All together now: Improving cross-sector collaboration in the UK biomedical industry

Louise Marston
Executive summary

A strong history in pharmaceuticals and chemicals, combined with world-leading university research, has created a significant competitive advantage for the UK biomedical sciences industry. This industry is important to the UK economy, accounting for 9 per cent of exports and 28 per cent of business R&D spending. It is an industry where the UK is objectively one of the world leaders, but our role is not secure. As Pfizer announces the closure of its UK R&D facility, the only one outside of the US, it is clear that our historic advantages will not be enough to sustain the UK’s position in the future. As pharmaceutical companies change their R&D strategies to a new, more outsourced model, and other countries improve their scientific infrastructure, we need to change to keep up. However, there is an opportunity to raise our game by building better connections between the assets we already have.

Many reports have examined this industry, but we believe that this is the first attempt to examine its competitiveness in terms of collaboration. The UK has significant assets in the NHS, research universities, large medical charities, pharmaceutical companies, and clusters of smaller companies. This report demonstrates that these assets deliver more by being better connected. Collaboration allows a better use of resources, avoiding duplication and improving access to specialist facilities and expertise. Most importantly, collaboration improves the capacity for innovation, which is critical at a time when the industry’s R&D productivity rates continue to fall and pharma increasingly looks to external partners for its drug discovery. This report primarily examines academic-industry collaborations, but also looks at the connections to smaller companies, clinicians and charities.

This report presents new data on the impact of collaborative working, showing that biomedical academic papers that are co-published with industry have greater citation impact than purely academic papers. This finding held true across all the countries we examined.

The UK starts in a very strong position: the relative citation impact of UK biomedical research is high, around 1.5 times world average in the academic sector and twice world average in the corporate sector. More research is conducted jointly with industry than in any other country except Finland. Academic collaboration with the corporate sector represents about 6 per cent of academic sector output. This compares with just 3 per cent in Germany and Japan.

Industry currently funds around 10 per cent of biomedical research in UK universities. If all universities were to achieve 15 per cent of industry income, this would mean an increase in industry funding for universities of 60 per cent, an increase of more than £100 million. This figure would represent just 8.4 per cent of extramural R&D spend by pharma companies, the same level spent in 2002.

However, although the UK performs well on this bibliometric output, the share has been static where other countries have grown their share of academic-industry papers more rapidly – Germany has seen 35 per cent growth over ten years, compared to 14 per cent in the UK. Moreover, industry’s contribution has been falling as a share of their external research funding. There is a danger that the UK will remain static while other countries grow and overtake us as a competitive destination for research and investment. The potential is clear – the university sector alone could increase

industry income by 60 per cent if it raised performance levels across all institutions.

Although the UK has maintained its share of approved trials within Europe, those trials fail to recruit patients all too frequently. New data presented in this report shows that the result is a declining global share of patients enrolled in clinical trials. The UK now enrolls less than 2 per cent of global patients in phase II trials, precisely the early stage of research where we should excel. The UK risks acquiring a reputation as a place where it is not worth attempting to run a clinical trial, with consequent impacts on research investment and on opportunities for healthcare.

Successful collaboration cannot be mandated. But it is possible to create the right infrastructure, develop skilled people and introduce the best processes to enable it to happen. The following measures can encourage collaboration in the UK system:

Infrastructure

• The UK should accelerate the development of electronic patient records to support medical research, and aim to become the world leader. These records have been successfully introduced in Scotland, and provide a valuable research resource. A revised approach where smaller systems are implemented for a local or disease-specific group can be an effective way to introduce records, while still being useful to researchers. The current pilot in NHS Ayrshire & Arran demonstrates one possible model for this approach. Greater public awareness is also needed, building upon existing support for the principle of using electronic records to support health research.

• Funders and public institutions should prioritise opportunities to share resources and services. By reducing running costs through greater sharing of labs, imaging centres, data and test results, and expertise, there could be significant savings that would allow more resources to be devoted to biomedical research. Such co-operation will also encourage greater collaboration. Funders can support this change in behaviour in their funding policies and assessment criteria. A group of major funders has recently set out their requirements to increase access to public health research data generated by work they fund.

• To support shared resources, the VAT system should be reformed to encourage rather than prevent research collaboration. Universities and charities must use their buildings at least 95 per cent of the time for non-business charitable purposes to retain a zero VAT rate on new buildings. Given the apparent importance of business collaboration to developing high quality research, this rule seems inappropriate, discouraging partnerships with industry, and with other charities, even on early-stage research. The consultation of the VAT rules relating to shared services, promised by the Chancellor in the June 2010 budget, should be completed urgently.

• Funders and career structures should increase their focus on research support services to expand the capacity of researchers. Greater development of specialised areas of research support can free up researchers or clinicians to focus on their specialism. This can also provide industry with access to the right researchers for a particular project.

People

• Industry needs to increase the number of industry placements and secondments. Undergraduate placements, training schemes and secondments to industry help to build contacts and introduce researchers to the realities of industry today. However, placements are declining, reducing opportunities to develop collaborative links between universities and companies. Knowledge Transfer Partnerships allow smaller companies to work with university researchers, and could be better used in this sector; the Wellcome Trust Translation Medicine and Therapeutics scheme provides a good model for involving larger companies in training. Industry can provide more opportunities, and public and private sector employers can place more value on this type of experience.

• Industry hiring and promotion criteria should take greater account of cross-sector experience. Those who work in both industry and universities are better placed to identify opportunities for collaboration. Few are able to move from industry into academia, and those who move in the other direction often lose their university perspective. Public sector employers in the sector should consider industry experience in
hiring criteria, and greater use of sabbaticals and secondments. Funders and research assessments also need to recognise relevant industry experience in awarding funding, or universities will not follow suit.

