

Pfizer Response To The Questions Raised By The Cooksey Review Of UK Health Research

Pfizer Ltd would like to thank Sir David Cooksey and the Review Team for the opportunity to participate in this important consultation.

Pfizer has been in the UK since the 1950s. Currently around 6,000 people are employed in the discovery, development, manufacture and marketing of human and animal medicines, 3,600 of whom are based at the Sandwich site, in Kent. We are the leading supplier of medicines to the NHS and every month in 2005, over two million patients in the UK were prescribed a Pfizer medicine. We invested £600mn of R&D in the UK and more than \$7bn, globally in 2005, making Pfizer the largest health R&D spender in the world.

Our response to the consultation represents the consensus opinion of senior leaders across the R&D spectrum in Pfizer Global R&D (Sandwich, UK) and Pfizer UK Ltd (Walton Oaks, UK).

Key Messages

In responding to the Committee's questions, six themes have emerged, which we summarise below:

1 Clear scope for more focused strategy and efficiency gains through merging MRC and NHS R&D budgets.

- In principle, Pfizer would support any change to the organisation of UK health research that resulted in improved joining up along the R&D continuum and resulted in a more effective, patient focused strategy as well as a more effective use of public funds.
- The overall level of funding for health research is crucial. The UK is, by far, the most important centre for clinical research in Europe. But this position is under threat. Given the scale of investment in the US through the NIH, the overall level of funding needs to be raised if the UK is to retain this status.
- The mix, as well as the level, of funding is important. Capital spend on facilities without associated training and related activity has led to under-utilisation of resources. The balance should be shifted to allow more resources to go into training. This needs to be coupled with appropriate incentives to attract the best scientists into clinical research careers as well as more traditional basic science roles.

2 Quality publicly funded health R&D helps make the UK a good place to invest in – but ensuring market conditions also favour innovation is key to sustain that investment and make the most of UK science.

- Supply of good science is vital to the health innovation system. But the market environment for medical innovation is equally important. R&D in healthcare is increasingly internationally mobile. There is now a much wider and better quality choice for pharmaceutical companies on where to locate clinical trials, than there has ever been.

- Many of the established characteristics that made the UK a good place to host pharmaceutical R&D are under threat or actively disappearing. Examples include:
 - Cost containment via local productivity targets - such measures are short-termist and damage: incentives to innovate; long term productivity and the quality of patient care.
 - Price cuts and uncertainty over the PPRS.
 - Health Technology Assessment Processes that fail to value incremental stages in innovation and impose barriers, burdens and delays on product launches.
- Information requirements from regulatory bodies, including for HTA, are different and more demanding than in the past. Clinical research is currently not optimally designed in order to meet those information requirements. This can act as a serious barrier to getting new medicines out of the labs and into patients. An earlier dialogue between industry and regulators would enable more effective research design to ensure information needs are met.
- Increased information requirements from clinical research may also result in pressures to rebalance research funding between basic and more applied work. Applied work that improves the HTA infrastructure should be developed but not at the expense of basic research, which is fundamental to what is needed from public sector science.

3 Do not over rely on existing 'metrics' to assess the performance of research

- Bringing together MRC and NHS R&D would present significant challenges for managing performance and career development. There are serious risks in an over reliance on current metrics as a means of measuring performance. Performance can only really be assessed by judgement on outcomes, informed by all the available evidence. If inappropriate (or incomplete) performance metrics are identified, perverse incentives are created. For example the RAE currently gives insufficient incentives to industrially relevant research. Two important steps should be taken:
 - Representatives from Government, Patient Groups, Healthcare professionals and Industry should be involved in assessing the High-level performance of health R&D activity.
 - Specific metrics on the commercial potential of publicly funded research should be explored.

4 Clear priorities for health research need to be developed through collaboration between Government, patients, healthcare professionals and industry. Long-term commitment to those priorities is vital.

- Healthcare priorities should be developed in partnership between government, patients and industry. Pfizer is keen to play an active role in such discussions.

- Government-funded healthcare priorities and research objectives must be clearly defined and given long term funding commitments, for example over 20 years.
- Key areas for R&D investment are the 1) treatment of diseases associated with aging and the achievement of “healthy aging”. 2) prevention of disease and the promotion of “wellness”, 3) pharmacoeconomic studies of the long-term costs of disease.

