CLINICAL RESEARCH IN THE UK:
TOWARDS A SINGLE SYSTEM THAT RELIABLY DELIVERS DISTINCTIVE QUALITY AND RAPID ACCESS AT REASONABLE COST
1. INTRODUCTION

2. EXECUTIVE SUMMARY

3. WHY COMMERCIAL CLINICAL RESEARCH IS IMPORTANT FOR THE UK
   Benefits of clinical research to ‘UK plc’
   The current state of UK clinical research

4. WHAT MATTERS TO INDUSTRY
   How industry decides
   Differences between industry segments

5. THE UK’S POSITION
   How the UK compares internationally
   How the environment is changing

6. TOWARDS A DISTINCTIVE UK VALUE PROPOSITION FOR CLINICAL RESEARCH
   The potential UK value proposition for clinical research
   Potential clinical research ‘Offers’ and initiatives to deliver them
   1. Linked commercial and academic centres of research excellence in specific therapeutic and technical areas
   2. System-wide health outcomes research capabilities
   3. Comprehensive and flexible healthcare IT system
   4. Motivated and educated physicians and patients
   5. An effective interface for industry that delivers the most efficient trial start and follow-up
   6. Transparent, system-wide measurement of research quality and productivity

7. WHAT SHOULD BE DIFFERENT BY JANUARY 2008

8. APPENDIX
The UK has a strong clinical research heritage. UK scientists and doctors are responsible for a wide range of medical advances, including discovering antibiotics, laying the foundations of molecular biology, inventing CT scanning, and pioneering mammalian cloning. Today, the potential for clinical research to improve human health has never been greater. In particular, there are unparalleled opportunities for progress from the public and private sectors sharing resources and expertise (e.g., practical application of genomics, proteomics, stem cell biology).

Yet the UK risks losing its position as a global leader in clinical research, as industry looks ever more widely for attractive locations for research activity.

Clinical research in the UK has been discussed extensively in recent years, resulting in a number of improvements in infrastructure and ways of working, most notably the establishment of the UK Clinical Research Collaboration (UKCRC). In response to the threat of the UK losing its leading position in commercial clinical research, the UKCRC initiated a project with three aims: to assess the UK's positioning in the global clinical research market; to articulate a clear overall value proposition to industry for clinical research, supported by distinctive ‘Offers’ that are attractive to industry when deciding where to place clinical research; and to suggest initiatives that the Department(s) of Health R&D Directorate(s) and UKCRC should consider to strengthen the value proposition.

As part of this project, the UKCRC commissioned McKinsey & Company to conduct a review. This had four components:

- A programme of interviews, surveys and workshops with over 100 key global stakeholders and decision-makers around the world from the pharmaceuticals, medical devices and biotechnology industries, academia and government
- A broader web-based survey of key stakeholders from industry, academia and government
- An evaluation of historical research and publications on the subject, including, among others, the work of the Pharmaceutical Industry Competitiveness Task Force (PICTF), the Bioscience Innovation and Growth Team (BIGT), the Healthcare Industries Task Force (HITF), and the Academy of Medical Sciences review (AMS)
- An analysis of secondary data on the nature and state of clinical research in the UK compared with other countries (e.g., growth, scale, nature of clinical research under way).

The aim of the review was to gain a clearer understanding of industry’s (i.e., the pharmaceuticals, medical devices and biotechnology sectors’) needs, and to suggest practical initiatives to improve the UK’s attractiveness.

The focus of the review evolved as interviews were performed. There was a shift in emphasis from identifying the UK’s Unique Selling Points (‘USPs’) towards identifying a compelling value proposition in a highly competitive global market. Underlying this shift was clear feedback that the UK lacked any significant, truly unique selling points which would in isolation attract industry, and demanded a more sophisticated consideration of the UK’s assets and capabilities.

This report summarises the findings and sets out recommendations for next steps. It does not attempt to record all of the many views expressed in the course of the review, but rather to draw out the common themes. The report was concluded before the English Department of Health’s new National Health Research Strategy was released for consultation. This includes proposals, which if implemented, will help to address some of the issues and opportunities highlighted in this report.

For reference the appendix gives a full list of the participants. However, all interviews and surveys were conducted in the strictest confidence and the report is written to disguise the identity of individual participants.

---

1 Clinical research in its broadest sense encompasses all formal, experimental study of human health and disease processes. Typically, commercial clinical research is the study of a drug, device or biologic in human subjects, carried out by or for pharmaceutical, biotechnology or medical device companies.

2 The term ‘medical devices’ is used to refer broadly to healthcare products including implanted and non-implanted general medical devices, diagnostics and other healthcare products that are subject to regulatory review.

3 The UKCRC has set up an Industry Road Map Group to identify ways the emerging infrastructure for clinical research in the UK can work with industry.

COMMERCIAL CLINICAL RESEARCH IS IMPORTANT FOR THE UK, BUT THE COUNTRY IS FALLING BEHIND IN LARGE LATE-STAGE TRIALS

Commercial clinical research provides major benefits to patients, such as improved outcomes for disease, lower side-effect profiles for treatments and less demanding administration regimes; financial, operational and scientific benefits to the NHS; and considerable economic and strategic benefits to the UK as a whole.

The UK has a good reputation for clinical research and attracts a disproportionate share of international activity. It is particularly strong in pre-clinical, experimental and early stage research. However, competition is increasing as ‘traditional’ locations position themselves as advanced clinical research centres and emerging market locations (e.g., India, China) attract more research, especially in the larger scale late-stage trials that account for the majority of industry’s clinical research spending. Late stage clinical research is therefore the focus of this report.

WHY INDUSTRY CHOOSES (OR REJECTS) THE UK AS A SITE FOR CLINICAL RESEARCH

Interviews and survey responses indicate five major criteria for choosing where to locate clinical research: strategic relevance, quality, time, reliability and cost. These criteria are similar across industry segments, albeit with some differences of emphasis. In practice, no country can fulfil all of the criteria optimally. Industry therefore focuses on locations that meet the strategic and quality criteria and makes final decisions based on distinctiveness on one or more of the three other parameters.

THE UK’S POSITION

Overall, the UK is not distinctive on any of the parameters that matter to industry. Indeed, while it is neither better nor worse than other comparator countries on the dimensions of strategic relevance and quality, it has longer trial start-up times, more recruitment delays, poorer reliability and higher costs. As a result of this and the increasingly competitive global environment, industrial investment in clinical research in the UK is at risk. The UKCRC and the Departments of Health have multiple efforts underway which could improve competitiveness. However, the majority of stakeholders were either unaware of many of these initiatives, or doubtful that their impact would significantly improve the attractiveness of the UK for industry.

TOWARDS A DISTINCTIVE UK VALUE PROPOSITION FOR COMMERCIAL CLINICAL RESEARCH

If UK plc and its National Health Service aspires to be a leader in commercial clinical research, then, having understood the criteria that matter to industry, and how the UK is performing against them, it must develop a distinctive value proposition for commercial clinical research. This should clearly and crisply encapsulate the UK’s ability to meet stakeholders’ needs. Interviews suggest that the UK should aspire to the value proposition of ‘A single system that reliably delivers distinctive quality and rapid access at reasonable cost’. To make this aspiration achievable, stakeholders suggested the following potential ‘Offers’ to industry, which if delivered, could significantly increase the amount of commercial clinical research performed in the UK.
Quality - Industry's ability to perform research with the right type, quantity and precision of data. 'Offers' would include:

1. Linked commercial and academic centres of research excellence in specific therapeutic and technical areas. These would give industry ready access to patients, high-calibre staff and specialist expertise.

2. System-wide health outcomes research capabilities. The UK’s system-wide cradle-to-grave healthcare provision offers a unique opportunity to examine a wide range of approaches to disease and health.

Time - Industry’s ability to access patients and expertise at the right pace, through:

3. Comprehensive and flexible healthcare IT system. Again, building on the asset of a single national healthcare provider, the UK could create the world’s largest integrated patient record IT system.

4. Motivated and educated physicians and patients. Physicians and patients willing to participate in clinical research would give industry larger recruitment populations, faster start-up times and better performance on enrolment.

Reliability - Industry’s ability reliably to predict the pace, quality and cost of clinical research, through:

5. An effective interface for industry that delivers the most efficient trial start and follow-up. The bureaucracy and barriers that make trial set-up complicated and cumbersome would be removed.

Cost - Consistent value-for-money and a clear and fair cost structure for all sponsors of clinical research placed in the UK, through:

6. Transparent, system-wide measurement of research quality and productivity. Industry would know what to expect, and investigators and Trusts would have new incentives for strong research performance.

Most of these ‘Offers’ would in practice address multiple needs of industry: for example, the transparency created by clear metrics is likely also to improve timeliness and reliability.

WHAT SHOULD BE DIFFERENT BY JANUARY 2008

While stakeholders all described hurdles to overcome, they were optimistic that the UK could become a distinctively attractive place to locate clinical research. This will require concerted efforts on each of the ‘Offers’. More specifically, interviewees feel that the following should be in place by January 2008:

Significantly improved communication

A clear statement on the key R&D priorities (i.e., therapeutic areas, diseases, technologies) for the NHS overall, and which should be the focus of collaborations

A mechanism in place to create clear and up-to-date information on the research interests and activities of NHS organisations and individuals,
academic centres, universities and industry. The mechanism should provide information about who is carrying out the research, budgets and mechanisms, and should collate and, where possible, match research priorities.

A communication programme in progress to explain the safety and benefits of clinical research to patients, physicians, and staff, undertaken in collaboration with patient groups, Royal Colleges and nursing and medical schools.

**Demonstrations of early success and learning**

Concrete initiatives in operation to help bypass bureaucracy and improve trial execution. This could include, for example, a single NHS-wide R&D sign-off, metrics on NHS Trusts’ R&D performance, and a streamlined interface between industry and the NHS including the creation of a body to resolve disputes.

