Review of UK Health Research
– Response from AstraZeneca plc

Why a strong health research base is important to the UK and AstraZeneca

The pharmaceutical industry is one of the most productive in the UK and is of critical importance to the UK economy. The contribution that the industry makes to GDP is highly significant. A flourishing science base in the UK is paramount to the continuing success of pharmaceutical research. The largest contributors to the UK economy through R&D and innovation are the pharmaceutical and aerospace sectors. Such companies rely on the UK science base for supply of trained scientists and engineers as well as generating opportunities for collaboration and the dynamic interactions with academia that engender the creation of ideas and promote innovation. **Clinical research is a key component of the UK's biomedical research capability and as such is intricately linked to the ability of the UK to sustain economic growth. AstraZeneca remains concerned that the erosion of the science base both in UK and Europe is having a negative impact on the level of innovation.**

AstraZeneca is a major international healthcare business engaged in the research, development, manufacture and marketing of prescription pharmaceuticals and the supply of healthcare services. It is one of the world's leading pharmaceutical companies with key products in gastrointestinal, cardiovascular, neuroscience, respiratory, oncology and infectious diseases. AstraZeneca's global R&D spend for 2005 was $3.38b and also encompassed inflammation research as well as technology development.

In order to sustain a vibrant and flourishing environment for economic growth it is imperative that medical research, development and innovation are elevated in importance and pursued vigorously.

Summary

AstraZeneca welcomes the opportunity to contribute to this important consultation. The future of health research in the UK is critically important to patients, healthcare providers and the economy.

- **AstraZeneca supports the merger of the MRC and NHS R&D research budgets** to create a research fund of over £1bn. The union of the MRC and NHS in this way is a positive step. A common source of funding for health research in the UK should provide a more efficient way to conduct relevant clinical research. Since the UK government is committed to improving the nation's health and the nation's ability to compete globally in a knowledge and research driven economy, then a single fund and unified administration of UK health research makes sense.

  At present, it is not clear where the new funding will be sourced from, what it is replacing, what will change if these funds are moved from supporting existing activities and whether this represents a total increase or decrease of current funding. An overall reduction in financial support for health research would severely hamper the UK's ability to compete internationally.

The creation of the fund represents a clear opportunity for the UK to be leading in health service research and translational science. However, this requires substantial funding, significant investment in R&D, focus on the health needs of the nation and a change in culture. It is therefore important that the best organisational structure and robust leadership is developed.

- **The creation of a new organisation to administer the fund appears to be a sensible approach. However, it is critically important that there is clarity of vision for the new organisation and fund.** The goals of the health research supported by the fund need to be clearly stated, with defined objectives, milestones, and visible evidence and metrics of success. Transparent mechanisms of allocation coupled with clear deliverable endpoints and project management will be important.

  Some of the building blocks are already in place or are being established such as the virtual National Institute for Health Research, technology platforms and research networks. It will be important to continue to build and implement fully what has already begun. The new funding body should not become a semi-independent organisation within the NHS but it must use the NHS infrastructure for health research. We strongly suggest that the National Institute for Health Research is established as an entity in its own right, rather than continuing to exist as a virtual body. It should have a real tangible existence with specific powers and obligations as well as the ability to contract in a transparent manner with the NHS for use of the NHS infrastructure. Otherwise the current investment may be wasted and ambitions not realized. This should not be viewed as an occasion to save money but as a strong opportunity to create a world-class health research organisation for the UK.

  Concerns remain however, in particular, it is unclear from the scope of the report how the research interests & infrastructures of Scotland, Wales & Northern Ireland will be represented Best Research for Best Health for example only applies to England. Furthermore the new system must not become so large or bureaucratic that effective decision-making and implementation is impaired.

- **The review contains little mention of the valuable role played by charities and the pivotal role of industry in health research** and this is reflected in current practice**.** These shortcomings must be remedied. One suggestion is to minimise areas where research conducted by different stakeholders overlaps and explore areas of synergy that could be developed further. The current interface between industry, charities such as the Wellcome Trust and universities, is reasonably well-developed, but could be shaped and enhanced, possibly through memoranda of understanding such that the parties can work together more easily.

