“For us, science and research constitute a front-line service, as they too, reduce distress and pain and save lives”.

(Dr John Reid, Secretary of State for Health, 22 March 2004)
The Research for Patient Benefit Working Party was set up following the reports of the Biosciences Innovation and Growth Team (BIGT) and the Academy of Medical Sciences (AMS). Its remit was to bring forward to ministers practical proposals for implementing the recommendations in the two reports.
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Executive Summary</strong></td>
<td>1</td>
</tr>
<tr>
<td>Membership of Research for Patient Benefits Working Party</td>
<td>3</td>
</tr>
<tr>
<td><strong>Final Report of the Working Party</strong></td>
<td>4</td>
</tr>
<tr>
<td>Interim Report of the Working Party</td>
<td>Annex A</td>
</tr>
<tr>
<td>Proposed Implementation Timetable for UK Clinical Research Collaboration</td>
<td>Annex B</td>
</tr>
<tr>
<td>Improving UK Patient Outcomes through R&amp;D: Embedding R&amp;D Incentives in the NHS</td>
<td>Annex C</td>
</tr>
<tr>
<td>Training of Clinical Scientists</td>
<td>Annex D</td>
</tr>
</tbody>
</table>
EXECUTIVE SUMMARY

i. The Research for Patient Benefit Working Party (RPBWP) was set up following the reports of the Biosciences Innovation and Growth Team (BIGT) and the Academy of Medical Sciences (AMS). Its remit was to bring forward to ministers practical proposals for implementing the recommendations in the two reports.

ii. Whilst the Working Party deliberations were taking place the Government issued a consultation document ‘Science and Innovation: working towards a 10 year investment framework’ and in their budget speeches the Chancellor of the Exchequer and the Secretary of State for Health announced substantial increases to NHS R&D funding over the next 4 years and called for the creation of the UK Clinical Research Collaboration (UKCRC).

Bearing in mind the above the RPBWP makes the following recommendations:

iii. **Vision.** The UKCRC should adopt as its long-term goal establishing the NHS as the world leader in contributions to clinical research*. It should use the power of partnership to achieve this thereby realising the twin benefits of improving national health and increasing national wealth.

iv. **The UKCRC** should be a partnership between government, the voluntary sector, patients and industry to oversee clinical research in the UK. Its membership should be that of RPBWP with some adjustments; its first meeting should be in April 2004 and thereafter bimonthly; it should report, bimonthly in the first instance, to ministers and the governing bodies of the partners. The chair should be the DH Director of Research and Development, a chief executive should be appointed as soon as possible and a core team assembled.

v. **Research Networks.** The new clinical infrastructure in the NHS will consist of a managed set of research networks. The cancer networks exist and the initial new developments will cover mental health, medicines for children, Alzheimers disease, stroke and diabetes. UKCRC will oversee their creation and a target of achieving half in 2005 and all the initial developments in 2006 should be set.

vi. **Experimental medicine.** There is a general consensus that more clinical research facilities are required and we propose that UKCRC oversees collaboration between research funders to create and sustain such facilities.

vii. **Incentives for the NHS.** The RPBWP has explored with an NHS reference group the concept of an ‘innovation scorecard’ and developed a range of suggestions to incentivise the NHS to embed a research culture in it. Ministers are asked to agree that further work should be done on these proposals.

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*The definition of clinical research in this report is a broad one and encompasses clinical trials, experimental medicine, translational research, epidemiological studies and public health.
viii. Clinical Research Programmes. In order to take maximum advantage of the NHS infrastructure developments there will need to be additional project, programme and clinical trials funding from MRC, charities and industry. Accordingly the Working Party recommends that the SR2004 bid from the MRC be funded in full.

It is proposed that the medical charity sector is represented by the Association of Medical Charities and the Wellcome Trust on UKCRC and that appropriate individual charities are closely involved in the specific workstreams of the overall programme to strengthen clinical research.

For industry it is proposed that the relevant sectors are represented on UKCRC and that industry liaison capability is built into the core UKCRC team and/or the individual networks.

xi. Research Workforce. The Working Party wishes to stress that extension of the infrastructure and programme support for experimental medicine and clinical trials will depend for its success on the availability of well-trained staff. It is recommended that research workforce development in general is one of the workstreams of UKCRC. Specifically in relation to Modernising Medical Careers the Director and National Co-ordinator would welcome a UKCRC sub-group to lead on academic medical careers. RPBWP agrees and proposes that the sub-group should be led by Dr Mark Walport.

x. The Regulatory Environment. The regulatory environment governing research has become complex and burdensome. RPBWP recommends that one of UKCRC’s immediate tasks is to set in train a detailed analysis of the cumulative effects of existing regulations with a view to seeking a way of streamlining the overall requirements. Further it is recommended that UKCRC includes as part of its core function the competency and capability to develop, communicate and spread best practice in relation to statutory regulations.

xi. Conclusion. The level of commitment to and interest in the work of RPBWP has revealed an eagerness to proceed with the above recommendations that ensures a very high probability of success. We ask Ministers to authorise us to proceed.
# Research for Patient Benefit Working Party

## Membership

### Chairman
Sir John Pattison  

### Secretariat
Dr Simon Dyer  
Dr Alison Austin  
Dr Chris Watkins  

### Member
John Bacon  
Professor John Bell  
Professor Colin Blakemore  
Professor Carol Black  
Professor Sir Alasdair Breckenridge  
Harry Cayton  
Glyn Edwards  
Dr Monica Darnbrough  
Professor Sally Davies  
Paul Devenish  
Dr Helen Glenister  
Professor David Gordon  
Dr Russell Hamilton  
Dr Chris Henshall  
Professor Trevor Jones  
Sir Ian Kennedy  
Professor David Kerr  
Dr Gill Morgan  
Dame Bridget Ogilvie  
Nick Partridge  
Professor Sir Keith Peters  
Professor Mike Rawlins  
Dr Alison Spaull  
Professor Bob Stout  
Dr Mark Walport  
Professor John Williams  

### Organisation
DH  

## Organisation
DH - Health & Social Care Delivery  
University of Oxford  
Medical Research Council  
Royal College of Physicians  
Medicines and Healthcare products Regulatory Agency  
DH – Director for Patients and the Public  
Bioscience Industry Association  
DTI  
DH - R&D Delivery  
HM Treasury  
National Patient Safety Agency  
The Council of Heads of Medical Schools  
DH – R&D Strategy & Policy  
OST  
Association of the British Pharmaceutical Industry  
The Commission for Healthcare Audit and Inspection  
University of Oxford  
NHS Confederation  
Association of Medical Research Charities  
Involve (Consumers in NHS Research)  
The Academy of Medical Sciences  
National Institute for Clinical Excellence  
Scotland  
Northern Ireland  
The Wellcome Trust  
Wales
INTRODUCTION

1. The Government’s consultation document “Science and Innovation: working towards a ten-year investment framework” recognises the need to strengthen clinical research in the UK and the power of partnership between government, industry and medical charities in achieving this. To support this endeavour substantial increases to NHS R&D over the next 4 years were announced in the Budget of March 2004 and the Government called for the creation of the UK Clinical Research Collaboration.

2. In his speech during the Health Budget debate the Secretary of State for Health, Dr John Reid, said that the purpose of the UKCRC was to oversee the effective and efficient translation of scientific advances into patient care. To this end he said he wished UKCRC to promote:
   - the development of a clinical infrastructure embedded in the NHS
   - an expansion of UK clinical research including clinical trials
   - an extensive and sustained increase in the research workforce and
   - the development and spread of best practice in relation to statutory regulations.

3. In terms of early priorities the Secretary of State stated his wish to establish a network of paediatric centres (working first on medicines for children), expand the mental health research network and develop an infrastructure to facilitate research into diabetes, Alzheimer’s disease and stroke.

4. The Interim Report of the Research for Patient Benefit Working Party (attached as Annex A) discussed the majority of the above items recognising, on the one hand, the value of the NHS and, on the other, the further developments needed to realise its full potential to support clinical research.

5. This Final Report develops more detailed recommendations to achieve the objectives set out in the 2004 Budget and in the reports by the Bioscience Innovation and Growth Team (BIGT) and the Academy of Medical Sciences.

VISION

6. The NHS provides equity of access to high quality care for the whole of the large and heterogenous population of the UK. As such it also provides unparalleled opportunities for clinical research. Our overall vision for UKCRC and its range of activities is that it will establish the NHS as the world leader in contributions to clinical research.

* The definition of clinical research in this report is a broad one and encompasses clinical trials, experimental medicine, translational research, epidemiological studies and public health.
7. This will be of benefit to both patients and staff since they have a common desire to reduce uncertainty about the best existing treatments and to evaluate new approaches to prevention, diagnosis and treatment as they emerge from basic science. Industry and medical charities are also key partners in this endeavour and by strengthening clinical research we have the opportunity of achieving the twin benefits of improving national health and increasing national wealth.

8. The strategic vision will be realised by developing clinical research through investment in a widely-applicable clinical infrastructure, with an appropriate workforce capability and with better regulation. The first two of these elements must be geographically distributed so as to be within reach of the great majority of interested clinicians and patients. The third requires national guidance.