Between three and five linked centres of excellence for commercial and public research, including at least one dedicated to health economics.

Between three and five joint ventures with industry (i.e., joint investment, joint expertise) in place on areas that are critical to both the UK and industry.

This could include, for example, joint ventures focusing on pharmacogenomics or the use of technology to monitor disease in residential settings.

A commitment to involving industry in Connecting for Health as demonstrated by influencing its design, exploring the potential of an interface between Connecting for Health and industry, and piloting NHS-industry collaboration.

**Expanded guidance to the broader NHS**

Publication of best practice guidelines for the commercial clinical research process, for example, Trust approval, set-up, costing, negotiation and contracting.

The prize available from better collaboration between the NHS and industry is immense, for patients, for the NHS and industry, and for the UK as a whole. Key to capturing this will be fostering more open communication and a full commitment to new ways of working.

---

4 The National Programme for IT, run by the Department of Health agency NHS Connecting for Health, aims to introduce networked health records for all users of the NHS in England.
This section outlines the benefits of commercial clinical research to the UK and describes current activity across the country.

**BENEFITS OF COMMERCIAL CLINICAL RESEARCH TO THE UK**

Commercial clinical research provides major benefits for patients. It is also beneficial to the NHS and the UK as a whole.

**BENEFITS TO PATIENTS**

Commercial clinical research plays an important role in improving the diagnosis and treatment of diseases that affect people in the UK and elsewhere. Commercial research in the UK has resulted in hundreds of innovations offering earlier detection of illness, improved outcomes for disease, lower side-effect profiles and less demanding administration regimes. These innovations are part of the reason, along with other critical factors such as better nutrition and sanitation, for the dramatic improvements in the health of the UK's population over the past 100 years, particularly since the 1950s. It is estimated that about half of the major medicines sold in the UK were developed in British laboratories.

Commercial clinical research may also provide direct benefits for those patients involved in clinical trials. The extent to which this is the case is still being debated. However, there is evidence to suggest that trials are more likely to have a positive than a negative effect due to: patients receiving closer medical attention, follow-up and continuity of care. In addition, early access to new treatments often provides patient benefits: for example, Parkinson's patients, who have limited effective approved treatments, have benefited from experimental treatments.

**OPERATIONAL AND FINANCIAL BENEFITS TO THE NHS**

Commercial clinical research provides hospitals, Primary Care Trusts and GP practices with additional funding for both core clinical and research activities. An example is GlaxoSmithKline's £72 million investment in Imperial College London's new Clinical Imaging Centre. In addition to high-profile one-off investments, industry contributes to the delivery of day-to-day NHS care; for example, 2% of the Royal Marsden's overall budget comes from industry collaborations that provide infrastructure, part-funding of personnel and other subsidies.

**SCIENTIFIC BENEFITS TO THE NHS**

The survey of NHS stakeholders suggests that early stage research benefits the NHS scientifically by keeping the UK at the forefront of research. Physicians and the research community have interesting opportunities and the funds to pursue them, and as a result, the NHS is more able to retain their talents, knowledge and skills in a competitive global economy.

**ECONOMIC AND STRATEGIC BENEFITS TO UK PLC**

Clinical research activity helps keep pharmaceutical, medical device and biotech industry spend in the UK. In 2003 the UK pharmaceutical industry had a trade surplus of £3.6 billion. The pharmaceutical industry spent £3.2 billion on R&D in the UK in the same year. Furthermore, the pharmaceutical industry has been shown to have an employment multiplier effect of 6.7 and an economic contribution multiplier of 3.9. These industries are also a major part of the knowledge economy, a strategic focus for UK plc overall.
5 ABPI, Pharmaceuticals and the UK economy, 2005.
7 For example, Cell Therapy in Parkinson’s Disease, Olle Lindvall and Anders Björklund, NeuroRx 1:382-393, 2004.
8 Free-standing bodies which directly provide a range of community health services such as general practitioner (GP), community and primary care services, and which commission hospital services from other NHS bodies (e.g., secondary or tertiary care)
11 ABPI, Pharmaceuticals & the UK economy, 2005 (data is for 2003).
12 ABPI, Research and Development, 2005 (data is for 2003).
13 Biopharmaceuticals industry contribution to state and US economics, Milken Institute, 2004 (US analysis).
16 In vitro and in vivo human biological research
The UK is an important location for commercial clinical research and attracts a disproportionate share of international activity, as can be seen for pharmaceuticals in Exhibit 1. Equally, commercial clinical research is a key part of the UK medical R&D landscape. Approximately 70% of medical research spending in the UK is funded by industry. Of the industry-funded part, the majority (70%) is clinical development, primarily in clinical trials, Exhibit 2.

This investment spans a broad range of activity. More specifically:

Within Europe, the UK is the leader in Phase II/III trials Exhibit 3, with more than 50% more late-stage trials than both Germany and France, despite being a smaller healthcare market in terms of value.

The UK has more basic research and early stage clinical research activity in both relative and absolute terms than anywhere else in Europe Exhibit 4. Interviewees attribute this success to the strength of academic research in the UK (e.g., the number and quality of key opinion leaders). Given the country’s success in experimental medicine and early stage clinical research trials, previous extensive examination (e.g., Strengthening Clinical Research, October 2003) and the relative importance of later trials, this report focuses on later stage trials (e.g., Phase II/III clinical trials of pharmaceuticals).

About half of the UK’s Phase late stage clinical research is concentrated in three areas - biologics, cancer, and central nervous system Exhibit 5.

Most research, around 80%, is conducted by the pharmaceutical industry as opposed to devices and biotech, Exhibit 6.
EXHIBIT 3: VOLUME OF PHASE 2/3 RESEARCH

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.</td>
<td>1,180</td>
<td>5.6</td>
</tr>
<tr>
<td>U.K.</td>
<td>344</td>
<td>2.9</td>
</tr>
<tr>
<td>Germany</td>
<td>233</td>
<td>1.6</td>
</tr>
<tr>
<td>France</td>
<td>191</td>
<td>0.4</td>
</tr>
</tbody>
</table>

* Ongoing commercial clinical drug trials
Source: Pharma Projects Trends Analysis, 2005

EXHIBIT 4: PROPORTION OF EARLY-PHASE CLINICAL RESEARCH

Phase 1 trials as % of all commercial clinical drug trials (1–3), 2004

<table>
<thead>
<tr>
<th>Country</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.K.</td>
<td>38</td>
</tr>
<tr>
<td>France</td>
<td>23</td>
</tr>
<tr>
<td>Germany</td>
<td>19</td>
</tr>
<tr>
<td>U.S.</td>
<td>15</td>
</tr>
</tbody>
</table>

Source: Pharma Projects Trends Analysis, 2005
EXHIBIT 5: U.K. COMMERCIAL CLINICAL DRUG Trials by Phase and Therapeutic Area
% of Pharma trials underway

<table>
<thead>
<tr>
<th>Phase 1</th>
<th>Phase 2/3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td>10</td>
</tr>
<tr>
<td>Blood-related</td>
<td>4</td>
</tr>
<tr>
<td>Musculoskeletal</td>
<td>5</td>
</tr>
<tr>
<td>Respiratory</td>
<td>5</td>
</tr>
<tr>
<td>CNS</td>
<td>9</td>
</tr>
<tr>
<td>CNS</td>
<td>16</td>
</tr>
<tr>
<td>Biologics$^4$</td>
<td>24</td>
</tr>
</tbody>
</table>

1 Excludes clinical trials involving reformulations of existing marketed products (119 in total)
2 Includes clinical trials in humans of unapproved phase (27 in total)
3 Includes anti-infective agents
4 Recombinant proteins and vaccines, monoclonal antibodies, gene therapy
Source: PharmaPundit, 2005

EXHIBIT 6: U.K. CLINICAL RESEARCH BY INDUSTRY SEGMENT
% 2003

100% = £4.2b

- Pharmaceuticals: 78%
- Biotech: 13%
- Medical Devices: 9%

Source: ABPI (pharma); BiCentury (biotech); ABHI-ETF report (medical devices)
### Exhibit 7: Growth Rate of Commercial Clinical Drug Trials

<table>
<thead>
<tr>
<th>Country</th>
<th>% Growth in Number of Trials, 2000–05</th>
<th>Trials in 2005 (#)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Russian Federation**</td>
<td>226%</td>
<td>26</td>
</tr>
<tr>
<td>India**</td>
<td>178%</td>
<td>25</td>
</tr>
<tr>
<td>Australia</td>
<td>101%</td>
<td>151</td>
</tr>
<tr>
<td>Canada</td>
<td>52%</td>
<td>332</td>
</tr>
<tr>
<td>USA</td>
<td>31%</td>
<td>1,736</td>
</tr>
<tr>
<td>Mexico</td>
<td>27%</td>
<td>33</td>
</tr>
<tr>
<td>U.K.</td>
<td>19%</td>
<td>584</td>
</tr>
<tr>
<td>Sweden</td>
<td>-16%</td>
<td>67</td>
</tr>
</tbody>
</table>

* Phase 1 to 3 and pre-launch trials in humans of unspecified phase
** Growth from 2001–05 to commercial clinical drug trials recorded in 2005

Source: Pharma Projects Trends Analysis 2005
However, for larger scale late-stage trials in particular, the UK faces growing competition from emerging market locations (e.g., India, China). <Exhibit 7>. In addition, other ‘traditional’ locations are positioning themselves as centres for advanced clinical research and are increasing their levels of clinical research faster than the UK.

Despite recent government initiatives, this changing global context means the UK needs an internationally distinctive clinical research value proposition to industry, making clear what the NHS could offer industrial partners and how industry could take advantage of this offer by better collaboration with the NHS.