- **UK Clinical Research Collaboration (UK CRC) is an excellent concept and one which AstraZeneca fully supports**. However, the changes have not yet been fully embraced and consequently the benefits are still not fully realised, although the recent publication of the UK Health Research Analysis report creates a firm basis from which to develop a clearer strategy. We wish to suggest that clearer objectives and focus for UK CRC would make the biggest difference.

- **The scientific advances and innovations that are currently available within universities and the NHS should be exploited more fully to the benefit of patients and the economy**. The recent wave of new SMEs is encouraging. Some are successful, other less so. It is important that emerging and developing companies are given the requisite support, incentives and encouragement to be able to compete in the current environment. We welcome the ideas to continue to maximise the impact of science on innovation, by the Government as set out in the Next Steps report.

- **AstraZeneca remains concerned by the lack of clinical research and training in the UK.** Currently, within medical training there are few incentives to carry out clinical research and the MD/PhD is not appropriately valued at present. For example, even holders of research posts in UK teaching hospitals are often contracted to work for much of their time in clinical practice. This appears to be a perennial problem partly due to the way that training is currently structured. In addition there is a lack of obvious career paths or structure for academic medical researchers. In an environment in which hospitals are under pressure to concentrate on delivering health care to patients, funding for clinical research is not given priority.

- **It is our firm view that the ethical review process in the UK could be markedly improved.** The level of expertise needs to be augmented and turnaround time for reviews need be improved. Approval by one hospital ethical review committee or scientific review committee in the UK should suffice for all DoH centres. We suggest that a single system with accountability to DoH should be built into the new model. This would ensure that all UK institutes and hospitals become part of the same system and would give the UK a significant, globally competitive advantage. A single unified UK system would also be simpler for Industry to engage with.

Review questions

1*. What are the strengths and weaknesses of the MRC and NHS R&D programmes at present? How do each of these support the research and training needs of the NHS, social care, industry and academia? Does more need to be done?*

The relative independence of the MRC supporting academic research and delivering good quality academic results are significant strengths. The MRC has a strong track record of support for basic health care research. The system of peer review works reasonably well and helps to ensure quality research is carried out and has led to international standards and a reputation of the MRC being considered as a hallmark of quality. Both clinical trials and programmes of research funded by the MRC have credibility in the academic community and basic research has received recognition through the award of several Nobel prizes. However, the MRC appears to be at present focused on molecular biology and genomic research and consequently has increasingly detached itself from medicine. Funds also appear to be targeted towards *in vitro* studies rather than whole animal physiology and pharmacology.

Even within the current organizational arrangements there are several unrealized opportunities for MRC to drive translational and clinical science through it's own major research centers. Although we are fully supportive of many of the fundamental research programmes at these institutes we would like to see less emphasis on

preclinical science and more experimental medicine with greater collaboration and co-operation between the centres to produce focus on real clinical problems from the molecular level, through animal models to human data and clinical practice.

We are aware that in a wider context also, different groups funded by the MRC carry out very similar work, rather than focus on core centers of excellence and avoid over lap. The current funding schemes do not appear to be well co-ordinated and we are concerned that valuable synergies could be lost.

The MRC Experimental Medicines Initiative is an example of success. The linked approach with charities, industry and SMEs coupled with an increase in the available funding has resulted in greater visibility, impact of results and more deliverables in the short term than has occurred in the past.

The technology transfer activities of the MRC are commendable and given the potential for significant innovation in health research, with the correct management and leadership, the organisation could be positioned to take even greater advantage of this asset. However, it will be important also, to consider the potential to create new companies around the innovative products, processes and technologies that a well-funded health research base could deliver.

Against a depressing trend of loss of critical mass in disciplines of vital importance to the continuance of a solid health care R&D environment, we observe that training is not well catered for in the current schemes, particularly translational science. As this field continues to advance it will become increasingly important to develop staff of all skill types and also to inform patients and carers of the need for translational science, what it involves and the risks and benefits of the R&D process.

