, for example to find commercial applications for their expertise in building robust instrumentation that can withstand extreme conditions. Science that has collected a body of reliable data can develop significant know-how resulting in opportunities for commercial work contracted for by outside parties. Several Research Establishments, including the British Geological Survey, have a significant volume of such commissioned work from the private sector, including the oil industry and this is an important form of knowledge transfer **(Figure 10)**. As well as seeking to obtain full value for the know-how included in such activities, Research Establishments need to consider the balance their overall portfolio of commercial opportunities in the light of policy priorities and the opportunities afforded by the nature of their science base - to assure themselves that commissioned work is the most appropriate commercialisation approach.

Industry and market demand provide good indications of the scale of an establishment's commercial potential

3.3 There is no equality of demand for the science of each Research Establishment. While the the Medical Research Council operates in the human healthcare market sector with significant external demand, the Biotechnology and Biological Sciences Research Council 's Silsoe Research Institute, for example, has traditionally operated in the agricultural engineering sector, where demand in the United Kingdom is lower. Most Research Establishments do not carry out formal assessments of prospective industry demand and do not generally have enough staff to follow a proactive industrial strategy, particularly on an international scale.

3.4 Research Establishments are generally concerned to strike a balance between responding to a thorough analysis of industry demand for products in the field and the broader social and economic goals of commercialisation policy. Industry demand is likely to provide the best indicator of commercial potential. Some Research Establishments have pursued worthwhile ideas with wider benefits where significant commercial applications or demand are not immediately apparent or where they may take a long time to come through. There are examples of such 'technology

10 Common Data Access Limited provides data to the oil industry including the DEAL web site through the British Geological Survey

push' being effective and some spin out companies and licensing opportunities have succeeded on this basis. Gendaq Ltd. is a start up company based on 'zinc finger' transcription factors, a technology that allows the company to specialise in customised regulation of human, animal and plant genes. Medical Research Council Technology considers this to be illustrative of technology push because although there was some market awareness of the scope for regulators in general, considerable new scientific research and development was required to demonstrate that separate and distinct regulators could be custom engineered. But there are also indications that such projects have a comparatively lower rate of success, exemplified by the difficulties they encounter in raising development finance, and they invariably require more effort and time from commercialisation specialists as well as the scientists.

Managing intellectual property and commercial activity on a portfolio basis could bring significant benefits

3.5 An investment made up of a group of assets is called a portfolio. Combining assets with different risk profiles into a portfolio reduces risk because better results tend to cancel out worse results. In accordance with this principle of risk diversification, rational stock market investors hold a portfolio of stocks rather than putting all their eggs in one basket. In the same way, developing a portfolio of commercialisation activity will help Research Establishments to diversify and benefit from successful projects outweighing the failures. There are two distinct portfolios that Research Establishments, individually or in collaboration with others (see paragraph 3.10), could aim to develop; where practical, a critical mass of intellectual property or know-how which they could actively manage; and if this is achieved, a portfolio of commercialisation projects based on different routes to market and incorporating different types of partnership with the private sector.

There is a framework for delegated management of intellectual property

3.6 The Baker Report strongly recommended that intellectual property generated by a Research Establishment should be owned and managed by the Research Establishment itself. The Biotechnology and Biological Sciences Research Council formally delegates the management of intellectual property to its individual Research Establishments and like other sponsoring Research Councils properly retains the right to be consulted on major or novel partnerships, setting a thresh-hold of £250,000 in expected annual revenues for this purpose. The case for building up decentralised expertise at the Biotechnology and Biological Sciences Research Council 's eight specialist institutes, each of a significant size, is reinforced by the different commercial sectors each addresses, ranging from agricultural engineering through agro-chemicals and food to animal breeding and some biomedical fields.

3.7 In the Medical Research Council and the Natural Environment Research Council, patented intellectual property is funded and managed centrally. The Medical Research Council's units (many of which are relatively small teams) are components of one corporate entity so that the Medical Research Council views them as if they form one large Research Establishment for the purposes of intellectual property management and commercialisation. The Baker Report recognised that the centralised approach in the Medical Research Council was effective. The Natural Environment Research Council have undertaken relatively little commercialisation based on intellectual property and retain intellectual property at the centre to make the best use of experienced staff. The precise level to which intellectual property management is delegated appears therefore to be less important than the capacity of the body to manage effectively the intellectual property it owns.

Councils and Research Establishments can achieve a critical mass of intellectual property

3.8 A significant or critical mass of intellectual property allows Research Establishments to take advantage of the incremental nature of most research by pulling elements of intellectual property together and thus providing a more attractive commercial opportunity. It also allows Research Establishments to begin to enjoy the benefits of portfolio management outlined below. In considering the appropriate level of delegation of intellectual property management, Research Councils need not apply a uniform policy to all their Research Establishments.

3.9 Although a single piece of valuable intellectual property can be successfully commercialised by individual Research Establishments it is often easier to commercialise a related body of intellectual property. Partly through centralisation, Medical Research Council Technology unquestionably has realised a critical mass of intellectual property. The potential to develop a critical mass of intellectual property may also exist in some Research Establishments. Babraham Bioscience Technologies, the commercialisation unit at the Biotechnology and Biological Sciences Research Council 's Babraham Institute, aims to build up such a portfolio. The Natural Environment Research Council adopts a centralised approach, recognises that it does not yet have a sufficient body of intellectual property to achieve the desired critical mass, but is confident that this can be achieved.

3.10 Where a critical mass of intellectual property does not currently exist some Research Establishments, even though they are often in competition for grant funding, may benefit from combining to create a significant body of intellectual property. Research Establishments in the same, or similar, market or geographical sectors could consider combining and such collaborations need not be limited to Research Establishments within the same Research Council, and could extend to universities. Research Establishments should also consider whether combining their intellectual property with that of existing centres at, for example, Plant Bioscience Ltd or Medical Research Council Technology could provide benefits through making use of their experienced staff.

3.11 Collaboration of the sort envisaged by the Biotechnology Exploitation Platform, referred to in paragraph 2.34, is at an early stage. There are few examples of actual joint ventures resulting from this initiative or from joint participations in the University Challenge funding scheme. The scheme was announced by the Chancellor in March 1998 as a collaboration between the Government (contributing £25 million), the Wellcome Trust (contributing £18 million) and the Gatsby Charitable Foundation (contributing £2 million) to assist universities in turning research projects into viable businesses. The total funding available was therefore £45m and was increased by a further Government contribution of £ 15 million in March 2000.

3.12 Funding for research programmes often comes from more than one source, and pooling intellectual property would also involve a number of sources. Different sources of funding can have different intellectual property policies and co-ordination is important to ensure that there is clarity about which policy applies and who will lead for commercialisation purposes. The Medical Research Council, where building significant intellectual property packages has often involved collaboration with universities, charities and other Research Establishments, has found that the element of co-ownership or revenue sharing complications has required resolution before commercialisation can take place.

Research Establishments can improve their Intellectual Property management

3.13 Active management of Research Establishments intellectual property portfolios would focus attention on worthwhile opportunities and has the potential to improve the value for money from patent costs. Across the Research Establishments we found that, to minimise patent maintenance costs, there is a general bias towards the abandonment of intellectual property patents if a commercial partner has not been found within a limited period of time, rather than deciding to allow patents to lapse only when they judge that the prospect of finding a commercial partner are no longer sufficient to justify further investment or the costs of maintenance. Medical Research Council Technology does actively manage its intellectual property portfolio in a number of ways as the box below shows:

Elements of Intellectual Property Management in the Medical Research Council

Action	Goal
Development of families of patents derived from different research teams	Combine complementary technologies to enable greater value than that attainable from separate licensing.
Assessment of the potential commercial value versus the cost of prosecuting and maintaining patents	Assess potential and risk of continuing prosecution and maintenance. Stages of patent prosecution and attendant costs provide assessment points.

3.14 Across the Research Establishments, existing and potential intellectual property are reviewed with the individual scientists involved. Reviews consider whether prospective and existing intellectual property have realistic potential for commercialisation and generally rely on the judgement of the Research Establishments' commercialisation specialist. No specific criteria have been developed to assess the potential of the intellectual property either in Medical Research Council Technology or in the Research Establishments that we examined. In Medical Research Council Technology these reviews are guided by the Medical Research Council exploitation objectives coupled with the experience of the Medical Research Council Technology management team. Partnerships UK have been developing guidance in this area, presented in summary form in **Figure 11** overleaf.

3.15 Reviews of existing intellectual property in the Research Establishments do not seek to place a financial value on the intellectual property. Although valuation would in principle provide a benchmark that could inform decisions to retain the intellectual property or allow it to lapse, valuation in practice is a very difficult task. Commissioning valuations can be expensive, and the intellectual property arising from public sector research is based on science that may take several years to reach the market as a product. The cash-flows associated with the commercialisation of any research at this stage of development cannot be predicted with any degree of certainty.