5 We need to build, reward and retain talent across the full spectrum of R&D.

- The career pathway, training programmes and rewards and recognition systems for R&D scientists need to be improved in order to attract and retain key scientific talent within the UK. In particular, significant attention must be paid towards enhancing R&D as an attractive career pathway for clinicians to work in translational research.

6 Political commitment at the highest level is needed

- Health R&D in the UK has a massive impact on patients and on the wider economy. As such, in our view, should be a major political priority. Any new, merged, organisation should be supported by Government at the highest-levels including representation at Cabinet.

Detailed Response to 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?*

A major strength of the MRC is its potential to link basic to translational to applied research. It has established world-renowned centres of scientific excellence and is a source of high quality scientists/post docs. This is especially notable in the fields of infectious disease, immunotherapy and developmental biology. However, other areas are not so strong.

The MRC's research strategy, however, is somewhat unfocused, and its scientific remit unclear e.g. with regard to other research councils such as the BBSRC. Significant research is often being conducted in areas that have already shown substantial progress (e.g. CHD, oncology), but with proportionately less funding of those areas where healthcare solutions are still badly needed (e.g. mental health). Additionally, there appears to be "tension" between research that is funded purely for the purposes of basic research and that which has clearer clinical relevance. This can lead to clinical R&D being perceived as being of "lower quality".

The perception that more clinically relevant research is somehow lower quality needs to be turned round before it seriously impacts on the number of young researchers coming through. Training in certain key areas needs to be improved e.g. *in vivo* scientists and "clinician scientists". With the latter, there is a need to introduce a career structure that attracts clinicians to pursue a career in translational research.

In general and when compared to other research councils (RC) that report into the Office of Science and Innovation (OSI), the MRC is regarded as being somewhat "isolationist". For example, it does not have the links with Industry that many of the other RC have, neither does it collaborate "from within" with these RC. Additionally, there is something of a perception of an "old boys club" about it, especially in relation to whom and which grant applications actually receive funding. There is therefore a greater need for transparency in its means of peer-review.

Overall therefore, the MRC needs to establish a clear vision of "what" its principal research targets are over the next 20 years and "how" it will ensure a robust connection between basic, translational and applied research. With regard to the former, this needs to be based on the government *a priori* establishing what the key priorities for health research are over this period. More needs to be done to encourage clinicians to pursue long-term careers in translational research. Increased levels of collaboration with Industry, especially in areas where research drivers are clearly shared (e.g. in the identification and clinical validation of biomarkers, development of clinical technologies), should be encouraged.

The great strength of NHS R&D lies within its ability to tap into its extensive scientific and medical expertise as well as its logistical infrastructure. With regard to clinical trial conduct and delivery, both need to be optimised with regard to Quality, Timeliness, Cost and Reliability. NHS R&D is only "average" in some of these areas (notably the interlinked issues of cost and timeliness) compared to other countries and the number of clinical trials placed in the UK by

Industry is currently falling. Here, the bureaucratic steps needed to gain Trust approval for a clinical trial, together with the absence of a standardised costing framework between Trusts (and therefore the need for Industry to negotiate with each Trust separately on financial contracts) are the key issues that cause the significant hit on time.

We strongly support the establishment of the UKCRC and its associated research networks. This should drive an improvement in the QTCR factors described above. However, we question why there is no established or conceptual network for respiratory diseases, given their high impact on public health? We therefore ask that the network structure is reviewed for completeness and appropriateness. Additionally, and similar to the MRC, there is a need to enhance the rewards and recognition systems in order to encourage clinicians to pursue long-term careers in R&D.

More work is needed to gain full buy-in of Trusts to the Network concept, in order to enhance efficiency and reduce “silos”. The Networks also need to work more closely with Industry (e.g. during their academic review of protocols) to understand the issues Industry faces with respect to the business and regulatory need for the “globalisation” of many protocols.

Importantly, it should be made clear what NHS R&D should not be for, and that is basic research.

With regard to the training needs of Industry, the MRC and NHS R&D scientists are clearly a major potential source for this, but are currently underutilised. Greater mutual collaboration between all parties on training would be of benefit in order to develop fully “rounded” R&D scientists.