We find the quality of training and the facilities of medical colleges in the UK to be good. However, in the current system, there are no incentives for clinicians to take time out of training in order to carry out a period of clinical research. This places the UK at a severe disadvantage for a number of reasons. The Government should provide encouragement and support for clinical research by ring-fencing some of the £1bn specifically for clinical research training. Whilst we support the MRC research training fellowships we urge the MRC and NHS to develop clinical research fellowships within the new budget. Such training is desperately required in the UK.

It is important to ensure that the any new funding organisation encourages and supports new young researchers and endeavors to fund excellent science wherever it exists.

It is our opinion that neither the MRC nor NHS caters for the needs of industry particularly well. SMEs represent a significant source of innovation, however there is currently poor engagement of the NHS with small companies. The UK could be missing a significant opportunity in this respect. The NHS has been slow to embrace innovation, knowledge and technology transfer which has been to the detriment of the UK, although there are some promising signs. The MRC has a number of industry relevant schemes although we feel that there is a certain amount of reticence from the MRC to embrace partnership and industrial involvement has been perceived (by industry) as largely unwelcome. Furthermore the MRC has a poor track-record of working on shared agendas with industry and involving industrial scientists in both strategic and operational roles, unlike many of the other research councils.

The NHS funds studies that otherwise would not be done, eg longitudinal and epidemiological studies, and therefore fulfils an important role. We find that research supported by the NHS is more variable with respect to quality and impact of research than the MRC. The NHS has no significant track record of research, no history of excellence, a lack of transparency in decision-making and, up to recently, lack of credibility of leadership. The expenditure by the NHS on research is not transparent and this major weakness must be addressed quickly. The NHS does not have a history of translational research, of developing products to market, and is even less adept at working with industry.

However, the NHS has the potential to be a good R&D organisation and attract international investment. The government currently provides targets for service providers of healthcare but not for health research. Providing clear objectives, milestones and metrics for the latter will be an important component in shaping the performance of the fund.

The DoH performs a good service for the association of patient records and archival tissue data, compared to the US for example. The UK practice base is more prepared to consider a greater level of risk taking than the US and we find the DoH has a more open mindset to risk taking for intervention and scientific curiosity than other territories. We believe that the UK could lead the way in having a valuable patient database for health research in the UK.

We find the process of contract negotiations is currently inefficient and wasteful of resources. The basis of cost calculation for each study is not clear and is highly variable between centres. We would like to see a move to a system of a single contract with DoH on a per patient basis, compared to the current system of layers of contractual negotiations with centres, universities and other providers.

The creation of the NIHR was a very positive step. The inclusion of the pharmaceutical sector to engage with this to develop the vision and forge the future was most welcome. However we find that the NIHR has been heavily dominated by academics and consequently driven from that perspective. Typically liaison with industry is not strong. The NIHR has a substantial set of initiatives that are challenging. However, if underpinned by better business activity, we believe that the NIHR will be able to make more progress. Tensions exist between MRC and NHS that need to be removed if the UK is to succeed in its ambition to deliver high quality health research.

Often the MRC and NHS are undertaking parallel initiatives and supporting similar areas science. There is currently fragmented funding for technology platforms in the genomics and proteomics field. Funding for these should be consolidated and centralized.

The MRC and NHS have access to different expertise, facilities and assets, the MRC basic laboratory science and the NHS patients groups. If the two could work together in a harmonious and co-ordinated way they could be very effective and make a significant contribution to the health and science objectives of the country.

2. ***What do you believe are the key scientific and organisational challenges facing health research, and underpinning training, in the UK over the next decade? How might the UK Government best hep address those challenges?***

What do you believe should be the Government's objectives for health research, and why?

The scientific and organisational challenges facing new health research and training initiatives in the UK are considerable. There is a huge gap between basic research and its application to develop new therapies and treatments. Consolidation of the service providing aspect of the NHS with the research intensive MRC will have particular issues.