11 Diagram from Partnerships (UK) Proposed IP Management Strategy

Intellectual Property Management

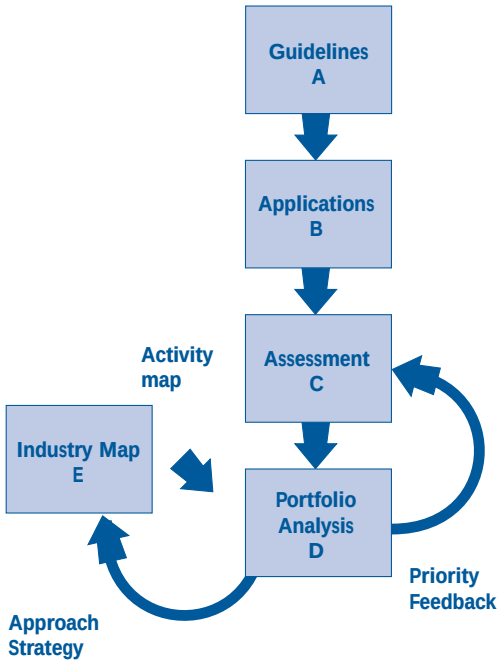
A) Education and Guidelines to Staff
Lab Book System for recording discoveries
Publications versus Patents
Awareness of patent procedure

B) Intellectual Property Right Applications
Logging and recording
Select appropriate type, e.g. patent, trade mark, design, copyright

C) Patent Assessment (repeat at each stage of development)
Ability to protect
Inventor support
Market potential and impact
Likely route to market
Valuation
Fit with existing priorities and portfolio

D) Patent Portfolio Analysis (provides feedback to C above)
Patent assessments at milestone times
New patent priority areas
Selection of key licensing targets

E) Map of Industry/Competitor Activity (informs strategy)
Map own current research strengths
Map competitors strengths
Map industry strengths, activities and wants



Source: Summary adapted from Partnerships (UK) Proposed IP Management Strategy/Partnerships UK

3.16 Although there is a risk that without a valuation Research Establishments may take the view that the intellectual property is worth what the market will pay for it, we do not consider that regular formal valuation of all intellectual property is necessary as a matter of course. Paragraph 4.18 suggests using a systematic categorisation to inform the comparative assessment of projects in a portfolio. There may, however, be circumstances - particularly during negotiations with a potential partner - in which it would be sensible to undertake a formal financial evaluation based on more than one set of market projections.

Research Establishments do not yet manage a portfolio of commercialisation projects

3.17 A well managed critical mass of intellectual property is a pre-condition for a significant, sustainable level of commercialisation. The Research Establishments we examined consider that developing and maintaining a portfolio of different commercialisation projects could have a number of benefits. They are also aware that portfolio management requires a certain level of activity and that many of the Research Establishments - or indeed a Research Council such as the Natural Environment Research Council - do not yet have a sufficient flow of commercialisation projects to facilitate management of a portfolio of projects. Medical Research Council Technology has the most deal flow and also has a variety of commercialisation projects covering licensing, joint ventures and start up companies.

3.18 The potential benefits of managing commercialisation projects as a portfolio include helping Research Establishments to predict cash flows more accurately, allowing planning for more constant income streams and also helping to avoid dependence on the financial and technical success of a single project or investment. Managing a portfolio as a whole would also help to minimise the impact of the inevitable failure of some projects on the Research Establishments' commercialisation programme in a number of ways. Successes would help to offset the loss of sunk costs and anticipated future revenues on those projects that, in spite of rigorous initial evaluation and ongoing risk management, are less successful.

3.19 A portfolio of projects including a mix of different types of commercialisation would also help to develop a balance between, for example, licenses which provide predictable cash flows and spin out companies where the returns may be less certain, and would encourage Research Establishments to adopt only projects that, in the context of the overall portfolio, can fail without

significant consequences. Additionally, it would also help the focus of accountability to be - as the Baker Report recommended - at the level of the overall commercialisation portfolio where one exists, rather than on individual deals.

Research Establishments can ensure that sufficient skills, expertise and resources are available to help turn good ideas into reality

3.20 Successful commercialisation requires Research Establishments to have a broad range of skills, expertise and facilities available. They can develop this capacity in-house or they can obtain it through collaboration or external advice. They also need to devote adequate finance to commercialisation to ensure that this expertise is available and to fund a minimum of pre-commercial activity.

Research Establishments can obtain commercialisation expertise through collaboration and external advice

3.21 Research Establishments can collaborate with other bodies to create a critical mass of intellectual property, skills and resources for commercial activity, or they can seek to develop in-house capabilities. Research Establishments can also make use of external advice and guidance where internal skills are not sufficient. External advisors have been used to help manage the commercialisation activities of some Research Establishments. The Biotechnology and Biological Sciences Research Council 's Silsoe Research Institute developed a partnership with BTG plc, a private sector company with relevant experience and skills, to commercialise their research.

3.22 Research Establishments should be aware of the constraints in which private sector partners may operate - for example, private companies may require a high level of return from projects, which may result in projects with social benefits being overlooked. The Silsoe Research Institute's productive arrangement with the BTG reduced as market conditions required the private sector body to seek projects with the prospect of higher returns than were considered likely from Silsoe. Other bodies such as MVM Ltd (which was established by the Medical Research Council) or Partnerships UK will be seeking commercial opportunities. Partnerships UK, on behalf of the Treasury and with a view to kick-starting the process, is offering free advice on matters, such as choice of commercial vehicle, partner selection and strength of business case to Research Establishments at least until March 2003. To avoid a conflict of interest Partnerships UK does not offer this review service for any project where it intends to play an investment role.

There are costs involved in building commercialisation capacity

3.23 Research Establishments need to devote adequate finance to resource commercial activities such as attracting and retaining commercialisation experts. These experts are expensive to recruit and to train relative to the costs of scientists. Another key financial cost is patenting. We found that, although Research Establishments understand the costs of filing patent applications, there is less appreciation of the cost of prosecution, maintenance and defence in the case of violation. Defending patents will take additional 'fighting fund' resources. Any build up of commercialisation activity would also involve making finance available for external advice on legal, tax and accounting aspects of commercialisation, which is expensive and difficult to budget.

3.24 A key requirement is for adequate finance to cover funding gaps early in the commercialisation process before the involvement of a private sector partner. Research Establishments currently have little 'pre-seed funding' available for commercialisation projects. This pre-seed funding is often necessary to demonstrate to potential partners the link between an invention or a range of intellectual property and the proposed new products or services, often called 'proof of principle'. Our survey indicated that scientists see the limited availability of pre-seed funding as a major barrier to commercial activity, which means that good ideas may not reach potential partners. Even if partners are attracted to an idea Research Establishments may receive less reward or control if the practicality of the idea has not been demonstrated.

Research Establishments have limited finance for commercialisation

3.25 All the Research Councils and Research Establishments that we examined have made some finance available to support commercialisation. Central commercialisation budgets differ in the Research Councils. Medical Research Council Technology, which is responsible for the commercialisation of all Medical Research Council intellectual property, has the largest budget - including £1 million for pre-seed funding that has so far funded experimental work on six projects. The Natural Environment Research Council recognised the need to provide pre-seed funding and set up a small innovation fund of £500,000 for this purpose. The Biotechnology and Biological Sciences Research Council 's Business Innovation Unit has a very small central budget and does not presently provide pre-seed funding although it allocates some £2 million to promote knowledge transfer aimed at commercialisation.

3.26 The Research Establishments have generally administered the available funding well. Innovative programmes have been developed such as the Bioscience Business Plan Competition, organised to raise awareness of business issues amongst the academic community and foster the development of new business ventures, and the Young Entrepreneurs Scheme, training two hundred graduate scientists, both run by the Biotechnology and Biological Sciences Research Council . Participants gain insight into different routes to commercialisation and develop a business plan with the help of a network of mentors. Other Research Councils have followed this example of good practice with their own competitions. The Department, in 1997, supported changes to allow Research Establishments to participate in a scheme now called the TCS scheme (formerly the Teaching Company Scheme) which encourages companies to sponsor two or three year innovation projects carried out by recent graduate staff. Research Establishments have also made some sound investments such as the Medical Research Council Collaborative Centres at Mill Hill and Edinburgh which have been developed to undertake work on ideas with commercial potential from throughout the Medical Research Council and to provide 'incubator' facilities for Medical Research Council Start Up companies.