UK CLINICAL RESEARCH COLLABORATION (UKCRC)

9. The UKCRC will create a partnership between government, the voluntary sector, patients and industry to oversee clinical research in the UK. It will consist of representatives of the main organisations involved in directing, funding, supporting, regulating and participating in clinical research. The different partners will contribute in different ways, and to different extents, depending on the nature of a particular issue and the degree of interest and/or responsibility that the individual partner has with respect to that issue.

10. We propose that the membership of UKCRC is that of the RPBWP with some adjustments. It should have its first meeting in April 2004 and aim at that meeting to agree terms of reference and take stock of, and where necessary initiate, the workstreams necessary to implement the various elements listed in paragraph 2. UKCRC should meet bimonthly and report to ministers and the governing bodies of the partners half-yearly in the first instance. The chair should be the DH Director of Research and Development.

11. It will be necessary for UKCRC to be supported by a small core team. This should be six people in the first instance and be headed by a chief executive. This team should be hosted by one of the partner organisations of UKCRC other than the two Government Departments. An implementation plan for UKCRC is attached at Annex B.

THE CLINICAL INFRASTRUCTURE

Networks

12. We propose that the new clinical infrastructure in the NHS will consist of a managed set of research networks which, over time, will enable research to be conducted across the full spectrum of disease and clinical need, and be of world class. It will facilitate the conduct of clinical trials and other well designed studies in the broad area of clinical research. It will support trials funded by both commercial and non-commercial organisations.
13. The clinical research networks will be made up of two types of infrastructure working together: NHS infrastructure, and research infrastructure. Examples of NHS infrastructure are health care staff, radiology services, pathology services, pharmacy services, the clinical information systems. Examples of research infrastructure are research staff, statistics services, tissue banks, clinical trials offices, and information systems to support randomisation, data capture and analysis.

14. Responsibility for providing the NHS infrastructure lies with the Departments of Health. Responsibility for the research infrastructure lies with all research funders. The partners will need to work together to ensure that the NHS infrastructure and the research infrastructure form a coherent whole to create national clinical research infrastructures.

15. The initial national networks will cover cancer, mental health, medicines for children, Alzheimer’s disease, stroke and diabetes but we wish to emphasise that in due course all diseases and specialities will be covered. To this end the first six research networks will operate in a co-ordinated fashion under a common management structure to ensure consistent best practice, avoid duplication of effort, maximise efficiency, generate economies of scale and create synergy. They will share a data capture system, data definitions, and establish common processes and protocols.

16. We have undertaken preliminary work on an implementation plan for these networks. For mental health where there is already a core capability we believe we can have an expanded network up and running by Jan 2005. With those networks for which the first step is to procure the national co-ordinating capacity the time scale is longer. However our preliminary work indicates that we could achieve half of what is required in 2005 and 100% in 2006.

17. The network for cancer research has already been established, is working well and no changes are currently proposed to its structure or funding. However, it is essential that we take advantage of the accumulated experience and expertise in the cancer networks. UKCRC must ensure that the individual networks co-ordinate their activities as described in paragraph 15.

Facilities for experimental medicine

18. There is a need to undertake some types of clinical research in facilities that are distinct from the wards, clinics and surgeries that are delivering the general NHS services. There are different models for these clinical research facilities and no one of them is right for all circumstances. However there is a general consensus that more clinical research facilities are required and we propose that UKCRC oversees collaboration between research funders to create and sustain additional facilities.

Incentives for the NHS

19. The BIGT report drew attention to the need to remove any cultural barriers in the NHS in order to promote clinical investigation. In order to make R&D-driven
innovation a priority they emphasised the need to provide incentives to clinicians and managers to pursue clinical research. The RPBWP has explored further with an NHS reference group the concept of the “innovation scorecard” mentioned in the BIGT recommendation.

20. The outcome of these discussions is attached at Annex C. Ministers are invited to agree that further work should be done on the proposals for embedding a research culture in NHS performance management.

CLINICAL RESEARCH ACTIVITY

21. In order to take maximum advantage of the NHS infrastructure developments described above there will need to be additional project, programme and clinical trials funding from MRC, charities and industry. The MRC has put forward a bid via OST for an initiative entitled Accelerating Research for Patient Benefit in partnership with NHS, industry and other funders.

22. The elements of this MRC initiative (human capacity building, enhancement of the vital NHS contributions to research capability, technology transfer and engagement with patients and the public) are wholly consistent with the proposed NHS developments for strengthening clinical research to benefit patients. Accordingly the Working Party recommends that the SR2004 bid from the MRC be funded in full to complement the additional resources from DH. Only by this means can the budget target of a government spend on medical research and research and development within the NHS of £1.2billion per annum by 2008 be achieved.

23. The medical charities will be an integral part of UKCRC. Medical charities often have research funds and some are very substantial funders of clinical research. All bring valuable linkages to their respective patient and carer groups and many are well connected to relevant researcher communities. It is proposed that the medical charity sector is represented by the Association of Medical Research Charities and the Wellcome Trust on UKCRC and that appropriate individual charities are closely involved in the specific workstreams of the overall programme to strengthen clinical research.

24. Industry is another key partner and the Pharmaceutical, Bioscience and Healthcare sectors will be represented on UKCRC. Industry will respond favourably to the new clinical research and clinical trials infrastructure if it is convinced that it can secure good value for its investment. Relations with industry should be actively managed and it is proposed that UKCRC ensures that necessary industry liaison capability is put in place either as part of the individual networks (as is cancer and mental health) and/or as a core competency of UKCRC itself.

RESEARCH WORKFORCE

25. The Working Party wishes to stress that extension of the infrastructure and programme support for experimental medicine and clinical trials will depend for its success on the availability of well-trained staff. There has not been time to
assess in every detail the issues that are leading towards critical shortages of research-trained personnel but certain general principles have emerged.

26. It is important to recognise that human resource capacity in a variety of manifestations is needed, it includes those who design and run research studies; those who work to enter patients into such studies; and those who are aware of, and use, the results of research. It is front-line health professionals by and large who undertake the recruitment and monitoring of patients in clinical trials. It is imperative that they receive appropriate recognition for this additional work and UKCRC must ensure that options for this are developed and implemented.

27. Many research funders have schemes for increasing the number and quality of people trained in research and these schemes cover a variety of subject areas and a range of professionals. But the coverage is not comprehensive and the BIGT report calls for new cadres of clinical investigators. RPBWG believes that the major government and non-government research funders must co-ordinate their existing and any new capacity development schemes. In the light of this it is proposed that a sub-group of UKCRC is established to consider further what needs to be done. This must take into account, amongst other things, the work commissioned by the Strategic Learning and Research Advisory Group for Health and Social Care (StLAR) and discussions with the NHSU.

28. There is a particularly acute issue about the training of medically qualified clinical academics as a result of some RAE-related disinvestment, the expansion of medical schools and other disincentives to taking up an academic medical career. In this (and in the other health professions) there is a need for better partnership working between the NHS, universities, research funders and regulators of training in order to create career pathways that are attractive to young potential clinical scientists.

29. The RPBWP received, commented on and endorsed the final version of the paper “Training of clinical scientists” which is attached at Annex D. Members of the Working Party have had discussions with the senior DH leads for Modernising Medical Careers (MMC) and it has been agreed that UKCRC will set up and run a sub-group to feed into Professor Aidan Halligan (Director) and Professor Alan Crockard (National Co-ordinator of MMC) proposals for the future training of clinical academics. Dr Mark Walport has agreed to lead this sub-group.

THE REGULATORY ENVIRONMENT

30. Regulation is necessary to project the rights, dignity and safety of patients and ensure the quality of research. Each regulation, in isolation, has elements which contribute to those objectives, but when taken together the existing and impending regulations often appear to be inhibiting the conduct of research without producing any societal benefit.

31. We therefore recommend that one of UKCRC’s immediate tasks is to set in train a detailed analysis of the cumulative effects of existing regulations with a
view to seeking ways of streamlining the overall requirements. This work should build on that done following the Pharmaceutical Industry Competitive Taskforce and by the Bioscience Risk Assessment Forum.

32. Some progress has been made in developing national standards and guidance with respect to existing regulatory requirements. However this type of work does not yet go far enough particularly bearing in mind the concern that there always is about any new regulations. A significant amount of this concern could be allayed by effective communication about what is required and the best ways of fulfilling those requirements.

33. RPBWP therefore recommends that UKCRC includes as part of its core function the competency and capability to develop, communicate and spread best practice in relation to statutory regulations. This will require additional staff to those in paragraph 10 and as a start they should number about four.

CONCLUDING REMARKS

34. The Chairman of RPBWP would like to thank the members of the Working Party for their considerable efforts in concluding the work in a short period of time. The attendance at meetings and the other contributions from very senior and busy people has been remarkable. This and the general interest following recent announcements indicates that the clinical research community together with the new structures will be able to achieve the objectives outlined in this report and those of BIGT and the Academy of Medical Sciences. Ministers are invited to empower them to do so.

PROFESSOR SIR JOHN PATTISON
Chairman
Research for Patients Benefit Working Party

Department of Health
April 2004
An emerging UK Clinical Research Collaboration.

The interim report of the Research for Patient Benefit Working Party.