Health research covers a broad area and therefore it is not easy to pinpoint specific activities, however, there is a clear need for stakeholders to engage and to develop the ambitions for the new fund.

It is important to focus on building a world-class health research organisation with well-funded facilities and centres of excellence that works for the needs of the UK as a whole. Uniting the MRC and the NHS R&D should create an organisation that covers all aspects of medicine from basic research, translational science, development and application of new therapies and epidemiology studies. In addition the new system needs to encompass the clinical research training needs required to create a world-class health research and health care system. The organisation should have a clear vision, with well-defined objectives and deliverables coupled to visible metrics of success. Use of the funds must be transparent to all, with robust peer review of projects with clearly measurable outcomes. The intellectual rigour and evaluation by peer review practiced by the MRC should be applied to the NHS and larger numbers of industrial scientists and clinicians should be encouraged to participate in a meaningful way.

Improving the science base and translational science in particular to make the UK a leader in health research, translational research, science and innovation should be at the forefront enabling the opportunity for the economic growth and societal benefit that is sought. Currently, there is not enough funding for translational science or centres of excellence in this area.

It is important to build on existing structures such as the NHS Research Networks with the spectrum of activity supported by academic medical centres and academic networks.

The NHS is a healthcare service provider and tries to be efficient and effective at this. Therefore it is currently not motivated to focus on research and does not have the mechanisms, knowledge, drivers, resource or finance to develop a clinical research base. The new fund creates an exciting opportunity to develop a world-class health research base in the UK. It is important to create the space and time to establish an environment in which researchers and service providers can develop solid working practices and clear career routes in the new system. The correct infrastructure for conducting healthcare and research must be established.

Technology platforms are not yet established. As these are very costly there is a need to encourage the concept of core centres for example in genetics, proteomics and imaging. New and emerging technologies have yet to establish their place, consequently we believe there is a need to develop a national centre for this. We can see benefit in having some technology platforms as a national resource with others regionally or locally-based, dependent on the type of technology in question.

We find that some centres are good at phase I clinical studies and others are less so. This suggests that a positive step may be to let those centres with strength grow and close or amalgamate others that do not have the required strength.

3. ***What should be the Government's priorities for health research? Is there anything it should stop doing or funding? What is it not doing or funding that it should do, and, in the absence of further sources of support, what can it lower in order to release the necessary funds?***

It is important to have clear vision, strategy and plans for health research in the UK. The development of this should involve all stakeholders, including international peer review. The strategy should encompass the scientific, health and economic objectives for the UK and take account of the innovative strength of the biotechnology and pharmaceutical communities in addition to the NHS and MRC. A different ethos is required to that observed today.

The research priorities should be those with the greatest achievable benefit and within therapy areas of significant disease burden and causes of mortality such as cardiovascular disease and cancer. For example, through a partnership approach with industry and SMEs, research focused on diagnostics, technologies, therapies, and targeted approaches to the needs of priority disease areas. Cancer prevention studies are poorly funded at present. This area is one that should be made a priority as it could bring significant reduction in disease burden. With the advances of personalised medicines there is a need for all stakeholders including, patients, funders, industry and regulators to be aligned to understand, tackle and deliver on the significant challenges in this area.

UK CRC has made a good start, but could improve by better expressing and making understood its strategy and policies.

Health delivery research should be built into other projects and become a routine part of running a Trust. Large items such as radiotherapy equipment should exist in centres of excellence that have robust and effective networks, utilising both delivery to patients and health research. At GP level, health delivery should be well coordinated and seek to improve efficiencies.

4. ***How should decisions be taken on the balance between the long-term economic and social benefits of a high quality biomedical research base and the needs for research to improve healthcare and other public services? What is the appropriate balance between public funding for investigator-led and priorities-led research? How do we balance funding for basic science, translational science and applied science? Is this something that should vary over time? What mechanisms should be used to make judgements about this balance?***

The balance of distribution of the funds between biomedical research, improved healthcare and public services is an important subject that should be discussed and agreed by all stakeholders. A partnership approach is most likely to deliver long-term benefit to patients and the economy. It is important to identify those priorities that will impact on the population in the short, medium and long-term time frames and to balance the use of the funds on the major scientific challenges.