17 Pharmaceutical Industry Competitiveness Task Force; Bioscience Innovation and Growth Team; UK Clinical Research Collaboration;
what matters to industry

Given the threat the UK faces, this section describes industry’s decision-making criteria for the placement of clinical research and outlines some differences of emphasis between the pharmaceutical, devices and biotech segments.

HOW INDUSTRY DECIDES

Interviews and survey responses indicate that industry has five major decision-making criteria for the placement of clinical research: strategic relevance, quality, time, reliability and cost. <Table 1>.

Interviewees acknowledge that in practice, no country can fulfil all of the criteria optimally. Therefore they often start with a list of locations where the strategic and quality criteria are met and then make the final decision based on distinctiveness on the remaining parameters (e.g., shortest time, lowest cost, superior track record in delivery).

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Relative importance</th>
<th>Key elements</th>
</tr>
</thead>
</table>
| Strategic relevance   | High                | – Value of the market opportunity  
|                       |                     | – Time for product to be launched and accepted in the market  
|                       |                     | – Degree to which key opinion leaders are needed for success.                  |
| Quality               | High                | – Prevalence of desired patient or disease  
|                       |                     | – Availability of skilled physicians and investigators  
|                       |                     | – Domain expertise (e.g., specialty devices, CNS, oncology)  
|                       |                     | – Quality of protocol adherence  
|                       |                     | – Tracking and data systems                                                   |
| Time                  | High-Medium         | – Approval time (e.g., protocol approval by ethical review boards and regulatory agencies)  
|                       |                     | – Site set-up time  
|                       |                     | – Patient enrolment time  
|                       |                     | – Speed of CRF completion and transmission                                    |
| Reliability           | Medium              | – Ability to forecast delivery against targets  
|                       |                     | – Predictability of delivery against targets                                  |
| Cost                  | Medium-Low          | – Trial or clinical investigation costs (e.g., investigator, site overheads)  
|                       |                     | – Level of R&D tax incentives                                                  |
Differences Between Industry Segments

Commercial biomedical activity can be split into three broad segments: pharmaceuticals, medical devices and biotechnology. All share the broad criteria of strategic relevance, quality, time, reliability and cost, but there are some differences of emphasis by segment, Exhibit 8.

Multinational pharmaceutical companies will often be able to be more flexible about clinical trial location than smaller companies and biotechs. They tend to run an internal bidding process in which they judge how well country affiliates’ locations match the needs of each individual trial.

Biotech start-ups are very sensitive to trial time and cost. Their limited funding demands fast results to secure further R&D investment. They tend to be smaller with stronger local links and therefore focus trials at ‘home’ unless there is a compelling commercial or scientific reason not to (e.g., access to an important market or key opinion leader).

For devices, the development process tends to be more iterative, often needing many sequential but relatively small clinical investigations with higher levels of investigator interaction. For this reason, accesses to high-quality physicians and superior guidance from expert regulators have tended to be the most important factors. Even so, larger device companies are now following the trend to do increasing amounts of research in emerging locations (e.g., India, China) for reasons of cost and time.

**Exhibit 8: Industry Segment Differences**

<table>
<thead>
<tr>
<th>Pharma</th>
<th>Devices</th>
<th>Biotech</th>
</tr>
</thead>
<tbody>
<tr>
<td>The primary inclusion criteria for late-stage clinical trials are:</td>
<td>Medical device research is very iterative, often requiring one high-touch, high-skill regulator.</td>
<td>Biotechs need rapid access to patients and perhaps even subsidies to get through development. If it is too difficult in the UK, then they will set up research operations elsewhere.</td>
</tr>
<tr>
<td>• Strategic need to place a trial there due to launch plans and market access</td>
<td>Device industry stakeholder</td>
<td>Biotech industry stakeholder</td>
</tr>
<tr>
<td>• Suitable patient population and/or clinical protocols for trial</td>
<td>For medical products like implants, it would be extremely helpful to develop one uniform method of collecting data, one uniform method to design protocol and to have one harmonised ethical approval process across hospitals.</td>
<td></td>
</tr>
<tr>
<td>Pharma executive</td>
<td>Device executive</td>
<td></td>
</tr>
<tr>
<td>The choice of the R&amp;D location depends on 5 main factors:</td>
<td></td>
<td>The key factors when considering a R&amp;D location are:</td>
</tr>
<tr>
<td>• Quality of research</td>
<td>• Tax credits and financial incentives</td>
<td>• Proximity to academic institutions and research hospitals</td>
</tr>
<tr>
<td>• Timeliness</td>
<td>• Access to people and skills</td>
<td>• Access to people and skills</td>
</tr>
<tr>
<td>• Cost</td>
<td>Biotech executive</td>
<td>Biotech executive</td>
</tr>
</tbody>
</table>

Source: Interviews
Given industry’s needs, this section compares the UK and other comparator countries against industry criteria and describes how the clinical research environment is changing domestically and globally.

**HOW THE UK COMPARES INTERNATIONALLY**

There is a large body of research that compares the clinical research environment in the UK with that in other comparator geographies. Although there are few consistently measured international performance indicators, overall the published research and our interviews indicate that the UK is not distinctive on any of the parameters that matter to industry. Indeed, while it is neither better nor worse than its European and international competitors on the dimensions of strategic relevance and quality, it has longer trial start-up times, more recruitment delays, poorer reliability and higher costs, (Exhibit 9). While interviewee responses and the published research were generally aligned in these views, interviewees were noticeably less positive about the state of UK research than the papers referenced.

Looking at each criterion in more detail:

**Strategic relevance.** Here the UK is on a par with its competitors. The UK is the third largest pharmaceuticals market in Europe and the fifth largest in the world. Market access is comparatively efficient, without the pre-launch pricing and reimbursement negotiation delay common in many other European markets. However, uptake of new products is slow (Exhibit 10). For example, major advances in medical technology—hip replacements, MRI and open heart surgery were all invented or pioneered in the UK—but low adoption rates have meant that technology advances made within the UK have often been commercialised outside of the UK.

**Quality.** Again, the UK is on a par with its competitors. Interviewees agreed that the UK has a long-standing reputation for quality and innovation in clinical research, and that patent and publications rates are relatively high.

**Time.** The UK is below average. Some hard evidence and anecdotes from interviews suggest that the UK is slower than other countries. Interviews further elucidate that poor industry interfaces increase trial and investigation set-up times and create unnecessary complexity.

**Reliability.** The UK is below average. The country has a poor record for delivering on agreed patient recruitment targets in clinical trials and this undermines the overall reputation.

**Cost.** The UK is below average. The UK’s clinical trials costs are among the highest in Europe, (Exhibit 12), and do not compete with those in emerging markets in Central and Eastern Europe, India and China (which are anecdotally reported to be 10 times lower than the UK).

The UK does however have R&D tax incentives that are comparable with those of the US and major European countries. UK-based biotechs in particular consider these incentives important to offset the cost of research, (Exhibit 13).

---

18 For example, Pharmaceutical Industry Competitiveness Task Force Performance Indicators (2001-2004); Academy of Medical Sciences Strengthening Clinical Research 2003.
20 See PICTF Performance Indicators 2004 for details of countries allowing free pricing at launch.
21 For example, the world’s first double-blind randomized controlled trial was conducted in the UK by the MRC in 1948.
22 See PICTF Performance Indicators 2004 for international patent and publications comparisons.
23 For example ‘30% of UK sites failed to recruit a single patient and only 30% of agreed recruitment targets were met’, PICTF Clinical Research Report 2002.
EXHIBIT 9: SUMMARY OF U.K. POSITION

- **Strategic Importance**: Uptake of new drugs is usually good after having done clinical trials – e.g., in Italy, France or Germany. This is not true for the U.K., where the uptake of new drugs is very low, even if the trials have been conducted in the U.K.
  - Pharma executive

- **Quality**: The U.K. is losing its clinical trials expertise. There are not enough experts being trained and not enough training positions
  - Pharma executive

- **Time**: The key drawback to conducting clinical research in the U.K. today is the speed of the approval process: the MHRA, COREC and centre R&D approval
  - Devices executive

- **Reliability**: NHS organisations and clinicians have an appalling track record for failing to deliver results as agreed in commercial clinical research
  - Pharma industry stakeholder

- **Cost**: Trust managers use clinical research funding as a way to raise extortionate funds. There are up to 4x differences in costs for the same trial across U.K. sites
  - Biotech industry stakeholder

Source: Interviews

---

EXHIBIT 10: MARKET SHARE OF NEW MEDICINES, 2003

<table>
<thead>
<tr>
<th></th>
<th>Share of new products*, 2003</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S.</td>
<td>28%</td>
</tr>
<tr>
<td>Germany</td>
<td>23%</td>
</tr>
<tr>
<td>France</td>
<td>21%</td>
</tr>
<tr>
<td>U.K.</td>
<td>16%</td>
</tr>
</tbody>
</table>

* Products launched 1997-2002
Source: ABR (IMS World Review)
EXHIBIT 11: STUDIES COMPLETED WITHIN PLANNED TIMELINES
% of studies

Source: CNR International reported in NCTT Performance Indicators 2004

EXHIBIT 12: COST PER PATIENT COMPARISON
Comparison of phase 2/3 costs per patient, 1995–2002
U.K. = 100 base

Source: Parnell R&D Statistical Source Book, 2004/05
EXHIBIT 13: R&D TAX INCENTIVE COMPARISON

Credit/incentive for R&D activity

**U.K.**
- Tax-deductible R&D spend
  - 150% for SMEs
  - 125% for large companies
  - Payable credit of £24 per £100 spent for loss-making companies

**U.S.**
- Tax-deductible R&D spend
  - 120% for incremental spend

**France**
- Tax-deductible R&D spend
  - 140% of incremental spend (<2003)
  - Additional 5% of total spend capped at €8m (>2004)

**Germany**
- Tax-deductible R&D spend
  - 100% of R&D revenue expenditure

EXHIBIT 16: SUMMARY OF RISKS TO THE U.K. POSITION

- The distinctiveness of the U.K., historically is access to wild and access to knowledge. These are fundamental differentiators, but that gap with other countries is closing.
  