Introduction

1. Over many years the National Health Service (NHS) has provided an authoritative and expert resource for the conduct of both national and international clinical studies. However the recent reports of both the Biosciences Innovation and Growth Team, and the Academy of Medical Sciences, stress that the NHS could do even better for patients in relation to the evaluation and adoption of new science-based approaches to the prevention, diagnosis and treatment of disease. They call for a boost to the broad area of clinical research in order to strengthen the effective and efficient translation of scientific advances into patient care. Such a boost would also promote the recruitment and retention of healthcare professionals into the NHS and greatly encourage the bioscience and pharmaceutical industries to maintain and increase their R&D activities in the UK. Both industry sectors recognise the strength of the NHS and the key role it plays. Such a strengthening of clinical research would achieve the twin benefits of improving national health and increasing national wealth.

2. The problems are not peculiar to the UK, or the NHS, since all health care systems and research institutes in Europe, North America and Australasia have similar problems. The NHS, however, provides an opportunity for equity of access both to high quality care for the entire population as well as unparalleled opportunities for clinical research that are greater than those of any other country. It is not unreasonable to suggest that the NHS could, for a relatively modest investment, lead the world in its contributions to clinical research.

3. Although they use different terminologies both recent reports recommend that any boost to clinical science must have the following major components:

- the development of a clinical research infrastructure embedded in the NHS;
- an expansion of the UK clinical research activity including clinical trials;
- an extensive and sustained increase in the research trained workforce; and
- the development and spread of best practice in relation to statutory regulations.

In practice government and charitable research funders have made some progress in each of these areas; but it is by no means sufficient in depth or breadth and is, at best, only poorly co-ordinated.

* The definition of clinical research in this report is a broad one and encompasses clinical trials experimental medicine, translational research, epidemiological studies and public health.
4. Models of good practice exist in, for example, the cancer research networks and the capacity building programmes. The former is repeatedly referred to in the recent reports, and rightly so. Such examples of good practice must be developed more completely and the sections below indicate the emerging conclusions of the Research for Patient Benefit Working Party (RPBWP).

Vision

5. There is an urgent need to evaluate new approaches to prevention, diagnosis and treatment as they emerge from basic science. But there is also a pressing need to reduce uncertainty about the best forms of managing disease with existing treatments. There is evidence that the great majority of people support clinical trials and associated research with state-of-the-art specialised treatments. Indeed, patients’ advocates press for more equitable access to trials, and patients themselves want a fast-track research process that can rapidly deliver reliable and relevant answers. Ideally, therefore, patients and clinical investigators should be partners in improving medical knowledge. It is notable that participation in a trial ensures the best possible standard care and an assessment, under carefully supervised circumstances, of whether there is a better treatment ready to be introduced.

6. **The strategic vision of the RPBWP is one of developing clinical research, through investment in a widely-applicable clinical infrastructure, with an appropriate workforce capability, and with better regulation.** The first two of these elements must be geographically distributed so as to be within reach of the great majority of interested clinicians and patients. In due course we seek to ensure that an infra-structure to support clinical research will extend across all disease areas and patient groups and be UK wide. But it would be unwise to attempt too much, too soon, The RPBWP has therefore considered what steps should next be taken towards realising the vision.

Research Infrastructure

7. **Research Networks: the cancer research model.** The National Cancer Research Institute (NCRI) was established on 1 April 2001 to take strategic oversight of cancer research in the UK. An early action of NCRI was to ask one of its members (the DH Director of R&D) to set up cancer research networks. The National Cancer Research Network (NCRN) is an NHS infrastructure able to support randomised prospective trials of cancer treatment. The National Translational Cancer Research Network (NTRAC) aims to maximise the NHS’s contributions to the national translational research effort with new methodologies, novel diagnostic, predictive and prognostic tests and novel therapeutic agents.

8. NCRI’s role is to identify gaps in current research and identify opportunities; plan and co-ordinate approaches between funding bodies to fill gaps and take advantage of opportunities; and monitor progress in implementing agreed plans and in achieving agreed objectives. It is a partnership between the nineteen largest funders of cancer research in the UK (including government, the voluntary sector and industry) together with cancer patient representatives. NCRI is not a ‘bricks and mortar’ institution, and it does not have an intramural research
programme. The funding bodies use their own budgets to fund initiatives directly. These may be NCRI initiatives where the funding is provided jointly by a number of funding bodies, or may be initiatives pursued by individual funding bodies. The NCRI has a Secretariat of five full-time staff funded by the partner organisations and with a single office location hosted by one of the funding partners.

9. NCRN seeks to enhance access to the best treatments for people in all parts of the country; to provide an effective and efficient mechanism for conducting cancer research; to increase the number of patients in research; to assure the quality of research protocols and the conduct of trials, and; to increase the number of NHS organisations and health care professionals involved in research. The NCRN networks were pre-defined because they mapped onto the 34 existing Cancer Service Networks. Each was included, however, only when specified standards had been met. NCRN provides the NHS infrastructure for large phase II and phase III trials.

10. NTRAC aims to apply the results of basic science to realising tangible benefits for cancer patients and those at risk of developing cancer. It seeks to harness the unique opportunities provided by the interface between “the campus and the clinic” to develop, and test, hypotheses aimed at understanding the causes and progression of cancer, and to develop strategies for its prevention, diagnosis and treatment. The NTRAC network comprises 14 UK centres selected through an open formal tender process and in all instances the contracts are with universities. NTRAC provides the NHS infrastructure support for phase I and early phase II trials if they are in only one or a pair of centres.

11. **Other Clinical Research.** The involvement of patients in the cancer research networks takes place in NHS wards, clinics and surgeries. For some other types of clinical research, major university / NHS centres have found it beneficial to develop clinical research facilities (CRFs); most frequently they have been developed with capital funding from the Wellcome Trust and infrastructure running costs from the NHS R&D programme. Such facilities allow experimental medicine research to be undertaken without compromising the delivery of general NHS services. They also provide opportunities for the personal development of staff. The CRFs funded by the Wellcome Trust are shortly to be reviewed. If they are judged to be a success there is a consensus that additional facilities need to be developed and supported in order to take full advantage of the UK’s unique potential in this area.

12. **RPBWP conclusions** The working party concludes that there is no reason, in principle, why the NCRN and NTRAC model should not be extended to other disease areas. The working party noted that success has depended on: a high-level, shared commitment amongst government organisations, charities, patients and industry to collaborate on the developments; excellent leadership at all levels; existing clinical care networks and research capability; realistic new resources; and extensive management of the scientific strategy and operational issues by the NCRI and it’s members. The RPBWP also believes that if CRFs are judged to be a valuable part of the infrastructure for clinical research then additional ones will be needed.
13. The Working Party is also conscious that a “suite” of subject-specific networks, covering all the major areas of morbidity and mortality, would take many years to establish and would not be the most efficient or cost-effective approach. Moreover confining initial public investment to a single area will not meet the disparate needs of patients with other conditions. Consequently the Working Party considers that, in parallel with the establishment of a further disease-specific network, the broad capacity of the NHS to accommodate clinical research that is not disease-specific (i.e. useful for all disease studies) should be developed.

14. Accordingly the RPBWP recommends:

(a) that the model of the national cancer research networks is extended to an additional disease area;

(b) that, simultaneously, the generic infrastructure capacity of the NHS to undertake and support clinical research in other areas with high priority for patients should be strengthened; and

(c) that research funders collaborate to create and sustain additional clinical research facilities.

15. Such an infrastructure will provide the necessary support for clinical experimental medicine and clinical trials extending from early “proof-of-concept” studies to late phase trials for the demonstration of clinical and cost effectiveness. Other disease areas could then “spin off” from this initial investment as resources and the public interest demand. It will also be important to develop the generic under-pinning activities such as human resources, genomics, proteomics and bioinformatics in a co-ordinated manner.

16. To work most effectively the necessary infrastructure and research culture must be firmly embedded in the NHS. It seems right to regard these NHS developments as something which should be predominantly undertaken by the NHS Research and Development Programme. However the benefits to patients, to the NHS, to public health and to the economy will depend upon a significant contribution from the other funders of clinical research.

17. Accordingly the RPBWP recommends:

(a) that funders (research councils, charities, industry) give a commitment to expanding UK clinical research capacity provided that good value for money can be demonstrated.

Capacity Building

18. All research funders have schemes for increasing the numbers and quality of people trained in research. In recent years there have been a number of schemes, using government, charity funds and industry money to develop capacity in a variety of subject areas and amongst a range of professionals (doctors, nurses and allied health professionals). However, there still remain
critical shortages of research-trained personnel and the BIGT report calls for new cadres of clinical investigators. But the problem is not solely one of finding resources for training: there need to be careers, within the NHS or Universities for those with the appropriate skills. It is also essential to recognise that the day-to-day recruitment and monitoring of patients in clinical trials is undertaken by “front line” health professionals: it is therefore imperative that they receive appropriate recognition for the additional work they undertake by participating in clinical trials.

19. Nor can all of capacity development be done nationally since the cancer model has shown us that the networks have a significant role to play in developing the workforce locally and there should be resources to the networks to do so. Moreover it is important to recognise that we need the human resource capacity in a variety of manifestations; it includes those who design and run research studies; those who work to enter their patients into research studies (as discussed above); and those who are aware of, and use, the results of research. Only by this means can a research culture and awareness be made to involve academic staff, clinical leads, research support staff and NHS managers.