There is still a need to determine keys areas of research for the UK building on recent activity eg UK CRC and others. It will be important to look at the overall benefit to the UK in order to place funds where they will have the most impact. There

is a clear need to focus on science, technology development, opportunities for innovation and growth and investment in R&D in the UK and to ensure that there is access to the fund and new structures for all.

The balance between basic, translational, and applied research will probably need to adjust and vary with time, according to the health priorities of the strategy. The UK is currently strong in basic and translational biomedical research, consequently we have the opportunity to build on this key strength. Basic science should always be funded substantially as this is often the inspirational source of innovation.

Whilst we can see a role for the NHS R&D to focus on public services and healthcare systems, epidemiology and health economics, it will be important that these dovetail with the research activities of the MRC. The basic science carried out by the MRC should be protected. Translational science should be established in university departments embedded in hospitals and include teaching hospitals. Projects should be peer reviewed. Funding should be directed to excellent science and be focused on key health challenges. The use of the funds should be audited.

5. ***In your experience, how have the results of publicly-funded health research in the UK been used, both in the development of new treatments and to influence/change wider policy and healthcare practices? What lessons can usefully be learned to improve the uptake of advances in science and medicine?***

Although it is possible to identify some positive outcomes of publicly funded health research in general we believe that use of results to develop new treatments and demonstrable improvements in practice have been poor. There appears little connectivity between the research phase and development of treatments and clinical practice. Whilst some universities have strong bioscience capability and have some good ideas, the medicinal chemistry and toxicology components required to design and develop new medicines are critically lacking in the UK universities. Therefore, we should look more closely at publicly funded institutes to analyze strengths and areas for improvements and enhance links with other centres of excellence that are properly equipped with resource and expertise. AstraZeneca continues to support the concept of a national centre for toxicology.

There is a lack of visibility in the use of the current funds and how successful they have been. Publicly funded research findings are not well publicized compared to the findings of private sector discoveries and results. There is also a perception with some audiences that publicly funded research is of poorer quality. We believe that the UK should take the opportunity to publish more in the future and to demonstrate the success of UK research. Particularly, publications of translational science research findings will highlight the benefits of new technologies and resulting improvements in healthcare.

6. ***How might better links be forged between "basic", translational and applied researchers, working across the whole field of health research, from the laboratory bench to the front line of the NHS? How might better links be forged across disciplines, e.g. with engineers, physicists, and social scientists?***

One approach would be to invite proposals that tackle particular issues and attempt to solve problems that are the key challenges facing biomedical research. Such proposals should link basic, translational and applied research as well as harness the exploitation potential of biotechnology companies. Proposals of this type may also

require larger amounts of funding. For strategic projects, up to three years of funding with the potential to be milestone driven may be appropriate.

In creating better links between basic, translational and applied researchers there will need to be a significant change in culture and approach to that observed today. Often simply by attempting to unify and harmonise different groups by, for example, putting people in the same building and, collectively identifying and tackling barriers to change, will bring about improved relationships and ways of working. The change in culture that is required should not be under-estimated. As mentioned earlier the NHS is driven by short term goals and has little experience of working with the academic and biotech community, and the MRC lacks flexibility because of the current rules of grant awards. In bringing these two together it will be important to know and understand the associated risks.

7. *How can the Government encourage translation, entrepreneurship and innovation in health research to improve public services in the UK?*

The current tax credit system for SMEs has had some positive impact, however alone it is not enough. Through increased funding for SME led research, eg smart awards and given the best management support, new companies may develop. In addition, a greater emphasis on linking funding with charities and industry in order for SMEs to learn from larger companies and tap into the wealth of research conducted by charities will be important. A range of incentives to support further existing SMEs, at all stages of development, is also required.

To change the NHS from a bureaucratic health service with little experience of science and research to a new system centred on health research, innovation and entrepreneurship is not trivial. To achieve this there is a clear need for leadership by those with experience of R&D and joined by MD/PhDs with a mixture of scientific backgrounds, and with a track record of delivery to develop teams capable of identifying exploitable results and ideas.