- The U.K. is perceived as a good place for clinical trials but it’s expensive and the Chinese system is catching up.
  
- Historically, the U.K. was a good place to do phase 1 studies because it was less bureaucratic, but from 2005 this advantage is lost. There are now no fundamental reasons to do clinical trials in the U.K. The costs and process are the same across Europe.
  
- The U.K. patient population is not distinctive and it can be harder to find eligible – treatment naïve – patients here than in countries such as Russia and India.
  
- The U.K. is slipping down the league table in terms of academic medical excellence which has repercussions for clinical research activity.
  
- The U.K. has little to distinguish it against its international peers except its high quality academic clinicians/science base but now that experience of good quality clinical trials is growing, there is little in the U.K. considered distinctive.
  
- Pharma companies have more choice in where they can place research. The more clinical research is placed outside the U.K., the less reason there is to have your pharma HQ and R&D in the U.K.
  
- Central and Eastern European countries have proved they can deliver equivalent clinical trials quality more quickly and more economically.

Source: Interviews
HOW THE ENVIRONMENT IS CHANGING

In recent years, significant thought has been given to improving clinical research in the UK, through PICTF, BIGT, the Academy of Medical Sciences and the UKCRC. Key players are collaborating under the auspices of the UKCRC and most efforts to improve the UK’s clinical research environment for industry are taking place under that banner, (Exhibit 14). For example, the National Cancer Research Network run by the Department(s) of Health (DH) has improved patient recruitment for some types of trials. Another example is the introduction of the model Clinical Trials Agreement (mCTA) as a first step to reduce bureaucracy in trial set-up.

At a higher level, the Ministerial Industry Strategy Group\(^\text{24}\) is developing a Long Term Leadership Strategy for Medicines. This will be a rolling programme of work designed to ‘secure the provision of safe and effective medicines for patients, maintain and strengthen the UK pharmaceuticals industry within Europe, and to advance healthcare innovation with the NHS’.\(^\text{25}\)

However, recent press suggests that other governments are also taking major steps to attract more commercial clinical research. For example, Sweden and Germany are developing IT infrastructure programmes which appear similar to the UK’s Connecting for Health effort but are being developed more collaboratively with industry. Clinical research networks are already well established internationally and are being strengthened (Exhibit 15). In the US, third parties can provide performance metrics and costing references for clinical trials from historic clinical trial and contract data\(^\text{26}\). And within the EU, there is already work under way to harmonise processes across six member states: Denmark, France, Italy, Spain, Germany and Sweden\(^\text{26}\).

While the current initiatives in the UK will clearly benefit the clinical research landscape, research suggests that there will still be significant room for improvement versus stakeholder aspirations, NHS ambitions, and the developing global environment (Exhibit 16).

---

### EXHIBIT 15: EXAMPLES OF CLINICAL TRIAL NETWORKS IN OTHER COUNTRIES

<table>
<thead>
<tr>
<th>Country</th>
<th>Network Name</th>
<th>Year established</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ireland</td>
<td>Cancer Consortium</td>
<td>1999</td>
<td>An Ireland, Northern Ireland, U.S. partnership</td>
</tr>
<tr>
<td>Ireland</td>
<td>Clinical Research Support Centre</td>
<td>2003</td>
<td>Fully supported (p.104-12 FTA of centres providing support services to commercial and non-commercial clinical trials</td>
</tr>
<tr>
<td>Australia</td>
<td>Association of Clinical Research Professionals</td>
<td>2002</td>
<td>Provides clinical research, administrative management, education, training, regulatory affairs, marketing, finance and clinical research databases worldwide</td>
</tr>
<tr>
<td>Germany</td>
<td>Twelve NS (Coordination centre for clinical trials)</td>
<td>1999</td>
<td>Offers advice and support in planning, conducting and analysis for clinical trials</td>
</tr>
<tr>
<td>Poland</td>
<td>Polish Society for Clinical Pharmacology and Therapeutics</td>
<td>1997</td>
<td>Initiates, risk assessment and support of clinical trials, Educational role at conferences and universities to promote clinical trial knowledge</td>
</tr>
<tr>
<td>Italy</td>
<td>Mario Negri Institute in Lombardia</td>
<td>1960</td>
<td>Focuses on research on chronic diseases and disorders, with an emphasis on oncology, infectious diseases, and neurology</td>
</tr>
<tr>
<td></td>
<td>Mario Negri Institute in Milano</td>
<td>(1962) CIRC</td>
<td>Provides services to researchers</td>
</tr>
<tr>
<td>France</td>
<td>21st Clinical Investigation Centre (ODS)</td>
<td>1992-2001</td>
<td>Focuses on clinical research in hospital-based facilities</td>
</tr>
<tr>
<td></td>
<td>Réseau pour l’Étude, l’Assessment Clinique</td>
<td>N/A</td>
<td>Focuses on methodology support for clinical trials, management, data collection and analysis</td>
</tr>
<tr>
<td>EU</td>
<td>European Clinical Research Infrastructure Network</td>
<td>N/A</td>
<td>Supports project to facilitate multinational clinical studies and promote EU directives implementation</td>
</tr>
<tr>
<td></td>
<td>European Forum for Good Clinical Practice</td>
<td>1992-3</td>
<td>Supports group to establish and implement ethical and scientific standards in biomedical research</td>
</tr>
</tbody>
</table>

Source: "Fellows Ministry of Education and Research; McKinsey"
Given the risk posed to UK clinical research activity by international competition, the UK needs a distinctive value proposition to attract industry to invest. This section describes a possible value proposition, focused on the key ‘Offers’ that would support it.

**THE POTENTIAL UK VALUE PROPOSITION FOR CLINICAL RESEARCH**

In seeking to assure its commercial clinical research activity, the UK has some very important assets:

- A large, diverse, geographically concentrated patient population
- The world’s largest, cradle-to-grave integrated healthcare provider spanning primary, secondary and tertiary care
- Highly qualified physicians and researchers.

By deploying these assets in a way that is attractive to industry, the UK has the potential not only to protect its share of the global clinical research market, but also fundamentally to reshape the way healthcare is practised and delivered. In a way no other system could, the NHS should be able to answer some of the most fundamental questions facing clinicians, providers and payors. For example:

- How should the components of the system be integrated? (e.g., how could epidemiological data, clinical history, radiological and in vitro investigations be used together to guide treatment and follow-up?)
- What should patient journeys for specific diseases look like? (e.g., which genetic sub-populations should be taking statins, what other factors put these populations at risk, and how should they be managed and followed up in the community and in hospital?)
- What is the most effective and efficient way to manage disease? (e.g., how should interventions be compared to give a clear view of the economic, social and lifestyle trade-offs?)

To seize this opportunity, the UK needs to increase its collaboration with industry, which in a global and competitive market means offering a value proposition that meets industry’s needs in a distinctive way.

By building on its assets, the UK could create a value proposition for clinical research of ‘a single system that reliably delivers distinctive quality and rapid access at reasonable cost’.

The promise would be that the UK will deliver against each of the four major industry stakeholder needs of quality, time, reliability and cost. Strategic relevance is not addressed because it is highly dependent on market attractiveness and access - areas unlikely to be directly influenced by NHS R&D. For each of the four needs, the UK would deliver at least one key ‘Offer’:

**Quality** - Industry’s ability to perform research with the right type, quantity and precision of data. ‘Offers’ should include:
- Linked commercial and academic centres of research excellence in specific therapeutic and technical areas
- System-wide health outcomes research capabilities.
CHAPTER SIX

Time - Industry’s ability to access patients and expertise at the right pace, through:
3. Comprehensive and flexible healthcare IT system
4. Motivated and educated physicians, staff and patients.

Reliability - Industry’s ability reliably to predict the pace, quality and cost of clinical research, through:
5. An effective interface for industry that delivers the most efficient trial start and follow-up.

Cost - Consistent value-for-money and a transparent and fair cost structure for all sponsors of clinical research placed in the UK, through:
6. Transparent, system-wide measurement of research quality and productivity.

Of course, most of these ‘Offers’ meet more than one of industry’s needs: for example, the transparency created by clear metrics is likely also to improve timeliness and reliability. The way the value proposition, the ‘Offers’, industry’s needs and the UK’s assets fit together is illustrated in Exhibit 17.

KEY OFFERS FOR CLINICAL RESEARCH AND INITIATIVES TO DELIVER THEM

This section details each potential ‘Offer’ to industry. It assesses the current status, outlining the barriers stakeholders see to the UK’s delivering the ‘Offer’, and finally suggesting initiatives to achieve distinctiveness.

1. Linked commercial and academic centres of research excellence in specific therapeutic and technical areas
Linked centres of excellence for commercial and academic research in specific therapeutic and technical (e.g., bioinformatics) areas could offer significant and distinctive benefits to industry. They would be single locations with: streamlined trial set-up processes; more predictable access to patient populations; experienced research and trial staff with likely lower turnover; extensive expertise in the therapeutic or technical area, and a direct link between core fundamental research and development. The centres would allow stakeholders to co-invest in critical facilities (e.g., diagnostic facilities, outpatients, pharmacies capable of handling biologics and radiotopes). Industry could further support these centres by exchanging and seconding staff.