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 help address those challenges? What do you believe should be the Government's objectives for health research, and why?*

The key scientific challenges facing health research over the next 10 years include the need to mitigate the impact of obesity and to minimise healthcare costs associated with aging by directing research into those areas that are “uncovered” by the aging process. Examples are renal disease and Alzheimer’s disease; in other words direct research towards the goal of achieving “healthy aging”.

Organisationally, the key challenges are to establish the necessary collaborative infrastructure to enable the full connection of basic to translational to applied research and then to determine how this will be funded. The infrastructure piece relates to optimising the quality and quantity of R&D staff as well as the communication systems (e.g. via “Connecting for Health”). Considerable organisational challenges face the optimisation of the CR Networks. Some have been described in question 1, but the “Connecting for Health” initiative is absolutely fundamental to this, as a means to rapidly pre-screen potential patients for trial inclusion. This would lead to an enhanced ability to reliably predict recruitment times and likely trial costs. It is recommended to use lessons learned from the Scottish electronic patient records system.

However, *a priori*, a R&D landscape in the UK must be created such that it can compete optimally in a global R&D environment. This requires attention to the “QTCR” principles described previously and patient educational programmes and infrastructure that facilitates patient participation in clinical research.

Government needs to determine who, in the future, will perform translational/experimental medicine research. It will not be the most efficient use of funding for both the MRC and NHS R&D to have significant degrees of overlap in this area. Our recommendation is for translational research to reside principally within the MRC.

The key challenges facing the training of scientists are related to 1) attracting sufficient numbers into R&D in the first place and then 2) retaining them. The career pathways (especially for clinicians), rewards and recognition systems currently in use should be reviewed.

The government may help address these challenges in several ways; 1) increase investment in the epidemiology and outcomes of the target diseases (currently grossly under-funded) in order to increase understanding about the true value of long-term investment in health rather than rely on a focus on the short-term cost of therapies to the NHS, 2) invest in the development of cheaper “preventative” markers/diagnostics – aim for use by the GP or by the patients themselves, 3) find ways to encourage patients to understand and therefore take better control of their pre-disease/disease state i.e. enhance the concept of disease prevention/management and “wellness” – what is the disease, what lifestyle measures or non-drug interventions can prevent or modify its course, how can newer, better medicines help, what are their risks and benefits, how can patients help themselves and others by participation in clinical research, 4) invest in a training, rewards and recognition system that encourages more people into a long-term career in R&D e.g. clinician scientists who have a solid

understanding of biology as well as clinical medicine. It follows that good teachers need to be identified and “revered”.

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?*

Pain, Alzheimer's and other causes of cognitive decline, obesity, COPD, diabetes, the stress of modern daily living, renal disease, modelling human physiology, epigenetics and a focus on "early disease detection" technologies for use in the doctor's office, are suggested as key priorities for health research. In some of these areas e.g. mental health, so relatively little is known compared to other disease areas, that key underpinning breakthroughs are likely to come from academic investment.

Proportionately less needs to be funded in oncology and heart disease, where substantial progress has been made already.

As far as possible, government should align its health research priorities with other major member states in the EU. Such an agreed strategy would optimise the deployment of both government-funded and Industry- funded resource, as well as facilitate the efficient conduct and delivery of the results of such health research programmes between governments and its partners in Industry and elsewhere.

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?*

There is no contradiction between 'long-term economic and social benefits...of biomedical research' and 'research that improves healthcare and other public services. The key is to identify win-wins: areas where knowledge-based activity can go on in the UK, generate high value jobs but that also meet long term public policy priorities in health.

To achieve this, short-sighted decisions, driven by annual and three yearly public spending cycles, need to be resisted. A more comprehensive approach to measuring full cost/benefit is required. In order to guide decision-making with regard to healthcare priorities, more work should be done to understand the full spectrum of benefits that therapies provide to society relation to the cost of disease, rather than the current focus on the short-term cost of medicines.

The bulk of funding should be directed towards the pre-defined areas of evidence-based priority research, but it should be remembered that investigator-led research can itself reveal areas of innovation that could influence or complement future publicly-funded priority research.