20. Furthermore, if clinical research is to flourish to its fullest extent in the UK then existing disincentives must be eliminated. Although various initiatives are underway (such as the Department of Health’s Clinician Scientist scheme) much more must be done. Better partnerships are needed between the NHS, Universities, research funders and the regulators of training in order to create career pathways that are attractive to young potential clinical scientists. The development of these career pathways will require collaboration between the relevant government departments, the medical royal colleges, research funders, the NHS and the university sector and changes must be linked closely to the Modernising Medical Careers initiative at the DH.

21. **RPBWP conclusion** It is clear to all in the working party that extension of the infrastructure and programme support for experimental medicine and clinical trials will depend for its success on the availability of well-trained staff. The tensions, for those aspiring to a career in clinical academic medicine are widely acknowledged. The difficulties in gaining, and maintaining, expertise in both clinical practice and clinical investigation are equally recognised. Resolution of the problem will require major changes to professional and research training.

22. The RPBWP has not had time to consider solutions in depth but recommends:

(a) That a further working party involving all key stakeholders is set up to coordinate and develop academic career pathways in the health professions.

(b) That the major government and non-government research funders coordinate their existing capacity development schemes and collaborate in developing new cadres of clinical investigators.

(c) In replicating the cancer research networks in other disease areas appropriate recognition is given to developing the local workforce in the networks.
The regulatory environment

23. The regulation of clinical research has increased substantially over the years. Each requirement, in isolation, has elements that contribute both to the quality of the research and to the rights, dignity and safety of patients. But taken together there is duplication, and administrative delays, which contribute nothing to the quality of the research or to the protection of patients. Indeed the working party is aware of clinical investigators who have abandoned research ideas because of the complexities and insensitivities of some of the current arrangements. In addition, some legislation (such as the Data Protection Act) impinge adversely on research (and, consequently on the public health) even though they were not conceived for that purpose. The time has come for a full assessment of the panoply of existing regulations governing clinical research; whether there are consequences that are not in the interests of the public and patients; and whether simplification of the research regulatory environment can be achieved without prejudicing the safety and rights of individuals.

24. There has also been a lack of uniformity in the interpretation of these requirements across the NHS. Some efforts have and are being made to develop national standards and guidance with, for example, a single form of contract for commercial trials in the NHS as well as the central guidance from the Central Office of Research Ethics Committees (COREC). Nevertheless the impending implementation of the EU Clinical Trials Directive is causing grave concern although the joint work between DH and the MRC may help to ensure that extreme interpretations of the requirements do not prevail.

25. These examples of national collaboration and best practice do not go far enough and it is clear the sum total of the regulatory requirements provide a disincentive to researchers, their employing organisations and industry investment in trials in the UK. Obviously direct responsibility for elements of the regulatory system (e.g. research ethics committees, trials authorisation) will have to remain with the competent authorities. But a significant amount of the concern about new and existing regulations governing research could be allayed by effective communication about what is required and what are the best ways of fulfilling those requirements.

26. **RPBWP conclusion.** In the light of the above the Working Party recommends that any new structure created to take forward the recommendations of the BIGT and Academy report:

(a) undertakes a detailed analysis of the cumulative effect of existing regulations with a view to seeing how the overall requirements can be streamlined. This work should build on that done following the Pharmaceutical Industry Competitive Task Force and by the Bioscience Risk Assessment Forum (BRAF)

(b) includes as part of its functions the competency and capability to develop and spread best practice in relation to statutory regulations.
Structure and Governance

27. The structural aspects of the cancer research model consist of direction by the NCRI, co-ordination by the National Co-ordinating Centres and delivery by the operational networks. As discussed above there seems little reason not to pursue a similar model for the next disease area(s). Some might argue that the national research institutes could be merged rather than replicated and that the same might be said of the National Co-ordinating Centres. At some point in the future this might turn out to be the case but not to start with. NCRI has benefited greatly from the focus and unity of having only the cancer research funders round the table and it is likely that the next disease area would similarly benefit from not being diluted by others with a different primary interest.

28. However as the research institutes proliferate there is a need for another element in the structure, notably an over-arching element concerned with overall strategy and with the developments that will be common to all disease areas. We call this the **UK Clinical Research Collaboration (UKCRC)** to indicate that it is intended to be UK wide, to cover experimental medicine, translational research, clinical trials and other well-designed studies and to be a collaboration which will work through the delegated authority of the Chief Executives of the participating organisations. Those organisations will not be relinquishing authority for their own research strategies but will be agreeing to co-operate and collaborate when it is in their mutual interest to do so and it adds value.

29. UKCRC will also provide a forum to share best practice and encourage extension of excellent local co-ordinating centres of clinical research that already exist. It will also drive forward the development of the generic infrastructure referred to in paragraph 14(b). The attached figure is a diagramatic representation of the current situation, the proposed next steps and the final vision outlined in paragraph 6.

30. The UKCRC will need to give a sense of ownership and influence to all key stakeholders. This requires a group consisting of members representing government departments, the NHS, the MRC, the Wellcome Trust, NICE, MHRA, the Association of Medical Research Charities, the Academy of Medical Sciences, the Royal Colleges, the relevant industries and patients. It should be chaired by the DH/NHS Director of R&D and the membership should evolve from that of the RPBWP.

31. **RPBWP Conclusions.** After it’s deliberations on the functions required to take forward the recommendations of the BIGT and Academy reports the Working Party recommends:

(a) **The establishment by ministerial authority of the UK Clinical Research Collaboration (UKCRC) to oversee the implementation of the recommendations in this report and further national developments to strengthen clinical research;**
(b) The establishment of a core team based at MRC HQ;

(c) The procurement by an open process of national and local structures similar to those which have been successful in cancer research for an additional disease area.

The next disease area

32. The Working Party recommends in paragraph 14 (a) and (b) above that the clinical research capability of an additional specific research area is enhanced at the same time as developing a more generic infrastructure. By this means a relatively quick and extensive win can be achieved for a particular area whilst the ground is laid for a more general capability capable of supporting a broad range of clinical research.

33. The decision about which specific area to support next is not an easy one and the Working Party has sought to develop a process that might help with such a decision. The process attempts to incorporate elements of clinical need, the capability of the service and research communities and the drive from patients and industry. In terms of clinical need consideration was given to the seven leading causes of morbidity and mortality listed in the report from the Academy of Medical Sciences. National Service Frameworks exist for the majority (4 of 7) of these.

34. In addition there is a published NSF for older people (which has a major section on stroke), one on renal disease in the process of being published and two in preparation, one about children’s services and one on long term conditions (which will cover some of the degenerative diseases of the nervous system). The Department of Health is also developing a strategy to achieve progress in the area of medicines for paediatric use and is thinking of a network of centres of excellence for the purpose. Finally the Working Party included consideration of Infectious Diseases because of their continued importance and capacity to generate new and re-emergent issues requiring rapid response.

35. The Working Party considered these various clinical conditions and patient groups listed in the paragraph above against a list of key leadership, clinical service, research and industry factors. Cancer has emerged well from this exercise but this may be a reflection of how well cancer does now rather than how it would have fared prior to the investments of the last three years. The exercise has so far failed to reveal convincing differences in the ranking of other disease areas or patient groups.

36. **RPBWP conclusions.** At this stage in its deliberations the Working Party can only recommend that:

(a) further work should be done before deciding finally on the next specific area to be taken forward and that this should include input from patient support groups, relevant charities, national clinical directors, senior officials and ministers.
Funding

37. It is possible to achieve some of the aims described above by using existing resources in a more effective and co-ordinated way. However there is little doubt that one of the factors which contributed to the success of the cancer research networks was the provision, at the outset, of an appropriate amount of additional funding. In relation to the cost of any enhanced NHS infrastructure it seems unarguable that this should fall largely to the NHS. As such this is an internal discussion for the duration of the current five year allocation for the NHS; thereafter (i.e. 2007/08 onwards) a case will need to be made in the government’s Spending Review (SR) of 2006 and this will be based on a detailed business case. Work on this will be in phase 2 of the RPBWP.

38. Additional project, programme and clinical trials funding will need to come from the MRC, charities and industry in order to take maximum advantage of the infrastructure developments. In relation to the first of these the increased funding for clinical research should begin in 2005/2006 and therefore needs to be the subject of an SR 2004 bid via OST. The MRC are proposing an initiative entitled Accelerating Research for Patient Benefit in partnership with the NHS, industry and other funders. The elements of this initiative (human capacity building, enhancement of the vital MRC contributions to research infrastructure, technology transfer and engagement with patients and the public) are wholly consistent with the RPBWPs vision for strengthening clinical research to benefit patients.

39. **RPBWP conclusion.** At this stage of its deliberations the Working Party can only recommend that:

(a) the clinical research component of the SR 2004 bid from the MRC be given the strongest possible cross-departmental government support.