3.27 One reason for the variations in budget between the Councils is that the Biotechnology and Biological Sciences Research Council devolves responsibility for commercialisation and management of intellectual property to its Research Establishments. This requires individual Research Establishment to allocate funding from their own budgets and the extent to which they do this varies. It is not clear whether the amount set aside for commercialisation reflects an assessment of the scale of commercial opportunity or the choice of some Research Councils or Research Establishments to give greater priority to research funding. The Baker Report recommended that Research Establishments needed to be explicit about the costs associated with commercialisation and some funds allocated if parity of esteem was to be given to the knowledge transfer mission.

The need to finance commercialisation is recognised and some additional funding is available

3.28 The Government has recognised that some additional funding may be needed to support commercialisation. The Office of Science and Technology held a £10 million competition in 2001, called the PSREFund competition, and received bids from Research Establishments and National Health Service Trusts. Up to half this fund was planned to build commercial capabilities in eligible bodies, with the balance intended for pre-seed funding. We believe that these are appropriate priorities and the limited extent of existing finance is indicated by the fact that bids for the fund are greater than the £10 million on offer even though Partnerships UK told us that some likely bidders were discouraged by what they considered the modest amount proposed. Their original recommendation had been a larger annual sum entirely dedicated to seed funding. On the basis of a 50:50 split between the two applications, the PSRE Fund has been over-subscribed by 11:5 for capability building and 13:5 for seed funding. The Office of Science and Technology guidelines for seed funding suggests that investments are made over a three year period. The guidelines recognised that the mission would be different from funds operated in the private sector, which seek to maximise financial returns and requested, however, that funds be managed in a way that ensure a good prospect of continued existence in the long term. Given the length of time taken for commercialisation work to yield a return, venture capitalists commented that this appears a difficult, and quite possibly unrealistic, objective. The Office of Science and Technology will, however, monitor the financial position of the seed fund, allocated £4 million funding after the PSRE Fund competition, with a view to understanding the prospects for the emerging portfolio of investments.

3.29 There are other sources of finance available to Research Establishments. Successful deals will produce income that can be recycled for future commercialisation. In the experience of Medical Research Council Technology and Plant Bioscience Ltd (paragraph 2.23), receipts can be used to build up seed funds to cover this crucial stage in the commercialisation process. The Government also encourages Research Establishments to explore other sources of finance such as those available from Regional Development Agencies, many of whom are working closely with universities, and the University Challenge scheme, which enables universities to establish seed funds to assist the transformation of good research into good business, to date providing some £40 million in two rounds alongside an equivalent sum from charities and university sources. Research Establishments can apply for University Challenge funding as part of a University bid. Information on Research Establishments' success in obtaining funding from these sources, including successful University Challenge bids, and how such funds are spent is not easily available. The Office of Science and Technology monitors funding committed to particular projects through the annual reporting process and makes summary information available at the aggregate level, but not at the detailed level.

Part 4

Realising the potential benefits from commercialisation activity

4.1 The Government has stated that it is encouraging commercialisation for the wider benefits it can bring such as job creation, the development of new products with social benefits and opportunities for UK industry rather than for revenue raising purposes. It has also emphasised that Research Establishments should seek the maximum possible return from commercialisation opportunities that is consistent with pursuing the wider benefits. This section considers how Research Establishments can best approach commercialisation opportunities taking into account the wider goals and the potential for the public sector to benefit financially.

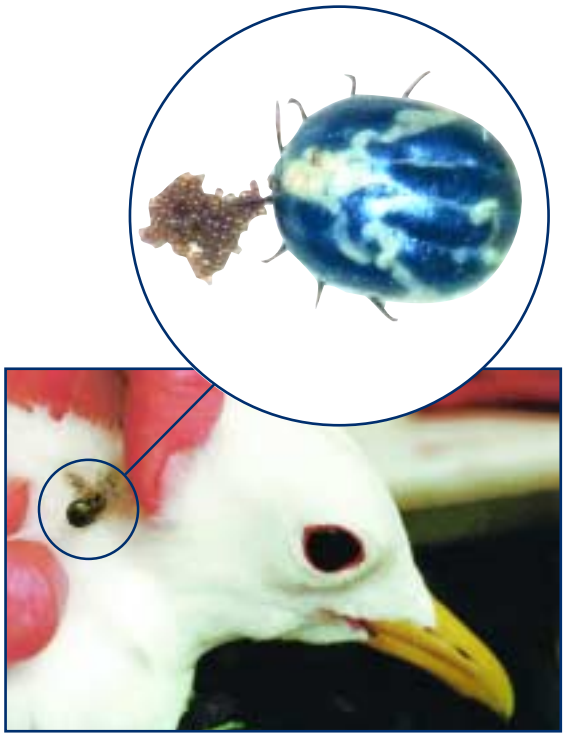
Research Establishments should develop a commercial strategy focusing on the desired outcomes

4.2 A clear focus on the desired outcomes from commercialisation and an understanding of what is appropriate to the market and science involved will help Research Establishments prioritise individual projects. It will also help them select the most appropriate form of commercialisation opportunity, taking into account the potential for social and economic benefits, such as job creation, as well as income.

Commercialisation can lead to new products with real social benefits

4.3 The addition of commercial impetus to public sector science will result in the development of products that may benefit human or animal health which would otherwise be missed. An example of commercialisation resulting in real healthcare benefits is the development of humanised antibodies, meaning antibodies engineered to be accepted by the human immune system which can then improve resistance to infection. This development was based on a Medical Research Council invention for which the first patent was filed in 1986 and which has enabled five new therapeutic antibody products to be launched since 1997, starting with Zenapax, a drug that prevents kidney transplant rejection. Many more are the subject of clinical trials. Another example that currently has promise is Evolutec Ltd.

12 Case example of Evolutec Ltd.



Evolutec was set up to exploit discoveries made by Professor Nuttall at the Centre for Ecology and Hydrology ("CEH") relating to the chemicals in the saliva of ticks. The saliva contains chemicals that control the natural processes in the body that try to stop the tick from feeding, including anticoagulants and anti-inflammatories. A family of highly potent anti-inflammatory proteins was isolated in 1995. The potential benefits include the more effective treatment of complaints such as asthma and conjunctivitis.

Evolutec received encouragement from the Natural Environment Research Council but it is unlikely that exploitation of the research could have gone ahead without external help and finance. A leading independent scientist, the late Dr. John Watermeyer had established a company in a similar area, and he helped the Natural Environment Research Council raise seed funding to extend the scope of the discovery and gain sufficient patent protection. The company has been able to raise venture capital to take forward the development.

Evolutec now operates as a "virtual" company with discovery and screening research being carried out by CEH and overseas by the Slovak Academy of Science. Its first product for the treatment of allergic conjunctivitis is in pre-clinical development.

Commercialisation can help firms to introduce new products to global markets

4.4 Commercialisation can encourage the development of products that give UK research-based firms opportunities to enhance and grow their business by taking their products into global markets, as in the following case.

13 Case example of Prolifix Ltd.

PROLIFIX

Prolifix was set up to exploit discoveries made at the Medical Research Council's National Institute of Medical Research in Mill Hill relating to the control of cell division. These discoveries could lead to new treatments for diseases, such as cancer, which involve uncontrolled cell division.

The company was formed by Professor Nicolas La Thangue, formerly with the Medical Research Council, and Dr. Christopher Hentschel, then scientific director of the Medical Research Council Collaborative Centre, with initial funding from the latter. Rights to the underlying technology were transferred to Prolifix by the Medical Research Council in exchange for a shareholding. The technology has been developed into a 'platform technology' enabling Prolifix to target a range of diseases as opposed to aiming at a single healthcare product.

In exchange for funding six scientists in two major research collaborations on cell cycle control, the UK company has a tri-partite agreement for research, manufacture and marketing the resulting products with Chugai, a Japanese company, in the Far East, and with Eli Lilly and Company for the USA. These two major collaborators co-market products in Europe. Prolifix has raised more than £15 million in share capital and employs over 30 staff.

Commercialisation helps to stimulate investment and create jobs

4.5 Commercialisation can contribute to the overall health of the UK economy by stimulating investment and creating employment in new companies. Among the best-known recent examples of spin-out companies is Cambridge Antibody Technology, one of the 250 largest companies, by market capitalisation, in the UK as at June 2001, employing 260 staff - planned to increase to 300 in 2002. Celltech Group plc, originally a start-up in 1980 based on Medical Research Council technology, as set out in paragraph 1.8 now has 1,150 research and marketing employees.