However, on the basis that basic research feeds everything else, we strongly recommend that the majority of public funding is directed here. It is an absolute "must" if the UK is to be a major force in the discovery of new medicines, diagnostics, devices and healthcare advancement. The relationship between basic and translational science is complex. Publicly funded translational research is highly important as a means to bridge the biological discoveries to the large scale (applied) clinical trial setting.

The distribution of basic, translational and applied research between the MRC and NHS needs to be carefully managed. Our recommendation is that MRC and NHS need to concentrate on their strengths: basic and applied respectively. However, to ensure that translational research does not fall between the cracks we believe it should be largely focused in the MRC.

On the basis that the NHS R&D funding would be directed towards applied research and be relatively less than that for basic and translational research, it would be optimally used to develop a few key CR Networks to world-leading status.

If the MRC and NHS budgets were merged it would be important not to lose the unique qualities and expertise of each body.

In the longer-term the management of research funds will have to develop robust ways of allocating budget based on a number of criteria: basic research 'excellence' and 'clinical usefulness' might be starting points, but a crucial third leg around the competitiveness of the UK's health industry should be added. To do this effectively an ongoing dialogue would be needed between industry and those responsible for

setting research priorities. Government could usefully draw on business experience and expertise in prioritisation and budget management.

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 the UK should be rightly proud of its track record of research excellence it has not, traditionally, performed well in terms of adoption of new medicines. This trend is not improving and there are significant risks that the climate for take-up of innovative medicines might become worse. These issues are dealt with in our response to question seven.

Although not performed in sufficient quantity, the epidemiological studies of disease outcomes have been impactful, as has government- driven disease education e.g. in infectious disease.

Examples of where MRC and NHS R&D have influence wider policy or healthcare practices include:

The Clinical Trial Service Unit, Oxford University have been central in the establishment of large-scale randomised controlled trials: The so-called mega-trials. Additionally they have also being closely involved in developing approaches to the combination of results from related randomised controlled trials: Systematic overviews or meta-analyses. They have had a particular focus on the treatment of heart attacks, of other vascular disease, and of cancer.

The studies that the Oxford Group produces are widely known because of their large size and international scope which have yielded particularly reliable results. These have generally changed the practice of medicine. Below are 3 examples of their work.

The "ISIS" trials [International Study of Infarct Survival] randomized a total of over 130,000 patients in 30 countries who were in the first hours of an acute heart attack. This provided particularly convincing evidence of the value of streptokinase, and demonstrated for the first time the substantial ability of aspirin to save lives. This evidence changed clinical practice.

They published findings of research involving 30,000 women with hormone sensitive breast cancer. This showed that Tamoxifen given immediately after breast surgery greatly reduced the chances of cancer recurring. Their subsequent worldwide overviews of such cancer trials provided the first widely accepted evidence that hormonal adjuvant therapy truly improved long-term survival. This work changed clinical practice worldwide.

Turning from the treatment to the prevention of disease, the Oxford Group has increased substantially the estimated importance of blood pressure and blood cholesterol as causes of vascular death. The Heart Protection Study which looked at vascular disease risk in a group of more than 20,000 patients randomized to the cholesterol lowering medicine simvastatin or placebo for over 5 years. The study showed that therapy rapidly reduces the incidence not only of heart attacks but also of ischaemic strokes even among individuals who do not have high cholesterol concentrations. The study also provided definitive evidence that therapy is beneficial for people with a history cerebrovascular disease. It provides direct evidence that cholesterol-lowering therapy is beneficial for people with diabetes even if they do not

already have manifest coronary disease or high cholesterol concentrations. This evidence has again changed clinical practice.

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?*

Again, this must begin with the establishment of clear priority areas for health research e.g. COPD, obesity, mental health, cognitive decline etc. An infrastructure needs to be put in place that allows a joined up “R&D continuum” to operate. This needs to include lessons learned from other areas of research e.g. the use of molecular profiling in oncology and the development of a common human systems physiology and biochemistry science discipline with maths, statistics, computational science, biochemistry and physiology as prime subjects.