Department of Health
6 February 2004
WHERE WE ARE NOW

Cancer research infrastructure
Research infrastructure for other disease areas

WHERE WE WANT TO BE

All disease areas

UKCRC
Careers
Regulation
Direction
Co-ordination
Delivery

NEXT STEPS

Cancer research infrastructure
Generic research infrastructure
Research infrastructure for one new area

UKCRC
Careers
Regulation
Direction
Co-ordination
Delivery

Figure 1
### Proposed Implementation Timetable for UK Clinical Research Collaboration

<table>
<thead>
<tr>
<th>Activity</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Jan</td>
<td>Feb</td>
<td>Mar</td>
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<tr>
<td>UKCRC</td>
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<tr>
<td>UKCRC holds its first meeting</td>
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<tr>
<td>UKCRC agrees terms of reference</td>
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<tr>
<td>UKCRC conducts process to identify its core staff</td>
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<tr>
<td>First UKCRC core staff start work [2 staff]</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>UKCRC starts <em>Clinical Infrastructure</em> workstream</td>
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<tr>
<td>UKCRC starts <em>Research Activity</em> workstream</td>
<td></td>
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<tr>
<td>UKCRC starts <em>Research Workforce</em> workstream</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UKCRC conducts process to identify its regulatory environment staff</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>First UKCRC regulatory environment staff start work [2 staff]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UKCRC starts <em>Regulatory Environment</em> workstream</td>
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<tr>
<td>All UKCRC core staff in post [further 4 staff]</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>All UKCRC regulatory environment staff in post [further 2 staff]</td>
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<tr>
<td>Cost per quarter (£k)</td>
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<td>2004</td>
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<td>2006</td>
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</table>

Planning assumptions: 1xAdministrative Director at £100k incl on costs + 9 other staff at average of £50k incl on costs + £150k workstream and running costs. Total = £700k per annum.
The purpose of this paper is to lay out four imperatives to incentivise R&D in the NHS. It is based on Research for Patient Benefits Working Group discussions their NHS stakeholder subgroup and interviews with selected stakeholders. Time unfortunately, was not available for broader consultation. In summary, the Working Group is making four assertions:

Healthcare R&D has significant direct and indirect benefits for patients – by finding new and better treatment regimes and new medicines, more lives can be saved, better health outcomes can be achieved, and health system productivity can be increased. Healthcare R&D has additional benefits for UK PLC, creating a platform for industry.

R&D in new medicines and new service interventions has seen spectacular growth globally over the past few years, but is facing a decade of severe challenges as industry R&D productivity is declining and health systems are under severe pressure and reform. Therefore, both industry and public R&D institutions are seeking new treatment and service system modalities to deliver higher productivity.

The institutions making up the NHS of England are uniquely positioned to become a global leader in healthcare R&D. The NHS is organized in a manner that is much more conducive to healthcare R&D than the fragmented healthcare systems of US, Japan and rest of Europe.

However, strong disincentives to NHS R&D currently exist, posing an obstacle to achieving this vision.

Therefore, the Working Group suggests exploring four approaches to incentivise NHS R&D and developing concrete action plans with key NHS institutions. These are outlined in Figure 1.
### Potential approaches to incentivise R&D in the NHS

<table>
<thead>
<tr>
<th>Current R&amp;D challenge</th>
<th>Preliminary approach to incentivise R&amp;D activities in NHS</th>
<th>Potential Owner</th>
</tr>
</thead>
</table>
| Lack of individual incentives for clinicians and Trust CEs | 1. Ensure consultant contracts recognize clinical research  
2. Incorporate points in GP contract for recruiting patients into trials  
3. Reward research collaboration (e.g., number of patients clinician enrolls in clinical trials) in the clinical excellence awards  
4. Incorporate clinical research criteria into standards governing evaluation of hospital performance | Trusts  
ACCEA  
The Healthcare Commission                                     |
| Lack of institutional incentives                           | 2.1 Ensure that HRGs fully compensate for treatment costs related to R&D  
2.2 Create a transparent system for allocating R&D funds  
2.3 Ensure that processes exist to meet new EU clinical trial directives with minimal additional regulatory burden  
2.4 Ensure that Foundation Trust status allows Trusts to create JV companies based on R&D with industry and thus to incentivize clinicians through equity | DH  
UKCRC  
OIR                                              |
| Lack of collaboration and coordination across disciplines and patient pathway | 3.1 Serve as the ‘facilitator’ for clinical trial management across the NHS by bringing together DH, NHS, MRC, industry, medical charities, patients, and other partners | UKCRC                             |
| Insufficient capabilities and systems                      | 4.1 Ensure the adequate provision of clinical research infrastructure  
4.2 Create a central database of patients, as part of the national IT infrastructure, who are willing to be contacted for relevant clinical trials | UKCRC  
National IT Project          |

### Introduction

The NHS currently has an unprecedented opportunity to incentivise R&D activities by strategically shaping the multiple developments currently occurring in its healthcare environment. These developments include the creation of new healthcare institutions, the introduction of new contracting systems, and the allocation of new funding to R&D through the 2004 Budget. As decision-makers chart the path forward for NHS R&D, it is important to holistically consider the focus and impact of these changes, and how they can be shaped to maximize improvement in patient care.

Developing this holistic view requires answering three key questions:

1. What is the definition of NHS R&D?
2. What challenges does NHS R&D currently face?
3. How can the recent developments in the UK healthcare environment positively affect NHS R&D moving forward?

This paper presents a preliminary view on each of these questions based on workshops of the NHS sub-group of the Research for Patient Benefits Working Group, as well as on interviews with relevant stakeholders in public healthcare institutions. Further analysis and review is required to validate the preliminary solutions outlined in this paper. For example, the direct and indirect costs of specific measures should be assessed and compared to the benefits, and priorities agreed (while many of the potential incentives outlined in this paper should be cost neutral, this needs to be tested). This paper only addresses the issues facing R&D in the NHS, as opposed to more broadly in the UK healthcare scene.
1. What is the definition of NHS R&D?

While individuals across the NHS may have varying definitions and aspirations for R&D, our interviewees revolved around one dominant theme: by virtue of its role as the largest healthcare service delivery organization in the world, the NHS should be focused on R&D that is ‘close’ to patients and that results in direct improvement in their care and healthcare outcomes.

A direct implication exists for the type of healthcare R&D that stakeholders believe that the NHS should undertake. Broadly, six main types of healthcare R&D exist (Figure 2): (1) basic science, (2) experimental medicine (3) large clinical trials; (4) clinical effectiveness; (5) operations/ service delivery research); and, (6) preventive care/public health research. At a high level, types 1-2 fall into the domain of ‘traditional research’, whereas types 3-6 fall into the domain of ‘applied research’. Interviews indicate that the NHS should be primarily focused on types 3-6 because the NHS’s structure and mandate make it well positioned to make a significant contribution in this arena.

The rationale for mainly focusing NHS R&D in these areas is as follows:

*Clinical trials:* Trials that are focused on new drugs can have a tangible impact on patient care. Interviewees indicate a broadly held belief that increasing the participation of patients in clinical trials is important to modernization of the delivery of healthcare in the UK. In particular, Phase 2 and Phase 3 clinical trials can provide UK patients with access to cutting-edge care, improving treatment outcomes by giving trial participants a chance for longer life. Trials often represent a patient’s best chance for survival for particular disease areas such as oncology. Moreover, trial experience can also advance the skills and awareness of UK healthcare professionals, elevating the overall clinical skill level in the country.

*Health Technology Assessment:* Health Technology Assessment (HTA) refers to large randomised clinical trials that assess the efficacy and cost effectiveness of different types of interventions. These interventions can include drugs, procedures, and medical devices (e.g. does endoscopy result in earlier cancer detection). These are very important questions for the NHS because they influence treatment protocols. Applied appropriately, Health Technology Assessment can accelerate the introduction of new procedures/devices/drugs to the delivery of care in the NHS, benefiting patients.
Six types of healthcare R&D exist

<table>
<thead>
<tr>
<th>Description</th>
<th>Traditional research</th>
<th>Applied research</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Basic science</strong></td>
<td>Lab research to understand disease triggers</td>
<td>Longitudinal research to discover the disease process in patients</td>
</tr>
<tr>
<td><strong>Translational medicine</strong></td>
<td>Phase 2 and Phase 3 trials in humans</td>
<td>Large randomized clinical trials focused on the effectiveness of interventions (procedures, devices, and drugs)</td>
</tr>
<tr>
<td><strong>Clinical trials</strong></td>
<td>Large randomized clinical trials to evaluate the safety and efficacy of new drugs or devices</td>
<td>Process optimization to improve the productivity of resources to deliver healthcare services</td>
</tr>
<tr>
<td><strong>Health technology assessment</strong></td>
<td>Evaluate the efficacy of a new drug on stroke patients</td>
<td>Evaluate whether a stroke unit and/or home rehabilitation lead to more effective and efficient healthcare delivery to patients</td>
</tr>
<tr>
<td><strong>Service delivery</strong></td>
<td></td>
<td>Research on how to prevent patients from getting the disease; healthcare inequity</td>
</tr>
<tr>
<td><strong>Preventive care/public health</strong></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Example (stroke)**