Commercialisation can lead to additional research funding

4.6 The Government allows Research Councils and their Research Establishments to retain the receipts from commercialisation, to be shared between them as they see fit. The Treasury has also changed its rules on budgeting annuality in recent years, generally allowing departments the ability to carry forward unlimited amounts of end-year flexibility from year to year. The devolution of these arrangements is a matter for departments, but the Treasury would consider it consistent with the Baker Report for Research Establishments generally to have flexibility in spending between years, including the ability to carry forward surplus where there is good business justification. The Government has disavowed any intention to reduce funding support to commercially successful establishments. While all public sector bodies are, of course, ultimately subject to periodic reviews of funding, it should generally be possible, therefore, to plough additional income from commercialisation back into research funding, allowing research projects to be funded that could not otherwise go ahead. Our parallel report on research funded by the Department for the Environment, Food and Rural Affairs examines a notable example at the Biotechnology and Biological Sciences Research Council sponsored Roslin Institute, where the nuclear transfer technology, pioneered by cloning Dolly the sheep, generated such receipts. The Biotechnology and Biological Sciences Research Council also anticipates that, if it is brought to market successfully, the Roslin Institute will earn substantial future royalties from a cystic fibrosis treatment currently undergoing clinical trials.

4.7 In the case of the Medical Research Council, apart from £1 million (which is a small proportion of past exploitation income) allocated in 2001 to a pilot study to validate and enhance the prospects for new commercialisation projects, surplus commercialisation income, after taking into account direct exploitation costs, is ploughed back into general research. The Medical Research Council allows Research Establishments to use a third of the commercialisation income to fund their own research, the remainder is allocated to research by the centre. The Biotechnology and Biological Sciences Research Council and the Natural Environment Research Council permit their Research Establishments to retain all the income from commercialisation, subject to consultation over large amounts, without any reduction in research funding.

Research Establishments should develop a risk management strategy

4.8 As in most fields of commercial activity, a thorough risk-management strategy will encourage well-thought through risk-taking. Although Research Establishments are assessing the risks associated with commercialisation projects they have not yet developed a structured approach. There are strategic risks to the main mission of concern to senior management and the risks on a specific deal that would be addressed by the research scientist and the commercialisation officer.

Research Establishments have a case by case approach to risk management

4.9 Our survey found little evidence that Research Establishments have developed a formal approach to assessing and then managing the aggregate or specific risks associated with commercialisation activity, including the risk of foregoing potential upside benefits. Research Establishments are generally limiting the initial risks to the public sector, however, by selecting commercialisation vehicles - either licensing or limited liability companies - that place the funding burden on the private sector and so reduce their potential exposure in the event of failure in exchange for accepting lower rewards.

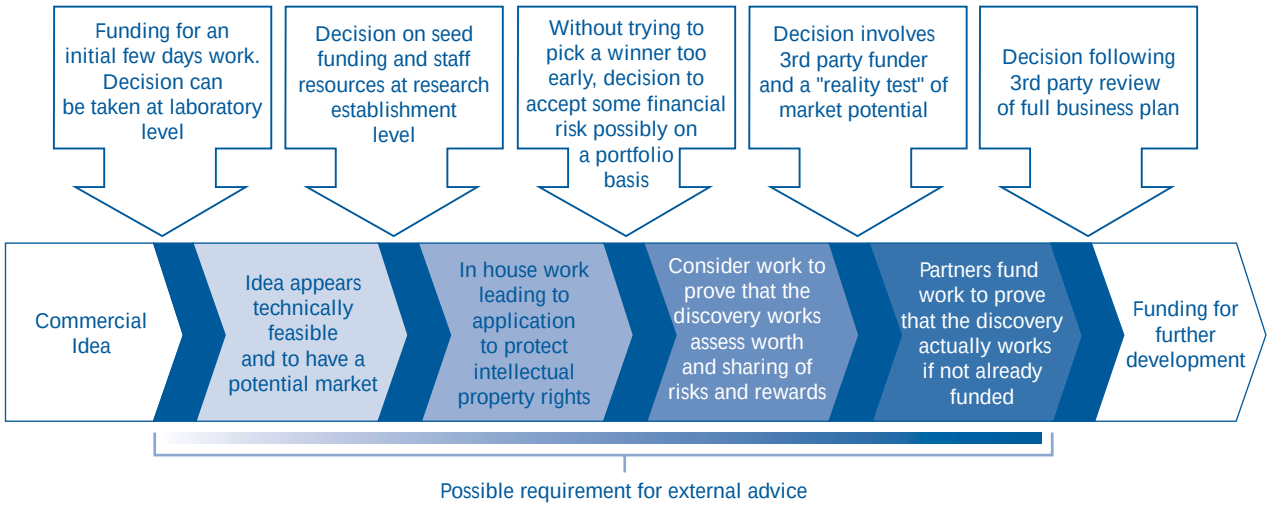
4.10 Currently, decisions on the form of commercialisation and the criteria on which decisions are taken, are largely devolved to the individual judgement of the team leader and the commercialisation officer within Research Establishments or Councils and based on the individuals' experience, although only a minority have had prior business or private sector commercial experience. In the cases we have examined these individuals have usually been the best placed individuals to take such decisions. Although we have no reason to believe they have not been diligent in taking up the internal advice available to them, they are not often required formally to explain their judgements to a management body organised, for example, along the lines of an investment committee. Strategic decisions on Medical Research Council technology transfer operations require approval both by the Board of Directors of Medical Research Council Technology and by the Medical Research Council itself.

Research Establishments should review the risks involved

4.11 Formally considering the risks and opportunities before a project enters each successive stage of development will help to safeguard value for money and the public interest. This should include assessing the potential level of upside opportunity - both financially and otherwise - under a range of market scenarios to ensure that, where appropriate, the public sector develops a robust negotiating strategy. While carrying out this examination we did not find an example of a formal risk assessment in a commercialisation project. Our report on Risk Management in Government Departments (HC 864 published August 2000) gave an example of how Glaxo Wellcome integrates risk management into its internal systems, reproduced in Appendix [4] of this report. Although Glaxo Wellcome, since merged into GlaxoSmithKline plc, has a very different mission to the Research Establishments there is some read across for some of them, for example, on quality control, clinical trial assurance and the opportunities that may arise for innovation.

4.12 A series of decision gates as shown in **figure 14**, where the specific opportunity is subject to formal management assessment of the value of continuing, may help Research Establishments to focus on key risks at key points in the process. The benefits of a formal approach would include greater assurance that potential had been assessed in a systematic way and that individual deals continued to fit within an overall strategy. This approach is compatible with the approach to managing intellectual property described by Partnerships UK (**Figure 11** see page 30).

14 Illustrative decision gate system for Commercialisation



Source: This illustration has been taken by analogy from the private sector - further details can be found in Robert G Cooper's standard textbooks on the subject of the StageGate process for managing corporate product development projects.

15 Case example of Ardana Bioscience Limited

A successful 1999 quinquennial review of the Human Reproductive Science Unit (HRSU) science, awarded the unit £17 million of funding over 5 years. In addition, about £2 million is generally raised from other sources.

- three quarters of HRSU programmes address particular problems, but are not limited to a particular targets although some may have commercial relevance.
- a spin-out company, specialising in woman's health, has been created drawing on intellectual property developed from the highly rated scientific research of HRSU as well as intellectual property purchased from third parties.
- prior to the creation of Ardana, HRSU had three patent applications - all relating to biology. One of these addressed an important gap in the knowledge of the reproductive cycle, but had failed to secure lasting commercial backing. The other two have proven to have little commercial relevance and have subsequently been abandoned.
- Ardana, based on commercial funding of £14 million, aims to discover, develop and market products for better reproductive health. After some fifteen months, based on intellectual property from HRSU and third party sources, Ardana claims an early-stage pipeline of 15 projects.

The deal is large and novel because Ardana has first option to rights to all HRSU discoveries for 5 years (not just improvements of technologies licensed at start-up), potentially benefiting from intellectual property which might arise from research funded by HRSU in the future. Initially the Medical Research Council has under 10 per cent of Ardana equity (100,000 shares of 1.1 million), but is due royalty provisions and 10,000 shares where options are exercised in the fields of:

- Gonadatrophin Releasing Hormones
- Angiogenesis
- Immuno-modulation and inflammation
- Anti-inflammatories
- Any other agreed areas

- Two leading HRSU scientists have been allowed equity in lieu of cash for consulting on behalf of Ardana - and each can use part of their Medical Research Council time on such consultancy. Nine other staff also hold share options. Unit scientists are permitted to have third party collaborations in their area of research that do not compromise the rights of Ardana.
- The Director of HRSU is required to refer to the Medical Research Council 's Executive Director any decisions relating to the Unit where he may have a conflict of interest, particularly to ensure that research follows the agreed scientific programmes.