There is a need for increased collaboration between Industry and publicly-funded research groups. For example, the MRC Technology group has enormous potential to synergise with Industry in those areas where common drivers and priorities have been identified. Pfizer has highly positive and ongoing experience with such “Collaborative Research Centres” e.g. the collaboration between Pfizer, Kings College and Kings College Hospital in pain research. Here, Pfizer investment allows for basic and early clinical research. Intellectual property (ip) rights pertaining to technology are owned by the College, whereas any future “product-related” ip is owned by Pfizer. Finding ways to incentivise and promote a wider range of such collaborations is important. For example, “ownership” of ip may be perceived as a barrier to such collaborations. However, as a general principle in Pfizer, there is not an absolute need to “own” ip, except where this clearly and directly relates to a proprietary drug product. What would always be important though, is for Pfizer to have “use rights” to the relevant “enabling technology”, the ip for which being “owned” by the institution. As the development of the technology in this instance would often be owned by the institution, but nevertheless would have been funded in large part by Industry, the institution should however, also be realistic about the “value” of its technological contribution to the overall drug development process. Accordingly, it should not therefore expect (as has sometimes been the case) to receive royalties on the sales of any future approved product. Having these “principles” and “expectations” of outcome clearly and transparently agreed upfront between potential partners, would help promote collaborations. To this end, two other examples of where Pfizer has valuable ongoing collaborations with Universities are with 1) The Karolinska Institute with regard to genomics and 2) Cambridge University with regard to pharmaceutical materials science. Consideration should be given to enhancing media coverage of successful partnerships.

We also recommend that the CR Networks are an appropriate and efficient means to establish additional multidisciplinary collaborative networks between government-funded research groups and Industry and we welcome their invitation. Indeed the CR Networks could go a further stage to exploit their full collaborative potential as an “enterprise hub”; include the MRC, the MHRA and NICE as partners. Additionally, a proportion of public funding to the CR Networks (and other potential groups involved in Government funded R&D as appropriate) could be specifically directed towards the identification of supply chain providers from the private sector. “Non-immediately obvious” synergies and partnerships may be created to the common business good.

Overall, we strongly recommend that the government follows the principles outlined in the “Innovative Medicines Initiative” from EFPIA

(http://ec.europa.eu/research/fp6/index_en.cfm?p=1_innomed). This describes the key bottlenecks that need to be overcome in health research namely;

1. Safety: Making medicines safer
2. Efficacy: Making Medicines more effective
Often disease specific, initial focus on 5 disease areas with high scientific challenges:
Cancer; Brain disorders; Inflammatory diseases, Diabetes and Infectious diseases
3. Knowledge Management: Using new technologies to manage and organise data to create knowledge so scientists can predict benefit and risk of new therapies
4. Education and Training: Addressing expertise gaps in Europe

Better links with other disciplines in the social sciences and other areas could be extremely fruitful. A merged organisation could benefit directly from operational research techniques around multicriteria decision making. Social as well as technical studies on the changing nature of health service delivery, e.g. telecare/telemedicine should also help shape the discussion on the 'future of healthcare', and hence research agendas.

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

Market conditions that encourage and reward innovation in health, which is needed to improve public services, are essential. Many of the established characteristics that made the UK a good place to host pharmaceutical R&D are under threat or actively disappearing. Examples include:

- Cost containment via local productivity targets - such measures are short-termist and damage: incentives to innovate; long term productivity and the quality of patient care.
- Price cuts and uncertainty over the PPRS.
- Health Technology Assessment Processes that fail to value incremental stages in innovation and impose barriers, burdens and delays on product launches.

As knowledge of the biology and genetics of disease increases, the development of new medicines will likely increasingly focus on select “target” sub-populations, rather than a population as a whole. The consequence of this of this is that patients will need more therapy choices, not less. It also means that highly innovative medicines will inevitably be undervalued by existing cost benefit methodologies. Much more sophisticated approaches to technology appraisal are therefore needed. We set out, in Box 1, five principles which we believe should guide more effective HTA:

Box 1: Five Principles for Improved Health Technology Assessment

1. *The views of physicians and patients are an essential component in assessing the value of medicines and healthcare decision-making*
 - HTA should formally incorporate physician and patient views
 - Guidance should recognise that patient preferences and responses to medicines vary and thus permit physicians to prescribe contrary to guidance without undue burden to justify their decision
2. *HTA should reflect the full value of medicines to UK society*
 - HTA should focus on cost and benefits of new medicines to society rather than the NHS alone
 - HTA needs to recognise that the value of medicines takes many forms and incorporates all these dimensions rather than focus solely on clinical outcomes
 - The development of new healthcare technology requires that HTA appraisals recognise and reward incremental innovation
3. *HTA, especially close to launch, requires a pragmatic approach to assessing evidence and developing guidance*
 - The real value of a medicine will only be confirmed after launch following sufficient and appropriate use in a real world setting
 - Uncertainty about treatment effect and economics will always exist. HTA needs to ensure that risk averse decision making does not stifle innovation and deny patients access to medicines
4. *The reliability of economic analyses need to be explicitly considered within the decision making process*
 - Measurement and valuation methods are evolving but remain imprecise
 - Models are only as good as the underlying structure and assumptions
 - Models often contain a high degree of uncertainty
 - Models can be relatively unstable – a small change in one or more parameters can lead to very different results and conclusions
5. *HTA must include an open, transparent decision making process that involve all stakeholders, covers all health technologies, makes full balanced use of all evidence, contains a fair appeal process, and makes decisions in a timely manner.*

- 8 *How can UK health research funding be most effectively 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?*

Improving the strategic focus of both MRC and NHS R&D should ensure that the maximum benefit is derived in terms of infrastructure right across the R&D spectrum. The NHS, in particular, has the potential to be unique, compared to health systems in other countries, as a platform for clinical research. Ensuring the NHS builds on its already considerable strengths in this area will have benefits that feedback to other phases of research.

The range of information required by regulators, including NICE, in order to grant widespread access to patients for new medicines is becoming much more significant than in the past. Clinical research in the UK is not currently optimally designed in order to best meet those information requirements. This acts as a significant barrier to getting new innovative medicines to patients. An earlier dialogue between industry and regulators, including NICE, would greatly help in improving the design of research and speed up the regulators and HTA process.

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?*

The obvious comparator for possible institutional changes is the US National Institute of Health, which is widely regarded as being an important driver of US health innovation. However, the impact on the US economy is likely to be more to do with the fact that it commands \$28bn of public money versus the MRC's approximately £3.76bn. While such levels of funding are not feasible for the UK government it is important to note that changing the institution alone will not give the UK an equivalent to the NIH.

The key lesson to draw from the US experience is the extent of partnership working between public and privately funded research bodies.

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.

There is presumably the potential for operational and efficiency gains from merging the two organisations. However, in exploiting those gains it is important to maintain the unique – and complementary – characteristics of the existing two bodies. Although there is some overlap in the current functions of the MRC and NHS R&D it is important, if a merger were to go ahead, that one half does not become overly dominant at the expense of the other. Any governance structure of a merged body would need to make resource allocation decisions through careful balancing of criteria such as basic, translational and applied research excellence as well as considering both the expertise and potential of the UK based health industry. There are, in addition, two strategic issues which should provide context for this:

- a. Public health policy priorities. As stated elsewhere, clearly stated priorities from the health policy community could help galvanise R&D effort from the lab to the pharmacy
- b. UK health R&D's position in the world. Developments in health R&D take place globally. The UK cannot – nor should it try to – maintain a world leadership in every area. A strategy – jointly developed by government, patients and industry – for where the UK should focus its efforts, could provide be a key backdrop to the future work of a merged health research body.

At least in the medium term – until management structures, decision making processes and stakeholder engagement strategies bed down – ringfencing of key budgets is essential.

11 To what extent does the success of recent innovations 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?

As described in the response to question 2, “Connecting for Health” is vital for the successful operation of the CR Networks. Its development and institution needs to be visionary and timely and as such should be regarded as a high priority activity for NHS R&D. Its successful institution would place the UK in a world-leading position for healthcare research and patient provision.

The West Lothian research network should also be used as a foundation to model how a “joined up” and integrated approach to the R&D process may be achieved.

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?

Bring this under a single governance body as previously described with the NHS represented by a person responsible for integrating the NHS plan into the devolved structure. Also invite the CSO and CMO for devolved countries onto this board.