- **Traditional research**
  - Understand the molecular mechanisms of a stroke
  - Understand how the molecular mechanisms of a stroke lead the development of different drugs
- **Applied research**
  - Evaluate the efficacy of a new drug on stroke patients
  - Assess whether a CT scan within the first 24 hours of a stroke can lead to a better health outcome
  - Assess whether a stroke unit and/or home rehabilitation lead to more effective and efficient healthcare delivery to patients
  - Assess levers for stroke prevention

**Service delivery research:** This type of research focuses on how healthcare providers can improve their service delivery to patients. It is directly tied to the priorities of Trust CEOs, clinical staff, and policymakers who want to achieve a real change in the quality of patient care in a short time-frame (e.g. 6-12 months). Examples of key questions include: How to organize and structure teams to deliver more efficient and effective care? How to configure services to ensure convenient access and optimal quality? At the core, this research is focused on how healthcare providers can use resources as productively as possible so as to deliver better treatment outcomes and better patient experiences (e.g. reduced waiting times). Moreover, the NHS is moving to a ‘payment by results’ system whereby Trusts are compensated on the basis of activity performed (as opposed to the past system whereby lump sums were exchanged between PCTs and Trusts that were not necessarily tied to activity). Under ‘health related groups’ (HRGs), a Trust receives a set payment by procedure (e.g. knee replacement, CABG) – if a Trust’s costs lie above this payment, then the Trust must absorb the additional cost. If its cost lies below, then the Trust keeps the difference. Under this system, Trusts are highly incentivised to engage in service delivery research in order to ensure that they are using their resources as productively as possible (so that their costs lie below the stipulated HRG payment level for each activity).

**Preventive care/public health research:** Preventive care research focuses on the cost effectiveness of action that can be taken to improve the health of the overall population, namely longer and healthier lives. Research topics revolve around how to prevent people from getting diseases, including disease management programs (e.g. diabetes) or management of lifestyle risk factors (e.g. smoking, obesity, physical inactivity). It also focuses on issues of healthcare inequity (e.g. how income affects the life span of population
segments). UK research on preventive care has reportedly been limited despite its wide potential to affect the population – the recently released Wanless Report (Feb 2004) states that “in the UK, there is generally little evidence about the cost effectiveness of public health and preventive policies or their practical implementation.” Despite its potential for high impact, little private for-profit investments in research are likely to occur in this arena because the output is a ‘public good’. As such, preventive care research naturally falls within the domain of the DH and NHS.

In short, the underlying rationale for why the NHS should undertake R&D in these areas is because they result in patient benefits. Clinical trials, health technology assessment, and preventive care research result in better treatment outcomes for patients, and service operations research results in more cost-effective healthcare delivery to patients. In addition, supporting R&D enhances the proposition to talented individuals in the NHS.

2. What challenges does NHS R&D currently face?

Achieving these high aspirations for NHS R&D requires overcoming existing operational challenges. Interviews and workshops indicate that four types of key obstacles exist today to NHS R&D:

*Lack of individual incentives for clinicians and Trust CEs:* At the core, Trust CEOs and clinical staff question ‘what is in it for me’ when faced with discussions of NHS R&D. They are currently under pressure to meet service delivery targets, and undertaking a research initiative is viewed in many cases as a non-core business. Moreover, little incentive exists for GPs and consultants to participate in NHS trials – they receive no monetary award and no apparent direct recognition for their efforts.

*Lack of institutional incentives:* At a Trust level, interviews cited two main disincentives that exist to pursuing R&D:

- First, the introduction of HRGs to Trusts is believed to unfairly penalize research Trusts because the HRG codes do not currently reflect a complex case mix (and the associated higher treatment and diagnostic costs). The Department of Health has provided transitional support and is currently investigating different approaches for managing this situation in future, but research-active Trusts could face significant losses (valued in the tens of millions of pounds, depending on the Trust activity) unless this matter is resolved.

- Second, interviews indicate that Trusts can be deterred from R&D because they do not perceive the current allocation of R&D support funding (for diagnostics, consenting patients, etc) to be transparent. This is particularly for those Trusts that are located outside of London. While some entrepreneurial non-London Trusts have looked outside the NHS for R&D funding (e.g. funding from the EU and from industry), these tend to be the exception rather than the rule. Current regulations also prevent Trusts from establishing true equity joint ventures with private industry in R&D.
Insufficient capabilities and systems: Successful research requires the right staff and supporting systems. Interviews indicate that NHS research efforts can falter because clinicians leading research do not have the necessary access to and support from statisticians, health economists, epidemiologists, clinical trial coordinators etc, hindering their ability to properly set up and analyze trials and studies. Likewise, clinicians collaborating in research can lack the skills for clean data capture. In addition, interviewees state that researchers tend to lack the appropriate supporting IT systems, and that no common standard exists across the NHS. Moreover, few sites have adequate IT systems that comply with public and industry clinical trial needs.

Lack of collaboration and coordination: An effective NHS research agenda requires collaboration and coordination across both disciplines and the patient pathway.

- First, regarding disciplines, research involves bringing together individuals from across public and private entities – academics, NHS clinical staff, NHS managers, industry, and policymakers. Interviews indicate that each party tends to have different research priorities – for example, NHS managers tend to be most concerned with service operations research that have a direct impact on patient lives while academics tend to be focused on research that can be published in esteemed research journals. This variation in priorities tends to restrict opportunities for designing and collaborating in research. Moreover, interviews indicate that clinicians generally view ‘traditional research’ as more prestigious than ‘applied research – this is at odds with the natural domain of R&D in the NHS. As the previous section outlined, the most significant contribution that the NHS can make to R&D lies in the applied domain, such as trials, clinical effectiveness, service delivery research, and public health. It is critical that incentives exist to reward R&D in the applied domain, which is not the case today.

- Second, regarding the patient pathway, organization boundaries are not consistent with the complete patient pathway, also posing difficulties for collaboration. For example, little R&D takes place across PCT and Acute Trust boundaries, which is a significant missed opportunity that will become more critical moving forward. Moreover, interviewees indicate that facilitating collaboration across the whole patient pathway also requires moving from only valuing research leadership to also valuing research collaboration. Making inroads into UK public health research entails understanding the cost-effectiveness of various public health and preventative measures – PCTs and Trusts will need to participate together in research on how to more effectively manage chronic conditions to promote the maintenance of good health for UK residents.
3. How can the recent developments in the English healthcare environment positively affect NHS R&D moving forward?

Multiple changes are currently occurring in the healthcare environment across the whole of the UK that can potentially facilitate NHS R&D overcoming these challenges and achieving its aspirations. These changes include the formation of new healthcare institutions, the establishment of new contracts for healthcare provision, and the creation of new systems/processes to support and govern clinical care.

To date, no entity has developed a holistic perspective of the net effect and interactions of these changes on NHS R&D. Doing so at this particular stage is important for two reasons. First, these initiatives are all at an early and formative stage, which means that a unique window exists to shape their agenda and role; and, second, maximizing the impact of the significant funds allocated by the Secretary of State for Health in England to NHS R&D is higher if a coordinated approach exists across all initiatives that can influence it. Based on interviews and workshops held by the Working Party, this section offers a preliminary view on the role that can be played by these initiatives in overcoming the current challenges facing NHS R&D (Figure 3). Further analysis and review by stakeholders is required to validate these solutions prior to pursuing them, particularly in order to understand net costs and benefits and the relative priority of each solution. This approach may need reviewing for Scotland, Wales and Ireland where structures incentives may differ.

**Figure 3**

<table>
<thead>
<tr>
<th>Current R&amp;D challenge</th>
<th>Preliminary approach to incentivise R&amp;D activities in NHS</th>
<th>Potential Owner</th>
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</thead>
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4. Incorporate clinical research criteria into standards governing evaluation of hospital performance | Trusts  
DH  
ACCEA  
The Healthcare Commission |
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DH  
UKCRC  
OIR |
| Lack of collaboration and coordination across disciplines and patient pathway | 3.1 Serve as the ‘facilitator’ for clinical trial management across the NHS by bringing together DH, NHS, MRC, industry, medical charities, patients, and other partners | UKCRC |
| Insufficient capabilities and systems    | 4.1 Ensure the adequate provision of clinical research infrastructure  
4.2 Create a central database of patients, as part of the national IT infrastructure, who are willing to be contacted for relevant clinical trials | UKCRC  
National IT Project |

1. Lack of individual incentives for clinicians and Trust CEs

1.1 *Ensure consultant contracts recognize clinical research:* Consultants sign contracts with Trusts whereby they agree a job plan. It is important the consultant contracts and appraisals recognize a doctor’s
role and commitment to clinical research, including trials and other well-designed clinical studies. This can be accomplished by ‘protecting’ the time of clinicians in their job contracts, allowing them to sign up for weekly sessions dedicated completely to clinical research. Job plans should be reviewed and updated respecting research activity on a regular basis.

1.2 Incorporate points in GP contract for recruiting patients into trials: Under a new scheme proposed by the Department of Health, GPs will be compensated by PCTs on the basis of ‘points’ they receive for meeting certain criteria (e.g. services offered, clinical management, patient experience). The goal of the GP contract is to improve the quality and productivity of care offered to patients. GPs can currently receive a total 1050 points, with a value of £75 per point rising to £125 per point in 2005/6. GPs claim the points upfront and then have them validated at year-end. If the GP contracts included points for recruiting patients into R&D efforts (e.g. preventive care and disease management research, trial participation), then they could have a direct incentive for R&D collaboration that does not currently exist today. Further evaluation of this imperative should include assessing the ‘cost-benefit’ of this scheme (e.g. payment to GPs results in how many patients are recruited into trials) and assessing whether ‘R&D’ points would constitute additional payments to GPs or a reallocation of the existing points.