4.13 It is sensible in general for senior and top management at the relevant Research Council, to be involved early and approve major or novel deals, in accordance with agreed internal guidelines of the Research Council and the relevant Research Establishment. As the level of activity increases and with the benefit of experience, there is scope for guidelines to be made more specific. An example of a deal novel enough to warrant Research Council top management involvement in considering its policy implications would be Ardana Bioscience Limited because it allowed options to outputs from the science from an entire Medical Research Council unit, the Human Reproductive Science Unit (HRSU), for a period of five years. The formation of Ardana and the associated input of market knowledge from the private sector has successfully generated an upsurge in commercial activity and was carried out under the delegated authorities of Medical Research Council Technology and the HRSU **(Figure 15)**.

Research Scientists are aware of non-financial risks

4.14 Our survey identified widespread awareness among scientists of non-financial risks, such as conflicts of interest, that could be incorporated into a risk management strategy. We also found that the moral hazard risks, for example the non-financial risks to the public sector of being a minority partner in a field of research that may be controversial, are being addressed on a case by case basis and similar risks will be examined in more detail in the parallel report referred to in paragraphs 6 and 1.16. Other business risks that may ultimately have unpredictable financial consequences should also be considered as part of the decision on the form of commercialisation. The example of potential legal liabilities, akin to those arising from the prescription of thalidomide to pregnant women after limited trials in the early 1950s, may be less relevant in this context since lessons have been learnt about the need for an extensive scale of planned clinical trials and tests looking at toxicity and side effects. Some risks, for example those associated with the failure of a venture, can be minimised by developing exit strategies and writing surrender clauses into projects in such a way that Intellectual Property rights will then revert to the public sector.

Research Establishments can make the most of the intellectual property they commit

4.15 Assessing the potential uses of the intellectual property or know-how involved can help in understanding what would be an appropriate balance of risks and rewards. To negotiate good deals Research Establishments need to produce credible business cases that include assessments of this - including the trade-offs between taking rewards in equity or up-front income, and trade-offs of outcomes - and that focus on the uniqueness of the intellectual property involved. **Figure 16** illustrates some of these trade-offs.

4.16 With the exception of Medical Research Council Technology and Plant Bioscience Limited, we have found little evidence that Research Establishments review the potential to build attractive packages of intellectual property. Private sector partners are, however, attracted to

16 Opportunities arising from intellectual property rights

Action	Risks	Opportunities
Apply for patent(s)	Small sunk cost	Gain time to develop opportunity
Take out patent(s)	Non-refundable costs	Exclusivity, build portfolio
Assign intellectual property to spin-out	Lack of competition	Take research forward with exploitation targets
Sell rights to future intellectual property	Little guide to value and may impact on other funders?	Raises extra funds early Vehicle to package IP
Sell an 'option' to buy future intellectual property	Third party's right to re-bid may inhibit competition	May secure a better deal from a better placed party
Take equity stake	Depends on level/dilution balanced with partner's strength	Sponsor may become a partner
Negotiate royalties	Licensee may not exploit	Undiluted earnings stream
Agree to secrecy	Less dissemination and open debate of the science	Protects potential value

Source: National Audit Office

developing "families" or "platforms" of intellectual property because this implies greater value to be unlocked, and spreads the product risk. Some Research Establishments may not be in a position to replicate this approach because of the expense involved in full filing for a series of related patents, and would, therefore, only do this if they had a clear commercial goal in mind. The approach followed by the Babraham Institute's trading company appears well matched to its situation, as holder of a relatively small portfolio and **Figure 17** shows how this can be managed.

4.17 The worth of the intellectual property will be tempered by the fact that the public sector is generally, by design, taking little management or financial risk in these deals. As a result, the balance of financial rewards and of management control will be biased towards the private sector funders and founders who are taking the greater financial risk. Financial rewards should be distributed accordingly and reflect the contribution made by both parties as well as the relative risks born. Except for limited investments of "seed money", a public sector portfolio could be expected to contain projects which are largely low risk, low return - often because of perceived non-financial benefits - and medium risk, medium return. This concept is illustrated by the charts A and B overleaf.

4.18 The evidence available to us in the course of this examination suggests that there is little formal assessment of the value of the intellectual property involved. There is, therefore, a risk that the public sector will tend to accept the private sector's valuation in the absence of any other benchmarks. Assessing the worth of intellectual property is difficult, and precise valuation is unrealistic, nevertheless, a systematic categorisation can inform the comparative assessment of projects in a portfolio. Categories, for example, may include: therapeutic area, market potential, competition, cost of manufacture (if knowable), complexity of development and time to market.

17 Case example of Babraham Bioscience Technologies

Babraham Bioscience Technologies is working towards a portfolio of inter-related patents rather than a disparate set of protected technologies, to enable it to offer depth to its commercial opportunities platform. The approach looks to address issues deriving from the need to protect intellectual property that in many instances covers opportunities that are far from market. A decision to file at such an early stage is often based on an incomplete picture of the opportunity and indeed incomplete supporting data. In commercial terms such opportunities would be considered too early, but timing needs to be balanced with the need to publish. Thus, if intellectual property is perceived to have potential commercial application an UK patent application will be filed in order to gain a priority date. Delivery of the utility defined in patents and identifying commercial potential over a 24-30 month period is then key to the process and if this cannot be recognised patents may be allowed to lapse. The objective is to maintain the portfolio as a vibrant source of opportunities for exploitation.

4.19 Research Establishments should consider using independent expertise, especially in cases where there might be a potential conflict of interest, or at times when expertise available from the Research Council is over-stretched. In the view of one Research Council's commercialisation officer, the public sector should have access to sufficient resources to get, at least, to the point where relevant intellectual property is protected, there is an understanding of the potential market and some technical feasibility work is done. If this is not achieved, the Research Establishment is disadvantaged when entering into negotiations with third parties, including sources of external finance.

Research Establishments should consider options and develop an appropriate and cohesive negotiating strategy

4.20 There is not always an array of partners eager to acquire the technology in question. In constructing deals, Research Establishments would benefit from seeking a choice of partner pro-actively, creating a choice where possible, and thinking carefully about what would be an appropriate negotiating strategy. A sound negotiating and commercial strategy depends on an understanding of the aims of potential partners. This becomes even more important in the absence of choice or when competitive tension is limited. Our report on 'The Radio communications Agency's joint venture with CMG' (HC 21 December 2000) identified four high level factors that are important for building co-operative and collaborative partnerships:

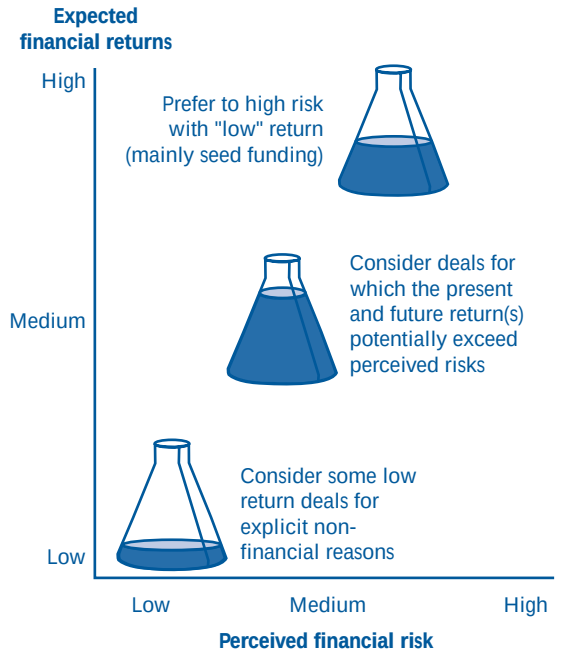
- the alignment of strategic business interests meaning that both partners would have the same business objectives for their joint venture;
- each party having a clear understanding of its role and obligations in the partnership;
- the establishment of a trust based relationship with open book accounting and backed up by contractual protection; and
- each party being satisfied with the risks posed by and the share of the benefits from the partnership.

Experienced negotiators are likely to help achieve the desired outcomes and a co-operative and trust based relationship between public sector scientists and their private sector partners. Evolutec, discussed in paragraph 4.3 benefited from advice from a central resource at the Research Council. Such expertise, however, is thinly spread. Where it is not available it may be worthwhile employing external expertise, as mentioned in paragraphs 3.20 to 3.23.

4.21 Although it will be important for scientists to buy into the eventual outcome of commercialisation negotiations, and be satisfied that their scientific and technical input has been fully considered, it will not normally be appropriate for the founder scientists to lead the commercial negotiations. We note that in the USA the National Institute for Health forbid their scientists' participation in such negotiations, and that the view of the Medical Research Council is that the commercial negotiations should be led by a central expert group, not usually the scientists involved. There is, however, a case for independent advice being made available to the scientists involved to help them understand their future role, and the basis of their share in the expected rewards from what is likely to be an unfamiliar commercial arrangement. If they accept at the outset, on a well-informed basis, that they have been recognised appropriately, this will avoid future resentment so that they will remain fully motivated to take forward the scientific aspect of commercial development and so contribute to the success of the venture.