As a result, a company conducting research in cancer, for example, would have: a clear lead NHS organisation as a thought partner for protocol design, a rapid approval process, a point of contact to help identify target patients across the NHS system; and staff and infrastructure to better manage the trial process, (Exhibit 18).

Interviewees were clear that these centres of excellence should be defined primarily by the NHS on the basis of disease prevalence, as this would ensure access to sufficient patients. Specific therapeutic areas mentioned included: cardiac disease, focusing on coronary artery disease and chronic heart failure; cancer (i.e., in addition to the existing UKCRC network), particularly because of the need for diagnostic infrastructure, dedicated staff and facilities which use ‘up-to-date’ clinical pathways (e.g., their use of innovative new medicines is not constrained by NICE, the National Institute for Health and Clinical Excellence); psychiatric disease, focusing on depression; and respiratory disease, focusing on asthma, COPD and allergy.

Current status: Although many UK public sector clinical trials units perform a certain amount of industry-sponsored research, formally linked centres for commercial and academic research are not currently available or planned.

Assets: The UK has several high-quality, well funded and well staffed academic research facilities, for example, the MRC Clinical Trials Unit focused on HIV and cancer and the Birmingham Clinical Trials Unit focused on cancer and clinical trials in primary care.

Barriers: Current centres of excellence focus on fundamental and academic research and trials, with limited or no commercial development activity. In addition there are only a few specialist research facilities in the UK, and some interviewees observe that their work is constrained by shortages of diagnostic capacity and trained personnel.

Initiatives: Stakeholder interviews and surveys suggest both short and longer-term initiatives for the UK to consider in developing linked centres of excellence.
EXHIBIT 17: U.K. CLINICAL RESEARCH BRAND PYRAMID

U.K. clinical research value proposition
- A single source for clinical research excellence
- Quality
- Time
- Reliability
- Cost
- Ensuring research in the U.K. is comparable

What the U.K. will deliver
- Performing at the high level of quality
- Assessing patients and treatments
- Maintaining sites

Key ‘Offers’
- Large diverse patient population
- Single multiprofessional research provider
- PHARMEXA standard quality control
- High-quality research base and well-equipped academic research facilities
- United education and qualification system for medical professionals
- Competitive tax incentives for UK investment in the U.K.
- In the future, dedicated funding could include specific named platforms (e.g., Connecting for Health)

Assets
- Centres of Clinical Research Excellence
- Systems for health outcomes research
- Comprehensive and flexible healthcare IT services
- Accurately recorded outcomes, staff and patient population
- Effective market for industry
- Transparent systems, referees and measurement

EXHIBIT 18: DEDICATED WORLD-LEADING CLINICAL TRIALS FACILITIES

Everyone in the NHS has a day job and are too busy to get their heads above the parapet to see what’s needed. They need clear direction and organisation to conduct trials otherwise they are carried out piecemeal.

Biotech executive

If the NHS were to build a chain of dedicated clinical trials facilities with full-time staff based at NHS Trusts, this would be highly distinctive.

Pharma industry stakeholder

You should create regional one-stop RCT shops for industry. These should be industry-friendly and offer expertise in clinical trials design, statistics and data management, dedicated facilities and staff, including trained nurses, credibility and access to the local NHS network.

Academic

Health technology cooperatives produce good results by linking industry and research. These cooperatives serve as catalysts in attracting clinical research funding and industry to the U.K.

Device executive

The NHS should set up semi-commercial clinical trial businesses which bid for work from industry. They would maintain a register of investigators ranked by their success and if they don’t deliver on clinical trials, they would get knocked off the register. This circumvents the main problem, which is finding investigators who deliver.

Pharma industry stakeholder

The U.K. could lead the way in creating Centres of Excellence in particular disease areas and linking these up with industry partners and other Colise in the U.S. and elsewhere.

Device executive

There is a great opportunity to create one-stop shops for clinical trials.

Biotech executive

Source: Interviews
CHAPTER SIX

SHORTER TERM (BY 2008):
- Create three to five world-class centres of excellence linking commercial and public research, in collaboration with NHS Trusts or NHS Foundation Trusts. Each centre should provide a physical site for commercial clinical research, including: supporting infrastructure (e.g., diagnostic facilities, consulting rooms), sufficient network to access large numbers of patients and streamlined processes for collaboration with industry (e.g., ethics, financial approval).
- Make clear the NHS’s R&D priorities at therapeutic area, disease and technology levels, and describe very specifically how industry could contribute and collaborate. Several stakeholders are frustrated by lack of clarity around the NHS R&D agenda, hindering deeper discussions on collaboration.
- Collate the research priorities of UK academic medical centres and facilitate discussions with industrial stakeholders who have similar interests. Several of the academic Trusts interviewed admit they lack the requisite networks with industry or the capabilities to undertake these negotiations.
- Incorporate stipulations to perform a minimum amount of commercial research in grants to leading academic centres.

LONGER TERM:
- Build future clinical research networks around a physical centre of excellence. This will act as a focal point for infrastructure, training of staff and expertise.
- Make sure that NHS specialist research facilities have the infrastructure for world-class commercial research. Pragmatically, this means investing to build the capabilities and capacity needed for world-class clinical development into existing and future centres of excellence (e.g., research nurses, diagnostic equipment and central labs).
- Link up with US or other international centres of excellence on a particular disease that is being approached in a fragmented way globally. The UK could lead the way to create the linkage with other centres.

2. System-wide health outcomes research capability

Healthcare is complex and it is often difficult to predict in the long run what will be the best therapy, diagnostic or clinical pathway. The UK’s system-wide cradle-to-grave healthcare provision creates a unique opportunity to conduct health outcomes research that examines a wide range of approaches to disease and health (e.g., invasive versus non-invasive diagnostics, drug versus device versus surgery, value of screening for early diagnosis and treatment, linking outcomes and cost). The UK could be the proving ground for what next generation therapy and care look like, how therapies tie together, and their overall impact on healthcare system operations and economics. For example, the NHS could assess the impact of monitoring (e.g., colonoscopy vs CT scanning), early diagnosis and prediction of colorectal cancer on patient outcomes, quality of life and overall health system costs, (Exhibit 19).

Current status: UK government healthcare bodies have not yet investigated a multi-disciplinary system focused health economics evaluation.

Assets: The UK has the ability to follow patient diagnosis, treatment and outcomes from cradle to grave and the potential to access system-wide cost of care and operational data. NICE and its collaborating centres have developed internationally recognised expertise in health economic evaluation. There are also a small number of academic health economics centres of excellence with extensive commercial partnership experience.

Barriers: Currently, there is little real partnership and no mindset for collaborative experimentation. Better access to data (e.g., system cost, operational, clinical) will be needed in order to map and understand the complex interplay of health system costs.

Initiatives: Stakeholder interviews and surveys suggest both short and longer-term initiatives for the UK to consider in developing system-wide health outcomes research capabilities.

SHORTER TERM (BY 2008):
- Define clear priorities for outcomes research (e.g., examining the impact of early diagnosis, workflow changes, remote care) and actively seek partners from industry to engage in it.

27 For example, Health Economics Departments at the University of York, Brunel and the University of Aberdeen
EXHIBIT 19: SYSTEM-WIDE HEALTH OUTCOMES RESEARCH CAPABILITIES

The government should fund large-scale prospective trials evaluating the impact of healthcare reforms on outcomes. This would enable the NHS to deliver healthcare more efficiently, build engagement and expertise and would foster a culture of R&D which would make the U.K. a more attractive place for industry to place trials.

Academic

The U.K. NHS has the ability to incorporate an established health economics academic infrastructure into clinical trials.

Pharma industry stakeholder

The U.K. can answer important questions such as linking outcomes and costs by creating a centre for integrated system-wide level health economics.

Devices executive

Source: Interviews

EXHIBIT 20: COMPREHENSIVE AND FLEXIBLE HEALTHCARE IT SYSTEM AND DATA SOURCES SUPPORTING A SINGLE CRADLE TO GRAVE HEALTH SYSTEM

The U.K. NHS could be the most unique clinical research location in the world if bound together by a single information system. The benefits would be inter alia, longitudinal records, institutional ability to identify eligible patients, common standards, protocols and practices.

Pharma executive

It would be extremely beneficial for the U.K., as a location for clinical trials in medical devices, to develop a solid incentives-driven framework to pull together data from hospitals.

Device executive

The U.K. could offer another distinctive feature: a developed and efficient integrated IT system through which access to patient data will be possible. The potential is enormous.

Pharma industry stakeholder

Visit a single consultant and he will be able to tell you immediately how many potential treatments are in his area – no need to send letters out to GPs and wait.

Pharma executive

The U.K. should develop its competence as a centre for bioinformatics with strong industry.

Institute collaborators

Biotech executive

The NHS should be uniquely placed to deliver large numbers of ethnically diverse patients to trials but this isn’t happening right now. The NHS is an unutilized.

Academic

Source: Interviews
CHAPTER SIX

- Reinforce and support existing capabilities in outcomes research (e.g., the Medicines Monitoring Unit, MEMO28, in Scotland; the General Practice Research Database29).

- Help industry accelerate product approval or uptake by co-presenting outcomes or health economics data to NICE and providers (e.g., NHS Foundation Trusts). This could take the form of an NHS stamp of approval for selected studies similar to the stamp being considered by the US National Institutes for Health in submissions to the FDA.

- Set up one or two health economics centres of excellence sited at NHS Trusts and encourage linkages between these institutions and industry.

LONGER TERM:

- Co-sponsor on a risk-sharing basis research into new ways of delivering healthcare that may have positive benefits for both industry and the UK (e.g., controlled trial for new clinical pathways for the prevention and management of colonic cancer).