1.3 Reward research collaboration in the clinical excellence awards: The ACCEA (Advisory Committee on Clinical Excellence Awards) awards NHS consultants for excellence in patient care. Currently, 30% of NHS consultants receive a clinical excellence award, which at the highest level (platinum awardees), effectively doubles their salary. Currently, the research criteria in the clinical excellence awards only address research, including trial leadership – these criteria could be broadened to also include criteria for trial and study collaboration (e.g. number of patients that a consultant has recruited into clinical trials or public health research) and for service delivery research. These direct monetary incentives can be important stimulators for NHS R&D.

1.4 Incorporate clinical research criteria into standards governing evaluation of hospital performance: On April 1, 2004, The Healthcare Commission (formerly referred to as CHAI) was launched. Its objective is to encourage improvement in healthcare by reviewing hospital performance against a set of defined standards and assessing healthcare value for money. Its remit includes both public and private sector. The Healthcare Commission is responsible for seven domains of standards, including clinical and cost effectiveness, accessible and responsive care, public health, and patient focus. A strong linkage can potentially be created between NHS R&D and these domains. For example, under the accessible and responsive care domain, one criterion could be the number of patients enrolled in clinical trials; under the clinical and cost effectiveness domain, a criteria could be the
number of studies to improve the productivity of hospital resources for patient care. Likewise, under the public health domain, a criterion could be participation in preventive health studies for priority areas, such as smoking, obesity, and diabetes; and lastly, under the patient focus domain, a criteria could be patient involvement in research approach (e.g. defining the desired research outcome). If R&D is built into Health Commission standards, then this could be an important way to incentivise Trusts and PCTs to participate in research. A prerequisite, however, is demonstrating that a clear evidence-based linkage exists between the outlined criteria and better outcomes in the Health Commission’s seven domains.

2. Lack of institutional incentives

2.1 Ensure that HRGs fully compensate for treatment costs related to R&D: One of the most important levers to get right for NHS R&D is to ensure that the new HRG codes reflect the likely higher treatment costs of research, often related to a complex case mix. DH is currently considering alternative approaches to managing this situation, and research and teaching trusts have offered their views to the debate. One potential solution is to offer a two-tier system of top-ups by a designated lead commissioner beyond the base case, whereby the first top-up goes to teaching Trusts to compensate for higher treatment costs, and the second top-up goes to Trusts involved in research activities. As the NHS develops a solution, it will be important to understand how other healthcare systems have managed this transition (e.g. US, Germany, Canada, Australia), and to identify relevant lessons learned.

2.2 Create a transparent system for allocating R&D funds: NHS funding for R&D infrastructure (as opposed to treatment costs) is distributed on what is seen by many hospitals on a non-transparent basis, with a historic weighting to traditional research institutions. The issues of the perceived adequacy and transparency of the NHS R&D budget will need to be addressed over time in order to counter this.

2.2 Ensure that processes exist to meet new EU clinical trial directives with minimal additional regulatory burden: Many regulations have been set up to protect patients but the cumulative effect can be bureaucratic. For example, the EU Clinical Trials Directive comes into effect in May 2004 and is intended to harmonize standards across Europe. Interviewees believe it will raise the cost of conducting clinical trials and that it will present a new barrier to undertaking clinical research. To manage this effect, the UKCRC can potentially play a role in ensuring that good clinical processes are in place to meet the EU directive with minimal undue burden.

2.4 Ensure that Foundation Trust status allows Trusts to create JV companies based on R&D with industry and thus to incentivise clinicians through equity: On April 1, 2004, the first batch of Foundation
Trusts was launched. A Foundation Trust is an NHS Trust that is licensed by the Office of the Independent Regulator to have increased governance and financial independence (e.g. earlier transition to ‘payment by results’ under activity-based contracts with PCTs, the ability to borrow money from commercial entities, and to establish local governance). The relevance of Foundation Trusts for NHS R&D lies in this greater flexibility – for example, FT status allows a Trust to create a joint venture with industry to pursue and to commercialise research, as well as to offer clinicians equity as a reward for their research contribution. Both can be very direct and powerful incentives for stimulating R&D activity in the NHS.

3. Lack of collaboration and coordination across disciplines and patient pathway

3.1 *Serve as the ‘facilitator’ for clinical research activity across the NHS by bringing together DH, NHS, MRC, industry, medical charities, patients, and other partners:* In an effort to facilitate clinical trials and research across the NHS, the formation of the UKCRC (UK Clinical Research Collaboration) has been announced to bring together the NHS, Medical Research Council, medical charities, industry, and patients. The objective is to speed up the development of new medicines and treatments from the laboratory to the patient's bedside, enabling more patients to benefit from the latest medical advances and to participate in clinical trials. The concept is modelled on the National Cancer Research Institute (NCRI) of Britain which has achieved significant success in increasing the enrollment of UK cancer patients into trials through the NCRN. The UKCRC has the potential to play a pivotal role in promoting clinical research and trials, acting as a facilitating platform (but not a centralised manager) for clinical trial management across the NHS. Potential roles include linking academic researchers and patient populations, and generating awareness of trial benefits across the NHS in order to increase clinician participation and patient enrollment in clinical trials.

4. Insufficient capabilities and systems

4.1 *Ensure the adequate provision of clinical research infrastructure:* Clinicians currently face challenges in trial set up and data management. As part of its mandate, the UKRC should provide central support staff to set up and manage studies, as well as analyze research results. This includes establishing uniform specifications for an IT system across NHS to facilitate data capture.

4.2 *Create a central database of patients, as part of the national IT infrastructure, who are willing to be contacted for relevant clinical trials:* The NHS is currently undertaking an initiative to create electronic patient records for all UK patients, tracking their health from cradle to grave. This information base has substantial potential to provide an unprecedented evidence base for public health research, improving the
understanding of disease prevalence and the management of personal risk factors. Moreover, the IT system could also potentially facilitate patient recruitment by creating a central patient data base – patients could be asked if they are willing to be contacted in the event of relevant clinical trials, which would significantly facilitate connecting researchers with the appropriate patient pool.

The next step is to further evaluate each of these approaches to incentivise R&D, and to discuss and agree them with stakeholders. As most of these initiatives are in early days, it is important to move quickly so as to shape their mandate and role.
Training of Clinical Scientists

Introduction
1. This paper outlines the challenges and opportunities in training the clinical scientists of the future and suggests the need for a career path that caters for the clinical scientist as a specific entity. It is proposed that a working party be set up to develop detailed proposals to achieve this outcome.

Background
2. The reports from the Academy of Medical Sciences (AMS - *Strengthening Clinical Research*) and the Biosciences Innovation and Growth Team (*Bioscience 2015*) have highlighted many of the issues confronting clinical research. The initial response to these reports has been gratifying and there is optimism in the academic biomedical community about the future of clinical research that has not been felt for a long time. The setting up of the working party Research for Patient Benefits, chaired by Sir John Pattison, is an excellent sign of the priority accorded to these reports by both the Departments of Health and of Trade and Industry.

3. One of the key recommendations of both reports is the development of stronger clinical research capacity. Current disincentives against the recruitment and retention of clinical scientists must be eliminated if this is to be achieved. Moreover, for progress to be made, there has to be a strong partnership between the Department of Health, the NHS, and those bodies responsible for the training and employment of clinical scientists. This latter group includes the Postgraduate Medical Education and Training Board (PMETB), the Medical Royal Colleges and their training committees, funders of research, the universities and NHS employers.

4. Currently the young clinical scientist finds him/herself at the centre of a triangle regulated and funded by three groups of bodies that have apparently different aims and objectives (Figure 1). It is therefore imperative that any new initiatives towards capacity building, through the creation of more attractive career structures for clinical scientists, are developed through collaboration of all of the bodies involved.
Disincentives for a clinical academic career

5. The Council of Heads of Medical Schools (CHMS) reported in 2001\(^1\) that over 10% of clinical academic posts in the UK were unfilled. Preliminary results from a more recent study suggest that the number of clinical scientists has fallen by about 12% between 2000 and 2003\(^2\). The decrease in staff numbers is particularly marked in junior grades – clinical lecturers and clinically qualified research fellows. A number of reports\(^3\)\(^4\)\(^5\) have highlighted the problem of recruitment and retention in the past and have comprehensively listed the deterrents for a clinical academic career. The key disincentives, which are still pertinent today, are summarised below.

Lack of a clear career structure

6. One of the most off-putting aspects of an academic career to the young potential clinical scientist is the lack of any clear career pathway through the morass created by the differing aims and objectives of the three main stakeholder groups.

7. To compound this problem, there is very little structured advice for junior doctors on how to pursue a research career, other than for example occasional articles appearing in the *British Medical Journal*’s careers section and conferences organised by the royal colleges\(^6\) and funding agencies. The junior doctors are often left to their own devices, with only word of mouth or anecdotal advice.