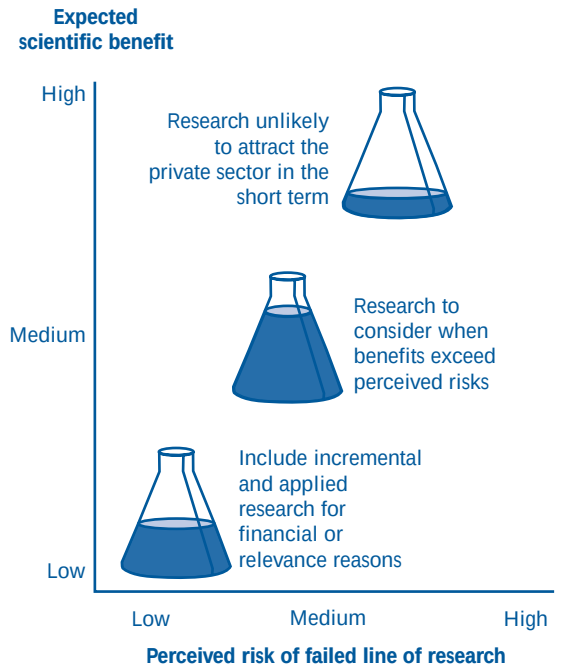
An exhibit for plotting individual projects
(beakers are suggested averages)

A Chart for mapping portfolio returns against risk



The following exhibit sets out some of the science-related parameters that may also have a bearing on risk assessment and portfolio selection.

B Chart for mapping scientific benefit against risk



Appendix 1 Methodology, parties consulted, and survey findings

Methodology

- **Review of the Baker survey:** Baker surveyed a majority of Research Establishments. We reviewed the available returns to establish a baseline for the varying levels of experience of commercialisation.
- **NAO survey of officers and institutions involved in commercialisation:** Our survey followed on from Baker's survey and was based on the issue analysis that we had developed. The aim of the survey was to obtain the views of a sample of those involved in commercialising research at a middle management level in the Research Establishments. The survey did not focus on individual deals, but covered barriers to and facets of commercialisation activity covering all three of our main study issues. Further details on the survey are provided later in this Appendix.
- **Case examples of commercial ventures in progress and those already completed:** The case examples were based on semi-structured interviews, some carried out by our consultants, and covered the views of those involved at the Research Council and Research Establishment from senior management to individual scientists and, where relevant, the views of potential or actual private sector partners.
  - Babraham Institute and Babraham Bioscience Technologies
  - Biotechnology and Biological Sciences Research Council
  - British Geological Survey
  - Centre for Ecology & Hydrology and Evolutec Ltd.
  - Human Reproductive Science Unit and Ardana Biosciences Ltd
  - Institute for Animal Health
  - John Innes Centre and Plant Bioscience Ltd
  - Medical Research Council Technology Ltd
  - MVM Venture Capital Fund
  - National Institute for Medical Research and Prolifix Ltd.
- **Literature and Internet searches:** The scientific community publishes extensive findings on topics related to this study that enhanced our understanding of current practice in the UK and internationally.
- **Semi-structured interviews with public sector bodies involved in commercialisation and with external experts on taking research to the market:** Interviews covered the Office of Science and Technology, the three Research Councils that have Research Establishments undertaking commercial activities, and key staff at other Research Establishments. These interviews confirmed and validated our understanding of what Research Establishments have been asked to do and the results achieved to date. We also met a range of leading participants who commercialise research and/or provide venture capital in order to understand the market environment, including Partnerships UK, 3i, and BTG.
- **Consultants:** Our consultants, Morgan Harris Burrows, provided expert advice on issues of management and valuation of Intellectual Property, maintaining competitive tension in a deal, and the structuring of deals. The consultants also made recommendations for benchmarking commercialisation practices of Research Establishments against good practices in the universities and the private sector, and undertook case studies.

Interviewee	Organisation	Purpose of Interview
Dr. Doug Yarrow, Director	Biotechnology and Biological Sciences Research Council, Swindon	Review of commercialisation policy
Mr. Philip Rutnam	Her Majesty's Treasury	Intellectual property guidelines
Dr. Michael Duggan	OST	Paper for first of three PSRE seminars
Dr. John Taylor, Director General of Research Councils Dr. Frances Saunders, Dr. Stephen De Souza	OST, London	OST objectives and oversight of the commercialisation initiative in the Research Councils
Dr. Mike Tricker, Dr. Jane Metcalfe	Natural Environment Research Council, Swindon	Natural Environment Research Council views on commercialisation
Dr. David Owen, Dr Martin Wood	Medical Research Council Technology	Medical Research Council views on commercialisation
Mr Jo Taylor	Venture capital finance with 3i	Financing early stage research deals
Mr. Martin Sandford	Technology Transfer at BTG	Patents and management of intellectual property

Key: Office of Science and Technology (OST), Research Establishment (PSRE)

Expert Panel Members:

Our panel, including members from other areas of the National Audit Office, met on 1st August 2001 and provided advice on the issues covered and aspects of our findings.

External panel members were:

Sir David Cooksey	Chairman, Advent Venture Partners
Dr Edward Dart	Chairman, Plant Bioscience Ltd
Mr. Owain Ellis	Partnerships UK Ltd
Dr. Richard Jennings	Director of Industrial Liaison, Cambridge University

National Audit Office Survey Findings

We surveyed research team leaders to obtain information about their views

1. The aim of the survey was to gather information from research team leaders at Research Establishments who are, or who had the potential to be, engaged both in core scientific research and in commercialisation activity exploiting intellectual property. We sent the survey to 155 staff at research establishments throughout the three Research Councils covered by this report. The majority of these staff were scientists and research team leaders, including some senior scientists with management responsibility for Units or Research Establishments. We also included some commercialisation specialists who were scientists by training.

2. The questionnaire was split into seven sections: about the respondent - background and role; the commercialisation framework; managing intellectual property; the commercialisation process; barriers to successful commercialisation; managing risks and conflicts of interest; and sharing and evaluating success. In the main, we asked respondents to provide answers based on their perspective of the position in their establishment only, although some of the discursive questions encouraged a more broad-ranging response. We have not reproduced the full questionnaire in this appendix but paragraphs 7 to 15 summarise the questions asked and some of the responses received.

The survey was sent by e-mail to scientists in each Research Establishment covered by our study

3. We e-mailed the questionnaire to the individual scientists in three batches, representing staff in each of the three Research Councils, in June 2001. The possible populations for the Biotechnology and Biological Sciences Research Council and the Natural Environment Research Council were all those scientists identified by the Research Councils and their Research Establishments as being research team leaders or the equivalent. The population for Medical Research Council scientists was provided from central information notified by Medical Research Council Technology Ltd. We stratified the sample to ensure that the survey was sent to randomly selected members of each Research Establishment in the Biotechnology and Biological Sciences Research Council and the Natural Environment Research Council and staff from a number of Units from across the Medical Research Council. The only exception was the Roslin Institute in Biotechnology and

Biological Sciences Research Council, which is not covered by this report because it is covered extensively in our further report on the commercialisation of research sponsored by the Department for the Environment, Food and Rural Affairs and we did not wish to overburden that institute with contemporaneous studies. We sent the survey to 48 scientists in the Biotechnology and Biological Sciences Research Council, to 39 scientists in the Natural Environment Research Council and to 66 scientists in the Medical Research Council, reflecting the different sizes of the populations and the desire to achieve broad coverage across a number of Medical Research Council Units.

4. Before undertaking the survey we had discussed the content of the questionnaire with the Directors responsible for commercialisation in each of the three Research Councils. We had also amended the questionnaire following responses to a pilot carried out with a team leader from the Medical Research Council. These discussions helped us to understand more about the relevant issues to cover in the questionnaire, in particular some of the possible barriers to commercialisation success. Once the survey had been sent out to potential respondents staff from the National Audit Office operated a telephone and e-mail based help-desk to provide any assistance required in completing the questionnaire. The questionnaire was designed to be completed in 30 minutes.

We received and analysed a total of 67 returned questionnaires

5. Following our initial cut-off date of 5th July we sent reminder e-mails to encourage additional responses. In total we received 67 responses which were valid and formed part of our analysis. This represents a response rate of 49%. Our survey was designed to produce information that would feed into the next stages of our study and this response rate was sufficient for this purpose. The number of responses from individual research establishments was limited and so we performed our analysis at the level of the research councils. However, because of the limited number of responses overall we have chosen to refer to amalgamated results for all three research councils in the body of the report.