3. Comprehensive and flexible healthcare IT system

With 60m30 patients and a cradle-to-grave system of care, the UK has the potential to create an integrated system of patient and clinical information with a broad range of potential applications (e.g., real-time disease prevalence, rapid identification of potential trial candidates, longitudinal studies across large patient pools). For example, there could be a single database which industry could use to conduct a retrospective study comparing pathway ablation versus device versus drug therapies for arrhythmias, <Exhibit 20>.

Current status: In comparison with many other countries, the UK has a relatively high-quality IT infrastructure, though it is not well connected across individual NHS Trusts or the UK. The Connecting for Health (CfH) initiative is under way in England to digitise medical and care records prospectively for every patient.

Assets: The NHS is a single integrated healthcare provider treating the UK population from cradle-to-grave across indications, specialties, primary and secondary care. The NHS keeps electronic and paper-based records of patient history, treatments and outcomes. Connecting for Health could therefore create the world’s largest integrated and shareable patient record IT system.

Barriers: Interviewees widely expect delivery of CfH to be delayed. Their understanding of the current specifications is that CfH does not incorporate the needs of industry for commercial clinical research. It is not clear that electronic patient record systems being developed in different parts of the UK (e.g., CfH in England, Informing Healthcare Strategy in Wales, Scottish Care Information initiative) will be compatible. There is no plan to incorporate historic patient data31.

Initiatives: Interviewees unanimously view a comprehensive healthcare IT system as difficult to implement, but critical to providing a globally distinctive research environment in the UK. They suggest a range of initiatives to make it happen.

SHORTER TERM (BY 2008):

- Create clear guidance on best practice for industry’s access to clinical data (e.g., on issues such as data protection, confidentiality, commercial terms).

- Influence the design of CfH so that it better meets the needs of commercial and public sector clinical research. This could include: expanding the scope of data capture; developing software to facilitate patient enrolment and monitoring, (e.g., tools to identify patients meeting specific eligibility criteria and to generate a ‘prompt’ on a clinician’s computer).

- Test the principle and practice of industry-NHS collaboration by trying it out on a small scale with forerunners of NPfIT/CfH (e.g., the University College Hospital system).

- Link together and more efficiently mine existing data sources, for example the General Practice Research Database32. A short-term focused effort to identify

28 A university-based organisation which works on the linkage of records containing health care data for the population of Tayside, Scotland
29 The world’s largest computerised database of anonymised clinical records from general practice
30 Approximate figure for England, Scotland, Wales and Northern Ireland
31 http://www.connectingforhealth.nhs.UK/programmes/
32 http://www.gprd.com
and link valuable information for clinical research could provide experience for the NHS and an early benefit to industry.

- Consider creating an interface between CfH and the industry similar to SWIFT in banking. This would comprise: an independent body acting as an impartial data clearing house between the NHS and potentially competing stakeholders; middleware that would extract data and interface with CfH without overburdening the existing development programme; and a clear set of guidelines for data usage.

LONGER TERM:

- Create formal linkages between NHS and industry R&D and Connecting for Health and the NHS Health and Social Care Information Centre to ensure that public sector and commercial clinical researchers are considered as core users of NHS IT systems.

4. Motivated and educated physicians, staff and patients

Improving patients’, physicians’ and broader healthcare professionals’ perceptions of research is key. Getting this right will help make these groups more willing to participate, leading to larger recruitment populations, faster start-up times, better performance against enrolment targets and lower drop-out rates. The NHS has the credibility to promote the benefits of clinical trials to all of these groups in ways that industry cannot. This should include: promoting the value of commercial clinical research to a largely sceptical physician and nursing population; educating stakeholders (e.g., physicians on GCP); and incentivising involvement in trials. (Exhibit 21).

Current status: In 1998, the Department of Health created ‘Consumers in NHS Research,’ a standing advisory group on consumer involvement in the NHS. The group was renamed ‘Involve’ in 2003 and its scope expanded to cover promoting active public involvement in NHS, public health and social care research. Involve also monitors the extent and effects of public involvement in research.

Assets: The UK has a number of patient and physician communities and networks, such as the British Medical Association, Multiple Sclerosis Society Research Network and the UK Medicines for Children Research Network, where increased education and improved communication could have an impact. In addition, the Royal Colleges constitute a unified education system for the UK of significant global scale and breadth.

Barriers: In contrast to, for example, their peers in the US, interviews suggest that UK physicians do not value clinical research as highly as fundamental or academic research. They are said to think that commercial clinical research is not aligned with their needs, system priorities or patient benefit. UK patients are unwilling to be test subjects in part because they are less likely to be aware of clinical research than their counterparts in Europe and the US. (Exhibit 22).

Initiatives: Stakeholder interviews and surveys suggest both short and longer-term initiatives for the UK to consider for improving patients’, physicians’ and staff’s perceptions of research.

SHORTER TERM (BY 2008):

- Collaborate with industry to publish NHS-branded educational materials and guidance for healthcare practitioners on key areas (e.g., consenting for trials) aimed at the non-expert (e.g., the GP who has never participated in a trial).

- Collaborate with industry (e.g., CROs) to publish NHS-branded leaflets, posters and educational materials for patients on the value of trials and the trial process.

- Use direct public awareness and education campaigns to promote the safety and benefits of research to patient associations (e.g., promoting access to novel medication).

- Facilitate additional data collection in large-scale commercial trials to provide valuable public health or fundamental research information. This would align physician, system and industry needs and increase physician interest in trials.

- Find ways for physicians to continue to be involved and informed of study progress beyond the completion of data collection.
EXHIBIT 21: SYSTEM-WIDE COHORT OF HIGHLY EDUCATED AND MOTIVATED PHYSICIANS AND PATIENTS

Physicians must be incentivised to get involved in clinical research via training, nursing support, involvement in the intellectual aspects of clinical research and making it part of their professional life.

In medical devices, we rely heavily on the goodwill of individual surgeons.

U.K. patients are afraid to be guinea pigs: they’re driven by an entitlement attitude to healthcare. By comparison, the U.S. is great for clinical research because although it has many problems, it has great doctors that are interested and patients that want to be involved. This contributes to high quality results and speed of enrolment.

The consultant contract should intelligently differentiate between clinical service and R&D activity. Right now, R&D is seen as a bottom activity for enthusiasts but in order to increase the amount of R&D the brightest and most curious clinicians need to be released and rewarded. The government needs to find a way to protect and promote academic clinicians as they are the bridge between industry and the NHS. They are a fragile and endangered species.

In the last 5 years the percentage of cancer patients enrolled in clinical trials in the U.K. has risen from around 3.5% to above 10%. This is higher than any other country for which data is available and shows the potential impact of effective investment in clinical research infrastructure.

We must get patients’ organisations motivated on this issue as patients in the U.K. generally are very keen to participate in research and this asset is currently under-exploited. Clinical trials work should count towards distinction awards for consultants.

Source: Interviews

EXHIBIT 22: PATIENTS’ ACCESS TO CLINICAL TRIALS INFORMATION

<table>
<thead>
<tr>
<th>Country</th>
<th>Ever exposed to information on clinical research studies from any source %</th>
<th>Received information on clinical research studies from GP %</th>
<th>Received information on clinical research studies from specialist physician %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Poland</td>
<td>84</td>
<td>6</td>
<td>14</td>
</tr>
<tr>
<td>Italy</td>
<td>76</td>
<td>15</td>
<td>19</td>
</tr>
<tr>
<td>India</td>
<td>70</td>
<td>15</td>
<td>18</td>
</tr>
<tr>
<td>France</td>
<td>66</td>
<td>14</td>
<td>11</td>
</tr>
<tr>
<td>USA</td>
<td>60</td>
<td>9</td>
<td>13</td>
</tr>
<tr>
<td>Germany</td>
<td>53</td>
<td>5</td>
<td>11</td>
</tr>
<tr>
<td>Spain</td>
<td>50</td>
<td>1</td>
<td>11</td>
</tr>
<tr>
<td>U.K.</td>
<td>49</td>
<td>8</td>
<td>11</td>
</tr>
</tbody>
</table>

LONGER TERM:
- Lobby to emphasise commercial research as part of the Research Assessment Exercise (RAE)
- Collaborate with Royal Colleges to create non-financial incentives for GPs, specialists, consultants and trainee consultants to participate in clinical research by making it an element or a requirement of Continuing Medical Education, or offering distinction points and corresponding pay rewards
- Incorporate clinical research education into training for physicians, nurses and support staff at centres of excellence and potentially at medical schools as well.

5. An effective interface for industry that delivers the most efficient trial start and follow-up
An effective interface for industry could make R&D approval, site set-up, access to patients, and follow-up (e.g., Case Report Form completion and transmission) much more reliable, efficient and timely. This could turn what many stakeholders see as one of the greatest problems with the UK clinical research environment into a major strength. For example, a company conducting a clinical study in the UK could have one clear point of contact within the NHS accountable for all aspects of approval, set-up, project management and close-out, (Exhibit 23).

Current status: In collaboration with industry, the Department(s) of Health has begun standardising NHS commercial clinical trials contracts and costing arrangements. The ABPI and the DH have developed and disseminated the mCTA (model Clinical Trial Agreement). DH and the ABHI are working on a standard contract for the devices industry. The National R&D Costing Initiative provides a framework for costing commercially-funded research in the NHS but does not go so far as to set out a fixed tariff. Interviews suggest that there is wide variation across the NHS in interpreting and implementing these guidelines, particularly in calculating ‘overhead’ costs. Although the introduction of the EU Clinical Trials Directive has harmonised ethical approval procedures across Europe and created a 60-day standard, interviews suggest that there is wide variation in its interpretation. The UK continues to be perceived as a rigorous, but sometimes frustrating, regulatory environment for late-stage trials.

Assets: The UK’s unified NHS healthcare system gives the opportunity to create a streamlined interface with industry along the entire clinical research process from design through data completion to transfer.