8. *How can UK health research funding be most efficiently used to provide the appropriate infrastructure for basic, translational and applied research, whether funded by the UK public sector or other sectors? How can UK health research funding be most effectively used to support the work of NICE, facilitate innovation and collaboration with industry, and address market failures in the application of healthcare?*

The infrastructure for health research funding should be build on the existing proposals of NIHR and accommodate the needs of academia, business, charities and the NHS. By focusing part of the new fund on grants for infrastructure this will help to ensure that research groups have the capability to do research rapidly, effectively and efficiently.

Increasingly, there is a requirement to determine how best to run trials and how the NHS and industry can work together better. The Clinical Trials Agreement is a positive step but more needs to be done. Attempts to standardise this have been useful and we hope to see the fruits of this later this year. As the NHS goes through the process of commercialization, the Clinical Research Centres need to be financially viable and develop stronger links with industry.

The NHS is finding it difficult to recruit research nurses, therefore an opportunity exists for industry to support CRC and local NHS for example by supporting research nurses in key centres or contributing more to the management of the CRC.

It is not yet clear how Foundation Trusts and Primary Care Trusts fit in to a new system. The current system is complex with many initiatives, making it difficult for industry to know whether to approach networks or centres.

AstraZeneca initiates clinical studies on a global basis. We do not look at the UK but at Europe has one geographical area in terms of patient population of diseased or normal subjects and whether the trials can be run quickly, cost-effectively and to quality standards. The variable approach of Trusts to R&D, costs, research governance and national versus local ethical review is forcing us to place clinical trials elsewhere in Europe. Furthermore the UK is not a very cost-effective place in which to carry out clinical trials as Primary Care Trusts often seek exceptionally high cost recovery rates.

The ethical review process in the UK is unnecessarily complex with layers of ethical review and multiple stakeholders involved. All of this is making the UK slow and less competitive. Although the Central Office for Research Ethics Committee has helped to improve the situation, more needs to be done.

We understand that by 2008 Primary Care Trusts will be commissioning bodies only and therefore not providers of R&D. Therefore it is important to know what is the anticipated role of these Trusts. The changing status of Primary Care Trusts and Foundation Trusts need to be taken account of in any new system. At present no funding is set aside for these Trusts to undertake research or to collaborate with other Trusts. If these Trusts are to participate effectively in health research then we strongly believe that there should be targets for research, and clear incentives to engage in research and with partners in industry.

A potential strength for the UK healthcare system, from the R&D perspective, is its integrated approach. It is essential that the government build on this strength rather than allow the complication and fragmentation of the system to erode this potential benefit.

The fund should not be used to support the work of NICE

Other points in this question have been addressed earlier.

9. *What lessons should the UK learn from other countries in making the proposed changes to the institutional arrangements for the funding of health research?*

Health research in the UK is severely hampered by lack of significant funding, fragmentation of research and inadequate connectivity between stakeholders.

It is widely acknowledged that leading edge health research is conducted in the US through the National Institute of Health and its subsidiaries such as the National Cancer Institute. There is a much stronger connection between the medical community, healthcare providers, clinical research and industry. The latter is seen as a viable source of funding for collaborative research. Importantly, interchange of people between clinical research, clinical practice and industry occurs in a flexible and frequent manner. The US health research system covers the entire spectrum from basic research through applied research and clinical research to clinical practice. The MD/PhD is embedded in the US research system with many clinicians being jointly qualified in research and medical practice.

The generosity of the US government coupled with the abundance of private investors has created a vibrant biomedical research base in the US. This encompasses basic, translational and clinical research with the discovery and development of new medicines and therapies. One factor in its success is the strong connectivity between the university, biotech and pharmaceutical sectors. However, it should be remembered that the US, due to its large size, enjoys economies of scale that the UK alone cannot realize.