6. The results of the questionnaire were used to inform our further work examining individual cases of commercialisation activity, to build up interview programmes and to help us develop our thinking on key issues. We have sought to indicate a few of the issues arising from our analysis of responses where relevant in this report. We coded written responses to discursive questions to identify common themes emerging from responses. Individual responses have not been disclosed to the management of research institutes or to the Research Councils themselves.

We asked about the background and commercialisation experience of our respondents

7. We asked the scientists to summarise their current main areas of research and to provide a percentage estimate of the relative proportions of funding provided from various sources. Respondents confirmed that the majority of their funding was provided by the relevant research council, although the proportions of funding varied between the research councils, with Medical Research Council researchers receiving proportionately more direct research council funding than other respondents. There was evidence of private sector funding across all three research councils. We also asked scientists about the extent of their involvement in commercialisation projects. Respondents from all three research councils had some commercialisation experience, including licensing and spin-out companies, with Medical Research Council researchers having relatively more involvement in these types of commercialisation projects.

Respondents knew that commercialisation was part of their role and mission

8. We asked the scientists whether they believed commercialisation to be a key and a formal objective within their organisation and to rate a number of potential benefits of commercialisation activity for themselves as scientists and for their organisations. Just fewer than 70 per cent of respondents agreed that they did see commercialisation as a key objective for their organisation - a proportion that was stable across all three research councils. Over 90% of respondents believed that their organisation did have a formal objective designed to encourage the commercialisation of research. When considering the potential benefits of commercialisation, the scientists most frequently mentioned the following benefits as most important for themselves and their organisations:

Rank	Benefit to Scientist	Benefit to Organisation
1	Continuation of funding for research	Meeting commercialisation objectives
2	Seeing an idea become reality	Continuation of funding for research
3	Scientific prestige	Financial gain from income generated

Respondents were asked about their organisation's approach to intellectual property management

9. A majority of scientists believed that regular reviews of existing and potential intellectual property take place in their organisation. They recognised the need to be involved in these reviews along with commercialisation officers and senior management. A majority of respondents also believed that they, as research team leaders, were responsible for and best placed to identify the commercial potential of original research or intellectual property generated from their work. Commercialisation specialists, either at the research establishment or research council level were also seen as having important roles in identifying research with commercial potential. Around 60 per cent of respondents were confident that research projects were reviewed to consider whether there was the possibility of patent applications. Around 90% of our respondents were aware of available help or guidance on intellectual property ownership, valuation or protection.

Respondents demonstrated some knowledge of the commercialisation process

10. We asked scientists to identify the key stages in the commercialisation of research activity and what activities might be undertaken in those stages. We also asked scientists to consider what assistance they might require at each of these stages. Scientists' responses to these questions were helpful in framing our understanding of the process and in developing our interview questions. Our respondents recognised that it was important to actively consider the commercial potential of their research prior to the publication of results and some scientists said that they would consider the commercial potential of the research when applying for funding. Over 70 per cent of our respondents also believed that either some or most of the research undertaken in their organisation could have commercial potential, with a majority believing some or most research identified as having commercial potential would result in licensing and collaboration with industry. Fewer scientists expected Joint Venture or spin out companies to be likely outcomes.

We asked scientists about barriers to success, advice and working with private sector partners

11. We asked the research team leaders to consider which of a number of potential barriers to the successful commercialisation of research they thought were the most significant. The most frequently mentioned of the potential barriers were: the lack of either public or private funding at the beginning of and during the process; the inherent unsuitability of the research; the conflict with the desire to publish findings; and the lack of recognition for commercial activities. In response to a specific question about career path of scientists around 70% of those replying suggested that the primary path of scientific advancement discourages attempts to commercialise research. Our respondents did believe that people in their organisations were likely to be able to adapt if they became involved in a commercial scenario, but most recognised that they would require advice to assist them. They also thought that such advice was available, primarily from fellow scientists or from commercialisation specialists either in their own establishment or in the relevant research council. Across the three research councils our respondents were evenly balanced as to whether the amount of commercialisation training they received was about right or too little.

12. We also asked the scientists receiving our survey to consider the extent to which people in their organisation might experience significant cultural differences between the approaches adopted by public and private sector partners in a commercialisation project. Around 90 per cent of our respondents thought that this would be the case to some or a large extent. We summarised the comments of respondents on the main areas of cultural differences and the most frequent themes were that the public and private sectors had different objectives, including the perception that the private sector profit motive was incompatible with a scientific desire to benefit society. Other themes included: the concerns about confidentiality restrictions on intellectual property and the need for public sector scientists to publish their work to obtain recognition; the perceived private sector focus on rapid results and short-term planning; and the limited nature of the applied - rather than pure - research associated with commercial research.

Risk management and conflicts of interest were considered in the questionnaire

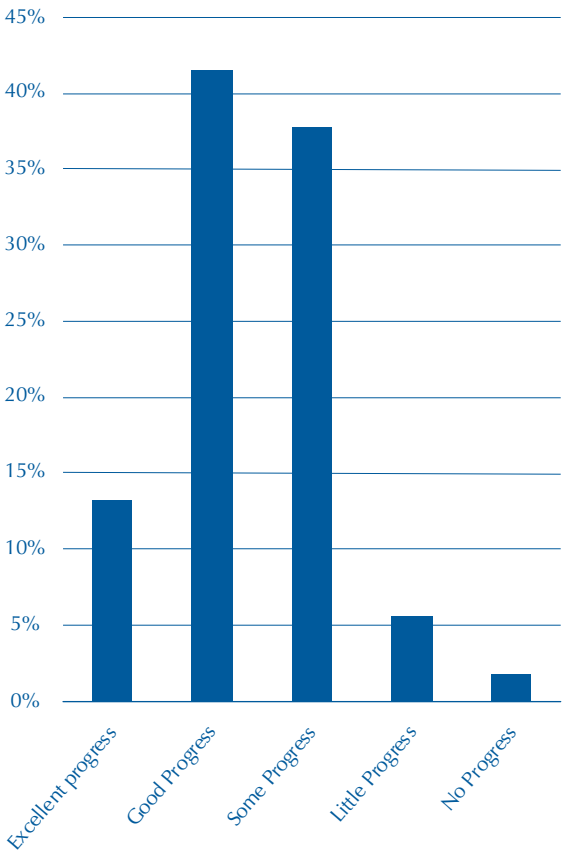
13. Respondents were asked about their perceptions of how their organisation considers the risks and potential conflicts of interest involved in commercialisation. More respondents believed that their organisation had a policy for managing or reporting the risks involved than did not believe this to be the case, but no clear picture emerged. There was a very limited awareness of whether a risk management approach was applied either to individual projects or on a portfolio basis. In general, our respondents believed it was for commercialisation specialists and senior managers to identify and manage the risks associated with commercialisation projects.

14. There was a degree of variation between respondents from different Research Councils about whether or not their organisation had a framework in place to manage potential conflicts of interest, with scientists from the Medical Research Council most certain that such a framework existed. To identify commonly perceived elements that are - or should be - part of these mechanisms for managing conflicts of interest we summarised the written comments provided by scientists. The most common mechanisms referred to were internal review and scrutiny of individual projects; ensuring that projects had a strategic fit with the core aims of the organisation; and an open policy of disclosing interests to safeguard the impartiality of advice. Respondents also mentioned the need to seek advice from governing bodies and to consider separating research and commercial activities.