Barriers: However, fragmented bureaucracy and non-binding procedures make trial/investigation set-up complicated and cumbersome. There are often additional barriers to arranging trials in primary care and in secondary care. Trust-level NHS R&D approval is not standardised and frequently creates delays. In practice, the separation of regulatory, ethical and R&D approval in the NHS results in duplication and frequent breaches of target approval time-lines. In addition the Scottish and Welsh procedures are evolving differently from those in England.

Initiatives: Stakeholder interviews and surveys suggest that a streamlined industry interface would be a very compelling ‘Offer’, but delivering it will require decisive action in a number of areas.

Many actions could be taken in the short term and suggestions ranged from hands-off guidelines to a more directive approach:
- Better communicate the role and scope of the UKCRC. Although most stakeholders interviewed were aware of the UKCRC, many did not understand its responsibilities and priorities or how to work productively with it.
- Provide clear guidelines (either suggested or mandated Standard Operating Procedures) for key steps in the commercial clinical research process such as ethical review, NHS R&D approval, set-up, costing and contracting (e.g., through standardised templates). This would provide a consistent approach across the NHS and minimise unnecessary re-work and local reviews. The NHS could begin by widening the use of the standard mCTA and R&D approval forms and by not creating new hurdles to R&D approval from additional facilitating bodies.
CHAPTER SIX

EXHIBIT 23: AN EFFECTIVE INTERFACE FOR INDUSTRY TO DELIVER THE MOST EFFICIENT TRIAL START AND FOLLOW-UP

U.K. pharma is shooting itself in the foot by having a second approval stage – NHS R&D approval – rather than the single-stage ethics approval that most other countries have.

Pharma industry stakeholder

Biotechs need fast studies. VOIs don’t understand lead times for ethics approval.

Biotech executive

There is huge variability and fragmentation of processes on site setup leading to delays and additional costs.

Pharma executive

PCTF should take on a role as central coordinator for commercial clinical trials.

Pharma executive

There is a need to minimise ‘red tape’ which is perceived to be much worse in the U.K. than elsewhere in Europe.

Pharma industry stakeholder

The NHS faces a command and control structure. Use this to advantage by centralising clinical trials. Don’t leave anything to chance.

Device executive

They need to stiffen up and consolidate ethics committees to enable them to become drivers of innovation. They should create a few lead ethics committees rather than many unskilled committees.

Device industry stakeholder

It would be extremely helpful to have harmonised uniform data collection methods, design protocols and ethical approval processes which could be applied in multiple hospitals, saving huge amounts of time, given the varying decision-making time and processes across hospitals.

Device executive

Source: Interviews

EXHIBIT 24: TRANSPARENT, SYSTEM-WIDE METRICS AND MEASUREMENT OF RESEARCH QUALITY AND PRODUCTIVITY

... set targets to improve quality of patient recruitment – e.g., for meeting criteria for inclusion/exclusion and for enrolling enrolment plans.

Pharma executive

The NHS has a poor track record in patient recruitment: 90% of trials are delayed because of problems with patient recruitment.

Pharma industry stakeholder

The NHS should set up semi-commercial clinical trial businesses which bid for work from industry. They would maintain a register of investigators ranked by their success and if they don’t deliver on clinical trials, they would get knocked off the register. This circumvents the main problem, which is finding investigators who deliver.

Device industry stakeholder

There are up to 4x differences in costs for the same study across U.K. sites.

Biotech industry stakeholder

The U.K. is the only country where hospitals/ universities are required to charge for overheads and infrastructure. There is a perception that commercial companies are subsidising the Professor of Poety through these charges.

Academic

There should be a single fee schedule across hospitals.

Pharma executive

Source: Interviews
- Implement a single NHS-wide R&D sign-off process for trials. This would be beneficial for public research as well as commercial studies, particularly large multi-site primary-care based projects, where the slow process of gaining the agreement of several NHS organisations across the country can make it very challenging to recruit enough patients to achieve statistical power.

- Create a body to resolve disputes between industry and the NHS. For example, an NHS body could address issues such as excessive site set-up delays, missed recruitment targets, and poor Case Report Form quality. This would provide a single point of contact for industry and reassurance that issues were being resolved.

LONGER TERM:

- Increase the numbers and quality of staff providing clinical trials management services within NHS organisations, regulatory agencies and ethics committees, through recruitment and training.

- Create novel linkages between industry and the NHS to optimise the overall research system. Examples might include a complete register of clinical research activity across commercial and public sectors to build awareness of activity by disease area across the UK, or a forum for combining or sharing protocols and matching interests between commercial and academic trials.

- Provide services directly to industry on behalf of individual Trusts - for example, create a one-stop liaison service to simplify multi-tier ethics and R&D approval processes and a single negotiating body to manage contractual agreements and costing arrangements for multi-site trials. Some interviewees suggest that the NHS could play a role similar to a contract research organisation (CRO) or that the NHS could partner with a CRO to deliver these services.

6. Transparent, system-wide measurement of research quality and productivity

NHS-wide transparent measurement of physicians’ and Trusts’ clinical research performance would be a truly distinctive ‘Offer’ for the UK. It would allow industry reliably to predict the pace, quality and cost of clinical research. It could also provide incentives to Trusts to be fair in costing and to investigators and Trusts to deliver quality and timeliness. For example, individual investigators and Trusts would report the percentage of patients enrolled by target dates and the percentage of Case Report Forms queried in their completed research projects. (Exhibit 24).

Current status: Northern Ireland has established a small group to provide data management support for both industry-sponsored and academic clinical trials and Scotland is in the process of introducing a similar effort. There are no plans at present for R&D metrics in England and Wales or for alignment of metrics across the UK.

Assets: The NHS uses performance indicators across a range of operating and outcome dimensions for Healthcare Commission star ratings. The UK is also experiencing a groundswell of political support for healthcare reform and performance measurement.

Barriers: Longer-term efforts on R&D measurement and metrics would need to be carefully designed in order to avoid risks of over-measurement, increased bureaucracy and added complexity for Trusts. In addition, metrics would need to flexible enough to allow for differences between Trusts in areas of focus and levels of clinical research.

Initiatives: Stakeholder interviews and surveys suggest both short and longer-term initiatives for the UK to consider in developing system-wide research metrics.

SHORTER TERM (BY 2008):

- Start tracking the effectiveness of any changes to the system (e.g., those laid out in the NHS strategy) through metrics such as number of patients recruited into industrial trials.

- Profile a leading NHS Trust with distinctive performance metrics as a model for best practice. This would create positive publicity for best practice in industrial collaboration. It would also provide a reference case for Trusts wishing to improve their collaboration with industry.

- Publish a small set of common metrics from industry-supplied data on historic Trust and investigator performance in commercial clinical research. These metrics should include bench
marks from competing locations (e.g., China). The NHS could do this or outsource it to a third party. One example already exists in the UK: the independent organisation Dr Foster “collects and analyses information on the availability and quality of health services in the UK”.

LONGER TERM:
- Incorporate metrics into Healthcare Commission ratings and link measures to additional research funding.
- Develop quality scoring to recognise investigators who deliver on enrolment targets and provide consistently good quality research to industry. With appropriate data protection in place, industry could use this to target investigators based on their past performance. The NHS could manage measurement and reporting centrally or outsource to a third party. A number of vendors have already developed this service for industry for US investigators and some are beginning to gather data on investigators outside the US.

34 http://www.drfoster.com/home.aspx
35 Theratech Consulting (TTC) product “Grantplan”, Fasttrack product “Grant manager”, and Rapid Trials product “Budgetbuilder”.
While stakeholders all described hurdles to overcome, they are also optimistic that the UK could become a distinctively attractive place to locate clinical research. Industry stakeholders were particularly enthusiastic about improved and broader collaboration with the NHS.

Strengthening the UK’s overall value proposition to industry for clinical research will require concerted efforts to deliver each ‘Offer’. Interviewees feel that the following actions are the top priorities and should in place by January 2008 at the latest:

**Significantly improving communication**

A clear statement on which NHS R&D priorities (i.e., which therapeutic areas, diseases, technologies) will be the focus of collaborations

A mechanism in place to create clear and up-to-date information on the research interests and activities of NHS organisations and individuals, academic centres, universities and industry. The mechanism should provide information about who is carrying out the research, budgets and mechanisms, and should collate and, where possible, match research priorities

A communication programme in progress to explain the safety and benefits of clinical research to patients, physicians, and staff, undertaken in collaboration with patient groups, Royal Colleges and nursing and medical schools

**Demonstrating early success and learning**

Concrete initiatives in operation to help bypass bureaucracy and improve trial execution. This should include: a single NHS-wide R&D sign-off, metrics on NHS Trusts’ R&D performance (e.g., volume of clinical research activity, length of start-up time, ‘overhead’ cost), a streamlined interface between industry and the NHS including the creation of a body to resolve disputes

The creation of between three and five linked centres of excellence for commercial and public research, including at least one dedicated to health economics, in collaboration with NHS Trusts or NHS Foundation Trusts

Between three and five joint ventures with industry (i.e., joint investment, joint expertise) in place on areas that are critical to both the UK and industry. These could include, for example, joint ventures focusing on pharmacogenomics or the use of technology to monitor disease in residential settings

A commitment to involving industry in Connecting for Health as demonstrated by influencing its design, exploring the potential of an interface between Connecting for Health and industry, and piloting NHS-industry collaboration

**Expanding guidance to the broader NHS**

Publication of best practice guidelines for the commercial clinical research process, for example, Trust approval, set-up, costing, negotiation and contracting

The prize for better collaboration between the NHS and industry is immense, for patients, for the NHS and industry, and for the UK as a whole. Key to capturing this will be fostering more open communication and a full commitment to new ways of working.
### APPENDIX