8. Pressures from the Research Assessment Exercise (RAE) have also reduced the number of clinical lecturer posts. Traditionally this served as an important first permanent rung on the academic ladder for clinicians, offering a chance to consolidate both research and clinical experience. However, in order to achieve a higher grade in the RAE without reducing volume, heads of medical schools have increasingly been under pressure to convert clinical lectureship posts to non-clinical ones which may bring ‘stronger’ research outputs. The remodelled RAE to take place in 2008, with greater emphasis on the assessment of discipline-specific metrics may alleviate this situation slightly, but there remains little incentive to re-establish clinical lecturer posts.

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\(^1\) A *survey of clinical academic staffing levels in UK medical and dental schools*, T Smith and P Sime for the Council of Heads of Medical Schools and Deans of UK Faculties of Medicine, London 2001

\(^2\) Personal communication with CHMS

\(^3\) *Clinical Academic Careers (The Richards Report)*, Committee of Vice-Chancellors and Principals, London 1997


\(^5\) *Clinical academic medicine in jeopardy: Recommendations for change*, Academy of Medical Sciences Working Group Report, London 2002

9. A recent discussion by the Strategic Learning and Research Advisory Group (StLaR), charged by the Department of Health and the Department of Education and Skills to enable effective joint working and strategic planning across all learning and research issues in health and social care at central government level, identified the following as some of the reasons why trainees were not choosing an academic career path:

- uncertainty about career progression and career structure;
- uncertainty about how to initiate an academic path;
- uncertainty about how to obtain funding for research;
- difficulties in identifying appropriate research area or research supervisor;
- worries about getting back on the clinical training ladder after a period in research – particularly at the pre-specialist registrar (SpR) stage;
- lack of advice locally on the best way to progress an academic career; and
- worry about having to answer to two institutions – the university and the NHS Trust – with both having expectations that outcomes will be similar to those of NHS clinicians or university non-clinical academics.

10. Similar issues were also highlighted at a recent Clinical Careers Workshop at Imperial College, London, hosted by the Wellcome Trust. Attendees outlined the difficulties they faced in obtaining good advice on career planning, particularly on strategic decisions and on achieving a good fit between the demands of clinical training and research progression. They also noted the pressure from their local deanery to complete their clinical training as early as possible, which in their opinion was due to the local NHS Trusts’ demand for filling vacant consultant positions.

11. It should be noted that there has been some movement in recent years to improve the career structure of clinical scientists, such as the creation of Clinician Scientist posts in response to the Savill report. These allow clinical scientists with outstanding research potential to enter a five-year post that enables them to complete clinical training while simultaneously extending their research base. Medical schools are encouraged to view these posts as a tenure track leading to a senior academic post.

12. However, the Savill report recommended that only 50 such posts be created a year and it remains unclear whether there are sufficient funds available to achieve even this target. At the workshop at Imperial College, the attendees expressed their concern that the entry point for the Clinician Scientist post is rather high.

**Insufficient flexibility of the training programmes**

13. Another major barrier for a clinical scientist is the lack of flexible training programmes that allow for the concomitant development of research and clinical careers. Clinical training remains regulated largely by specified lengths of training (with certain minimum times set out in European law), which are
used as a surrogate for the development and assessment of the required clinical skill base. There is also a high degree of focus on achieving a licence of specialist qualification, rather than recognising that clinical skills mature, evolve and develop throughout the career of a medical practitioner. Furthermore, there is an additional barrier posed by regional training committees with inflexible Record of In-Training assessments.

14. It might be argued that a flexible route for the training of clinical scientists already exists in the form of the academic and research medicine route for entry to the General Medical Council specialist register, operated by the Specialist Training Authority. However, the Specialist Training Authority guidelines (STA Information Sheet 5) indicate that this route is intended to be exceptional and specifically, “....this means of entry to the Specialist Register cannot be a prospective route and will only be suitable for a small number of doctors.”

15. Such inflexibility contrasts with the approach that is taken to the research training of clinical scientists. The irreducible core of training for research is a period of doctoral training. Subsequent research support for clinical scientists is predominantly in the form of fellowships. Most fellowship schemes provide considerable flexibility to tailor to the individual's needs. A research fellowship proposal explicitly sets out what research is proposed and how this fits with the career structure of the individual. There is no parallel provision of tailored clinical training of clinical academic staff.

16. MB-PhD schemes also illustrate the challenges to the satisfactory training of clinical scientists. Those that enter these schemes are amongst the brightest and most research orientated undergraduates entering medical training. The immediate output is a medically qualified graduate with a PhD, often in a rather basic area of medical science. The next stage of their career is one year of pre-registration house officer posts, followed by three to four years as a senior house officer, before they are able to enter higher specialty training. There is minimal prospect of further research experience or training during this period. There is a danger of two outcomes; the first is that the MB-PhD graduate essentially becomes a basic scientist and never practises clinical medicine; the second is that the prolonged period of full time clinical training means that they become increasingly remote from their science and that they never return to research.

17. The issue of current clinical training not being flexible enough was also highlighted during the Workshop held at Imperial College and in the study by StLaR. Furthermore, some perceive that NHS Trusts are increasingly unwilling to support new clinical initiatives that are not part of their stated strategy. Such rigidity may lead to their failure to grasp unpredicted opportunities for clinical innovation.

18. Most clinical researchers are also, appropriately, involved in teaching and training. However, some individuals may wish to progress along a career pathway in which their predominant activity will be as a medical educator. Such individuals are badly needed to enable the expansion in training of doctors and other clinical practitioners and to enable the development of programmes of
continuous professional development. A similar triangle to that shown in Figure 1 can be drawn for the trainee medical educator, with the NHS, the universities and the training regulators at the vertices. The proposal set out in the next section of this paper could be readily adapted to meet the needs of trainee medical educators as well as clinical scientists.

Length of training period

19. The length of training period and the prolonged insecurity compared with contemporaries is another deterrent for a clinical scientist. The implementation, from 1 January 1997, of a shortened SpR training has further widened this gulf. Although there are variations, an NHS trainee in hospital specialties can now hope to become a consultant by the age of 32 or 33. In contrast, with an increasing demand to complete a period of post-doctoral research training, a clinical scientist is more likely to achieve his/her first permanent post at the age of 37 or 38.

Financial disadvantages

20. Coupled to the prolonged insecurity from the length of training is the lack of parity of income with a clinical career, arising from earnings lost during training and the inability to earn from private practice. Indeed, this was one of the major deterrents for a clinical academic career identified in a questionnaire survey conducted and published in 1999.

21. The study by StLaR also identified the same issues as listed below:
   • concern about whether pay parity will be maintained between NHS and academia;
   • concern about parity with NHS colleagues in terms of on-call payments; and
   • poor comparability with NHS funded service posts in terms of initial packages such as relocation costs.

22. The problem of pay parity may be further exacerbated by the introduction of the new Consultant Contract. It is vital that the new Contract is implemented in such a way as to prevent any further financial disincentives being created.

Proposal

23. This paper proposes that a career path is created to cater for the clinical scientist as a specific entity. Key to the success of this proposal is the creation of explicit partnerships between the NHS, research funders, universities and the regulators of training. This is essential so that the stakeholders can:
   • share the responsibility for the overall training package;
   • share the financial responsibility – the research funder will provide for the research training and support and the NHS will fund the clinical training of the individual; and
   • jointly address the issue of career progression of clinical scientists.

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24. The assessment of clinical trainees by the training committees of the Royal Colleges and PMETB must be in a manner that is ‘fit for purpose’. There has to be recognition that the product is a clinical scientist and not a district hospital consultant. An ad personam identification of what clinical skills will be needed and assessment based on attainment of these skills, rather than time served, would be vital.

25. For this, there needs to be a flexibility of approach that requires a separate mechanism to be established specifically to supervise the clinical training of these individuals. Possibilities for the future could include the existing specialist advisory committees (SACs) setting up subcommittees designated to deal specifically with academic trainees. It should be emphasised that creation of such subcommittees and the use of competency-based assessment does not equate to a dilution in the clinical standards that the individuals have to attain. Rather it is a pragmatic approach to allowing the particular challenges faced by the academic in training to be recognised.

26. An additional feature required for success is a recognition that clinical training is not complete the moment that a Certificate of Completion of Specialist Training (CCST) is issued – on the contrary, clinical training evolves throughout the working lifetime of a consultant – and that a clinical scientist may evolve towards either a broader or a narrower clinical practice. There must be explicit mechanisms developed that facilitate changes in the practice of clinical staff after the award of a CCST.

27. Most clinical scientists will develop a highly specialised practice and will work in an environment where clinical cross-referral is the norm rather than the exception. Training requirements also need to recognise this reality. If a clinical scientist changes the scope of his / her clinical practice, then further training will be necessary, but this should form a normal part of continuous professional development, available to all doctors in clinical practice.

Conclusion

28. The establishment of integrated career pathways for clinical scientists is an important piece in the jigsaw necessary to revitalise clinical research for patient benefits. It is therefore proposed that a high level working party be established with senior membership from each of the relevant stakeholders, with the terms of reference to develop detailed proposals that can be implemented.

Dr Mark J Walport
Director, The Wellcome Trust
On behalf of Research for Patient Benefit Working Party
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