Respondents had positive views about the progress of commercialisation

15. Respondents did not seem to be clear about how the success of commercialisation projects would be assessed, but in response to two summary questions most replies provided positive responses about commercialisation. The majority of respondents (just over 55%) considered themselves to be supportive of or enthusiastic about commercialisation with just over 10% declaring themselves to be either uncertain or sceptical - the remainder were neutral. **Figure 18** shows all responses from respondents asked to rate their organisation's approach to commercialisation:

18 Scientists views of their organisation's approach to commercialisation



Appendix 2

Baker Report Recommendation	Government Response
Risk Management:	
■ Treasury and the Office of Science and Technology should work with the NAO and the Public Accounts Committee to promulgate an accountability framework for commercialising public sector research which emphasises portfolio risk management and transparency of operation rather than incentivising risk avoidance.	The Government welcomed the statement by the NAO that we will adopt an open-minded and supportive approach to commercialisation by Research Establishments, focussing on their commitment to exploitation, the quality of their risk management, and the lessons that can be learned for Research Establishments as a whole.
Commercialisation & Knowledge Transfer:	
■ All Government purchasers of public sector research should have as part of their research mission the explicit objective of transferring research outputs to the wider economy; this should be explicitly reflected in all contracts.	The Government will ensure that by the end of 2000, all relevant departments and Research Councils, in partnership with Research Establishments, have produced timetabled action plans for ensuring that Research Establishments can effectively pursue knowledge transfer activities. These plans will address the need to have: ■ An explicit knowledge transfer mission ■ Necessary financial freedoms ■ Control and ownership of intellectual property ■ Access to necessary skills and advice ■ Personal incentives for staff
■ Research Establishments themselves should have knowledge transfer as an explicit part of their mission. The knowledge transfer objective should be embodied in the job description and personal objectives of the chief executive and be seen as his or her personal responsibility. It should be cascaded through the personal objectives of senior management and scientific staff.	
■ Chief executives should be required to develop, implement and secure staff support for a strategy for identifying and realising opportunities for translating research outputs into wealth creating products and processes. In particular these strategies must address the management systems that will support the commercialisation effort, acquisition of the necessary market knowledge and the management of conflicts of interest.	
■ Chief executives should develop performance measures and targets against which their knowledge transfer efforts can be assessed.	
Ownership of Intellectual Property:	
■ Property generated by an establishment should be owned by the establishment and assigned by authority of the chief executive, unless effective alternative arrangements already exist.	The Government believes that control & ownership should go together, and that Research Establishment Directors would normally be vested with these responsibilities. Draft guidance on the handling of intellectual property will be published.

Baker Report Recommendation	Government Response
Financing and Retention of Receipts:	*The responses cover*
■ Some Research Establishments lack the freedom to maintain and deploy surpluses despite the Treasury's guidance on Wider Markets that public bodies should be allowed to retain their receipts from commercialisation activities.	■ The Government accepts this recommendation.
■ Arrangements for dividing the proceeds of commercialisation between Research Establishments and their parent Research Councils should err on the side of generosity and provide proper incentives for the institutes.	■ Arrangements for dividing commercialisation receipts should provide a proper incentive to Research Establishments.
■ Departmental Research Establishments should be put at greater arm's length from Government departments. Ministers should consider how this should best be done for each of these Research Establishments, with the presumption in favour of a move to less central control.	■ The Treasury & OST will keep under review the case for putting departmental Research Establishments at greater arm's length from government and will ensure it is examined thoroughly in the next Prior Options Review of Research Establishments.
■ In agreeing future income streams with parent bodies and other purchasers, Research Establishments should be explicit about the costs associated with implementing a knowledge transfer strategy. Government must be prepared to meet these costs if it wants to give parity of esteem to the knowledge transfer mission. Government should consider earmarking some funds to meet the costs of knowledge transfer in the Research Establishments.	■ Research Establishments will have enhanced access to government schemes for knowledge transfer. Sponsors of Research Establishments will be required to demonstrate that knowledge transfer activities are adequately resourced. The Government has also agreed to make £10 million available to help bridge the gap in finance for seed investments.
Incentives:	
■ As an immediate priority Ministers should review the application of the civil service management code to the special circumstances of science commercialisation. The effective bar on certain forms of direct participation by serving Government scientists in the commercial exploitation of their research - in particular receiving equity or share options - should be removed.	Changes to civil service conduct rules to allow government scientists new incentives and rewards, subject to safeguards, for participating fully in exploitation have now been made. Guidance has also been produced on staff incentives and the management of conflicts of interest.
Access to Commercialisation Expertise:	
■ Ministers should consider creating a small expert unit within central Government to drive forward the knowledge transfer agenda - and provide advice, help and encouragement to Research Establishments and their sponsors on knowledge transfer.	The Government recognises the need of Research Establishments for advice to help them commercialise their discoveries and inventions; and this includes a role for Partnerships UK.

Appendix 3 National Audit Office Press Notice

Commercialisation Activities by Public Sector Research Establishments

9 November 1999

The NAO has announced today that, in line with its encouragement of worthwhile innovation in the public sector, it will support well thought through risk taking and experimentation in the exploitation of research by public sector research establishments.

Mr John Baker's report "Creating Knowledge, Creating Wealth" welcomed the statement of the Public Audit Forum, which includes the National Audit Office, that they do not want fear of the risk of change to stifle worthwhile innovation designed to lead to improvements. Commercialisation is still of course in a formative stage and in the typical case the establishment is likely to be developing a range of deals, each of which will incur some cost and some risk. As recognised in Mr Baker's report the National Audit Office, in line with the statement of the Public Audit Forum on the implications for audit of the Modernising Government Agenda, will:

- Adopt an open-minded and supportive approach to innovation (including the use of techniques tried elsewhere), examining how the innovation has worked in practice and the extent to which value for money has been achieved;
- In the process, support well thought through risk-taking and experimentation; and,
- Consistent with their independent role, provide advice and encouragement to management implementing Modernising Government initiatives by drawing on their audit work in this area, seeking to identify and promote good practice so that experience can be shared and risks minimised.

In these ways we believe auditors can support and encourage worthwhile change, while providing independent scrutiny and assurance and fulfiling effectively their statutory and professional responsibilities.

When examining commercialisation activities in public sector research establishments, and in keeping with this approach, the National Audit Office will be addressing in particular:

- Whether the establishments concerned have adequate procedures in place for identifying and developing research outputs with commercial potential;
- The extent to which opportunities are identified and explored;
- The quality of risk management: assessing the extent to which the establishments have proper risk management systems and adequately assess risks against potential benefits; and
- The lessons that can be learned for public sector research establishments as a whole.

Appendix 4

Glaxo Wellcome's approach shows how risk management is integrated into existing quality assurance and control mechanisms.

Why is risk management important?

1. Risk management is central to the science-based business. The pharmaceutical industry is highly regulated and operates multinationally. Clinical trials and quality control assurance are part and parcel of the core activities of the business to provide assurance about the quality of medical products to patients and healthcare providers and to limit the cost of insurance against possible litigation in the United Kingdom and worldwide. Losing a major licence to sell a product would put the company at risk. Risks also arise from health, safety, and environmental and ethical issues.

How is risk management being developed?

2. The company reviews and updates its assessment of the risks affecting the business and the policies and procedures by which these risks are managed in response to the extended requirements of 'Principles of Good Governance and Code of Best Practice' (the Combined Code) issued by the London Stock Exchange in 1998 for the guidance of listed companies.

3. The responsibilities of the Group have been reinforced, and internal reporting procedures converted from exception reporting to a process of positive confirmation. The assessment of Group risks is now reviewed and updated annually. At the operating level companies are required to undertake risk assessment and mapping and ensure adequate risk control measures are in place to manage the identified risks. Compliance Boards have been established in the main Group functions and at the major subsidiaries, and review reports from independent compliance teams. Risk management within Glaxo Wellcome includes:

   - A Policy Manual outlining all relevant compliance and corporate risk policies within the organisation;
   - Self-assessment and sign-off procedures for Group companies to report on policy compliance;
   - On-site audit and monitoring of policy compliance by central function (including product quality, manufacturing standards, environmental care, health and safety, insurable risk and financial practice);
   - Major Group functions reporting regularly on risks and how they are managed to Internal Audit, with upward reporting to both the Executive Committee and the Audit Committee which in turn reports to the Board. The Audit Committee reviews the key risks inherent in the business. The company has identified 14 major risks, which include IT compliance.

What are the advantages of effective risk management?

4. Some of the benefits of risk management are protection and improvement of the business and better allocation of resources. For example, risk assessment techniques identified that 15 production sites were key as they were associated with major revenue streams. These were then targeted to receive increased fire and loss protection systems.

5. Risk assessment techniques are also used when addressing health, safety and environment issues so that corporate targets on for example lost time accidents are achieved. Risk is also an important factor when outsourcing, working with others or procuring goods and services as poor risk management by third parties can put the organisation's reputation and business at risk, for example any suppliers providing raw materials or components for medicines have to be carefully monitored as this is a tightly regulated business.

6. The business and risk priorities also take account of global issues. This can provide opportunities for innovation and new products, for example, Glaxo Wellcome has had a 10 year programme in place to develop alternatives to, and phase out ozone depleting chlorofluorocarbon (CFC) propellants in metered dose inhalers (MDI) used by asthma sufferers. To date Glaxo Wellcome non-CFC MDIs have been launched in over 20 countries including the UK.

What are the lessons for effective risk management?

- Concentration on management of key risks.
- Use of other systems to support risk management such as quality control.
- Importance of assessing risks posed by suppliers.
- Risk response provides opportunities for innovation.

Source: Reprinted from 'Supporting Innovation: Risk Management in Government Departments' HC 864 published in August 2000 before Glaxo Wellcome merged into GlaxoSmithKline plc.