The recent willingness of the FDA, NIH, companies and other stakeholders in the medical community to discuss the challenges facing health care today and to develop the Critical Path document is an example of what can be achieved by working in harmony. The Critical Path tries to pull together areas in translational and applied research that are of strategic importance in healthcare and to invest substantial funds in the identified areas. This is a work stream that the UK government and other stakeholders should explore.

In a similar way the European Innovative Medicines Initiative has identified bottlenecks in the R&D process and developed clear programmes of activity with significant funding to address these issues on behalf of the EU. This programme was industry led and focused on specific health research goals. The UK should actively explore engagement with IMI as it progresses and develop UK specific strategies.

In the Nordic countries the health care system is well developed and links between universities, hospitals and private firms are in place. AstraZeneca for example has developed strong links with the Karolinska Institute and together they have created many important research findings.

In Australia, there is parity of funding between government, the biotech community and industry, eg CSIRO. Centres of excellence received substantial funding from government and training for Doctors is excellent.

10. ***In implementing the single fund for health research, to what extent should the MRC and DH/NHS R&D be merged or brought together? And to whom should the single, ring-fenced fund be accountable? Please provide reasons and any supporting evidence for your response.***

In order to implement the new fund one organisation with representation from MRC and DoH would appear sensible. The funding organisation should be accountable to government through the DoH and be given a clear mandate. The independent body needs to develop a strategy with robust targets, deliverables and performance indicators and metrics. A board and council will be required to implement this. This is an important development and it will be critical to ensure that particular areas of research and/or groups are not excluded for significant periods of time. There is also the requirement to balance basic, translational, applied, epidemiological and public health activities as indicated previously in this document.

In addition, as the new fund is founded upon innovation then consideration of how intellectual property should be protected in this new system needs to be addressed

11. ***To what extent does the success of recent innovation in health research (e.g. Clinical Research Networks) and the proposed structures rely on the new Connecting for Health NHS IT system, and to what extent should it do so?***

The clinical research networks are an important initiative that ultimately should provide patient benefit. At present it is not clear how the quality of the research is assessed and what the structure of the networks should be. The NCI protocol review mechanism is trying to achieve increased numbers of patients in clinical trials. This positive step also encourages individuals to think about research and its value who may not have done so otherwise.

The IT networks can be productive and help with the daily management of healthcare systems. The system has potential to be great but was poorly developed and consequently it is difficult to know when it will deliver. It needs to be improved radically. Critical to the building of any new system is the need to consult all stakeholders including those involved with day-to-day processes. A thorough review and consultation may be required in order to remedy this situation alongside the proposed pilot study in Connecting for Health.

The UK CRC network is good in oncology. It has led to improved recruitment and increased the quality of results and therefore the ability of the UK to compete in this area. Even so, we are aware of delays in setting up research programmes and evaluating proposals.

The EU clinical trials directive remains a major hurdle. This has added to the complexity of conducting clinical trials such that we often find it easier to place trials in others countries than the UK.

12. ***Given that NHS R&D is currently devolved, but that the work of Research Councils is not, how can these functions work best together to maximise the health and economic benefits to the UK?***

Currently, research in the NHS is under-valued, does not work well and is fragmented. There is an urgent need to move to a model of an integrated health care system for the UK including R&D and excellence in medical and clinical research training. This could make a huge impact on patient benefits, scientific advancement and the economy.

In England, the type of research, pace and quality is measured but no link exists between these elements; the amount of funding given to a Trust to conduct these activities is based on a historic formulae – this needs to change if the UK is to become world-class.

High level support by government is needed to look at this particular issue. We can see a requirement for certain national facilities to be supported by government and used by hospitals and universities as appropriate for their activities. Some large centres and technology platforms could have a regional basis, but it would be important to ensure that the UK research is not fragmented by region. Different areas of the country need to encourage research activity as at present there are clear pockets of activity and in some regions it is altogether absent. Support for regional distribution at some level based on population size may be useful in some circumstances.

We hope that this response is useful to you in developing the purpose, shape and impact of health research in the UK. We have only touched on important topics in this brief response and would be pleased to speak with you in detail on any of the points raised.