<table>
<thead>
<tr>
<th>NAME</th>
<th>AFFILIATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adrian Grant</td>
<td>Scottish Health Services Research Unit</td>
</tr>
<tr>
<td>Alan Boyd</td>
<td>Ark Therapeutics</td>
</tr>
<tr>
<td>Alan Needham</td>
<td>BioPharma Practice Ltd.</td>
</tr>
<tr>
<td>Alison Austin</td>
<td>Department of Trade and Industry</td>
</tr>
<tr>
<td>Anthony David</td>
<td>Mental Health Co-ordinating Centre</td>
</tr>
<tr>
<td>Anthony Walker</td>
<td>Onyxvax Ltd</td>
</tr>
<tr>
<td>Carol Parish</td>
<td>Merck</td>
</tr>
<tr>
<td>Catherine Johns</td>
<td>Department of Health (Research &amp; Development Directorate)</td>
</tr>
<tr>
<td>Chris Shepherd</td>
<td>GlaxoSmithKline</td>
</tr>
<tr>
<td>Chris Watkins</td>
<td>Medical Research Council</td>
</tr>
<tr>
<td>David Moss</td>
<td>Novartis</td>
</tr>
<tr>
<td>David Ullis</td>
<td>Fujitsu</td>
</tr>
<tr>
<td>Diane Sheridan</td>
<td>HepCgen</td>
</tr>
<tr>
<td>Gareth Lewis</td>
<td>Pfizer</td>
</tr>
<tr>
<td>Geoff Lee</td>
<td>GE Healthcare</td>
</tr>
<tr>
<td>Graeme Scott</td>
<td>Pleiad Group</td>
</tr>
<tr>
<td>Helen Campbell</td>
<td>Department of Health (Cancer Research Portfolio)</td>
</tr>
<tr>
<td>Helen Howard</td>
<td>UK Clinical Research Network</td>
</tr>
<tr>
<td>Janet Darbyshire</td>
<td>Clinical Trials Unit (Medical Research Council)</td>
</tr>
<tr>
<td>Janet Messer</td>
<td>NHS R&amp;D Forum</td>
</tr>
<tr>
<td>Jill Dhell</td>
<td>Department of Health (Research &amp; Development Directorate)</td>
</tr>
<tr>
<td>Jim Connelly</td>
<td>Department of Health (Research &amp; Development Directorate)</td>
</tr>
<tr>
<td>Joanna Nakelow</td>
<td>Eli Lilly</td>
</tr>
<tr>
<td>Joanne Donkings</td>
<td>Roche</td>
</tr>
<tr>
<td>John Cohen</td>
<td>Department of Trade and Industry</td>
</tr>
<tr>
<td>John Kelly</td>
<td>Kowa</td>
</tr>
<tr>
<td>John Mathews</td>
<td>Wyeth</td>
</tr>
<tr>
<td>John Wilkinson</td>
<td>Association of British Healthcare Industries</td>
</tr>
<tr>
<td>Judith Syson</td>
<td>AstraZeneca</td>
</tr>
<tr>
<td>Kate Lloyd</td>
<td>Pfizer</td>
</tr>
<tr>
<td>Konstantinos Karras</td>
<td>Whipps Cross Hospital</td>
</tr>
<tr>
<td>Liam O’Toole</td>
<td>UK Clinical Research Collaboration</td>
</tr>
<tr>
<td>Louise Wood</td>
<td>Department of Health (Research &amp; Development Directorate)</td>
</tr>
<tr>
<td>Magnus Jaderberg</td>
<td>Wyeth</td>
</tr>
<tr>
<td>Maria Palmer</td>
<td>Bristol Healthcare</td>
</tr>
<tr>
<td>Mark Lewis</td>
<td>North West London Strategic Health Authority</td>
</tr>
<tr>
<td>Matthew Hallsworth</td>
<td>UK Clinical Research Collaboration</td>
</tr>
<tr>
<td>Maxine Stead</td>
<td>UK Clinical Research Network Coordinating Centre</td>
</tr>
<tr>
<td>Michael Atkins</td>
<td>Roche</td>
</tr>
<tr>
<td>Mick Boroff</td>
<td>DePuy Int</td>
</tr>
<tr>
<td>Nick Deaney</td>
<td>Merck</td>
</tr>
<tr>
<td>Nick McNally</td>
<td>University College London</td>
</tr>
<tr>
<td>Nish Chaturvedi</td>
<td>Diabetes Co-ordinating Centre</td>
</tr>
<tr>
<td>Noreen Cane</td>
<td>Department of Health (Research &amp; Development Directorate)</td>
</tr>
<tr>
<td>Paul Woods</td>
<td>Department of Health (Medicines, pharmacy and industry)</td>
</tr>
<tr>
<td>Philip Bath</td>
<td>Stroke Co-ordinating Centre</td>
</tr>
<tr>
<td>Philip Needham</td>
<td>Cardionetics</td>
</tr>
<tr>
<td>Rebecca Stratford</td>
<td>National Cancer Research Institute</td>
</tr>
<tr>
<td>Richard Tiner</td>
<td>Association of the British Pharmaceutical Industry</td>
</tr>
<tr>
<td>Rick Kaplan</td>
<td>UK Clinical Research Network</td>
</tr>
<tr>
<td>Robert Tansley</td>
<td>Arakis Limited</td>
</tr>
<tr>
<td>Roberto Solari</td>
<td>Medical Research Council Technology</td>
</tr>
<tr>
<td>Sheila Casserly</td>
<td>UK Clinical Research Network</td>
</tr>
<tr>
<td>Simon Bickelhup</td>
<td>Sumed</td>
</tr>
<tr>
<td>Stuart Dellow</td>
<td>GlaxoSmithKline</td>
</tr>
<tr>
<td>Sue Bourne</td>
<td>UK Clinical Research Collaboration</td>
</tr>
<tr>
<td>Susannah Keeing</td>
<td>UK Clinical Research Collaboration</td>
</tr>
<tr>
<td>Til Wykes</td>
<td>Mental Health Co-ordinating Centre</td>
</tr>
<tr>
<td>Tony Nunn</td>
<td>Medicines for Children Coordinating Centre</td>
</tr>
<tr>
<td>Vanithree Patel</td>
<td>St Ormond St Hospital</td>
</tr>
<tr>
<td>Wendy Russell</td>
<td>Department of Health (Research &amp; Development Directorate)</td>
</tr>
<tr>
<td>Allan Baxter</td>
<td>GlaxoSmithKline</td>
</tr>
<tr>
<td>Alasdair</td>
<td>Medicines &amp; Healthcare</td>
</tr>
<tr>
<td>Breckenridge</td>
<td>products Regulatory Agency</td>
</tr>
<tr>
<td>Alison Spauli</td>
<td>Scottish Executive</td>
</tr>
<tr>
<td>Allan Ritchie</td>
<td>DePuy Int</td>
</tr>
<tr>
<td>Bill Castell</td>
<td>GE Healthcare</td>
</tr>
<tr>
<td>Bill Clarke</td>
<td>GE Healthcare</td>
</tr>
<tr>
<td>Brian Gennery</td>
<td>University of Surrey, Medical School</td>
</tr>
<tr>
<td>Carol Black</td>
<td>Royal College of Physicians</td>
</tr>
<tr>
<td>Craig Stevenson</td>
<td>Pfizer</td>
</tr>
<tr>
<td>David Cooksey</td>
<td>Advent Venture Partners</td>
</tr>
<tr>
<td>David Jefferys</td>
<td>Eisai</td>
</tr>
<tr>
<td>Diana Dunstan</td>
<td>Medical Research Council</td>
</tr>
<tr>
<td>Diana Garnham</td>
<td>Association of Medical Research Charities</td>
</tr>
<tr>
<td>Donald Black</td>
<td>GE Healthcare</td>
</tr>
<tr>
<td>Erich R Reinhardt</td>
<td>Siemens Medical</td>
</tr>
<tr>
<td>Ian Smith</td>
<td>Synexus</td>
</tr>
<tr>
<td>James Shannon</td>
<td>Novartis</td>
</tr>
</tbody>
</table>
### NAME | AFFILIATION
--- | ---
Jane Eisner | Quintiles
John Bell | Academy of Medical Sciences
John Jeans | GE Healthcare
John Patterson | AstraZeneca
Jonathan Michael | Guy’s and St. Thomas’ Hospital
Jörg Reinhardt | Novartis
Kate Anderson | Eli Lilly
Keiron Day | Sonin
Mads Krosgaard | Novo Nordisk
Thomsen | Novo Nordisk
Manfred Haehl | Boehringer Ingelheim
Mark Walport | The Wellcome Trust
Marilyn Turbitt | AstraZeneca
Michael Rawlins | National Institute for Health and Clinical Excellence
Neil Tierney | Lightweight Medical Ltd
Oliver Wells | Imperial College
Paul Devenish | HM Treasury
Paul Rollett | Fujitsu
Peder K. Jensen | Schering Plough

### NAME | AFFILIATION
--- | ---
Peter Arnold | Smith & Nephew
Peter Selby | UK Clinical Research Network Co-ordinating Centre
Philipp Wright | Association of the British Pharmaceutical Industry
Richard Barker | Association of the British Pharmaceutical Industry
Robert Stout | Health and Personal Social Services (Northern Ireland)
Sally Davies | Department of Health (Research & Development Directorate)
Sarah Haywood | Department of Trade and Industry Bioscience Unit
Sharon Allen | Eli Lilly
Steve Cook | Huntleigh
Tachi Yamada | GlaxoSmithKline
Timothy Wells | Serono
Tom Walley | Liverpool University, Dept of Pharmacology and Therapeutics
Vincent Lawton | Merck, Association of the British Pharmaceutical Industry
notes