- **Recognise the importance of co-located facilities.** Locating industry, charities and universities close to each other in clusters could bring real benefits in shared knowledge and discourse that can be invaluable in sparking new ideas. Such clusters could also facilitate easy movement between sectors without having to move home. The success of a cluster depends on having a mixture of different organisations located together – both public and private – as well as an environment that encourages open discussions of work.

- **Create organisational structures that support applied work and collaboration.** Organising research around problems rather than disciplines can help academic departments to engage with industry. Providing simple entry points for small pharma companies engaging with universities could increase the degree of co-operation with these firms. Having people dedicated to seeking out opportunities to solve problems through collaboration can provide much-needed momentum, as it does at MIMIT in Manchester.

**Process**

- **Introduce common standards for researchers in industry and universities to make collaboration easier.** There are different approaches within commercial and academic laboratories, which can make translating academic results into a commercial context difficult or impossible. Common standards and expectations could make collaboration easier.

- **Government research funding should be reformed to remove penalties for collaborative research.** It’s easier to get research council funding for an academic project than an industry collaboration project. Current funding allocations tend to favour blue-sky proposals over applied work, and despite some planned changes to the Research Excellence Framework, this is reflected in the excellence criteria used to judge good research departments. Those academics who build collaborative links should be recognised for this. Funders should prioritise the development of appropriate collaboration metrics. It should also be possible to fund research done in collaboration with companies in certain circumstances.

- **University intellectual property policies should be more consistent to enable successful collaborations.** Universities too often overvalue intellectual property. They sometimes make it too hard to establish collaborations, as IP negotiations are disproportionate to the size of the research project. There should be much greater consistency and alignment between universities and the NHS across the UK on IP agreements, based on an objective of developing the research further rather than income. Academic Health Science Centres could provide a useful lead on this matter.

- **The NHS and universities should factor in the full benefits of industry co-operation into its pricing policies so that collaboration is not deterred.** Universities factor in Full Economic Costs to assess what they charge industry for research work. Universities should share more of the risk and the reward of shared work, and should factor in benefits gained by working with industry into their pricing. Otherwise they are pricing themselves out of the international market. Universities that wish to charge commercial rates for work should also be able to deliver high standards of project management.

**Conclusion**

The diversity of perspectives and organisational systems is vital to innovation – if everyone worked in the same way, these collaborations would be much less valuable. But the barriers of mindset and incentives can be modified to embrace collaboration. The speed with which we develop new cures, drugs and approaches to patient care is dependent on the extent to which we allow biomedical innovations and trials to take place.

The pharmaceutical industry is undergoing a seismic shift, transitioning from large internal R&D facilities to more external collaborations and partnerships. Recognising the importance of collaboration to the industry and to innovation will mean changing the funding, incentives and career structures of the UK biomedical sector.
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Part 1: Introduction

1.1 Biomedical research is an important UK industry investing heavily in R&D

The biomedical science sector is a rapidly growing sector, and a source of economic growth for the UK, employing 143,000 people and generating over £30 billion in turnover.2 Encompassing pharmaceuticals, medical technology and medical biotechnology, it is a high-tech and highly innovative sector, closely linked to the research excellence of UK universities.

UK pharmaceutical industry R&D expenditure is third in the world after the US and Japan3 – £4.4 billion in 2009.4 Biomedical science also represents a sector that is economically important for the UK with more than 9 per cent of UK exports worth £21 billion and 28 per cent of all UK business Research and Development (R&D) spending.5

An ageing Western population and increasing access to healthcare in the BRIC countries positions this industry as one that is likely to grow strongly in the 21st century. Many other countries have recognised this and invested in their research capabilities. There is a growing awareness that the UK is vulnerable to competition, and that we cannot be complacent about our position. Between 1990 and 2008, R&D investment in the United States grew 5.6 times, whilst in Europe it only grew 3.5 times.6 Singapore has invested over £6.25 billion to develop the biomedical sciences sector since 1996,7 and is preparing to invest a further £7.5 billion between 2011 and 2015. Other countries have used recent economic stimulus spending to support the biomedical industry – the US National Institutes of Health receiving an additional $10.4 billion (£7 billion) over two years, and France’s ‘Grand Emprunt’ (big loan) injecting €22 billion (£20 billion) into research labs and universities. These investments come at a time when UK biomedical research budgets have been maintained in real terms, but not increased.

1.2 This is an industry dependent on high quality research

Pharmaceutical companies say that research excellence is their main driver for locating research and trials in the UK. These companies look for the best researchers, and the most interesting and relevant work; that is what they find in the UK. They also invest heavily in R&D themselves: six of the top 25 R&D investors in the UK are pharma or biotech companies.8 However, pharma companies also acknowledge that their R&D model is changing. GlaxoSmithKline now does 50 per cent of its drug discovery externally. The vulnerability of this position has been made clear as three UK R&D facilities have been closed by pharmaceutical companies since 2010, including Pfizer’s recent announcement of 2,400 job losses in Sandwich. That figure is equivalent to two-thirds of staff at the MRC. These closures and job losses at GlaxoSmithKline’s Harlow plant mean the loss of up to 4,100 jobs.

The relative citation impact of UK research can be measured using international citations. The impact and importance of UK research can be seen from the following examples:

- The relative citation impact of UK biomedical research is high, at 1.5 times the world average for academic research, and twice the average for industry publications. This is greater than the impact of US research in this field which is 1.37 and 1.68 respectively.

- The impact and importance of UK research can be measured using international citations.
The UK has a strong reputation for world-leading science in the field of oncology (cancer research). UK spending on cancer research is estimated at €13.18 per capita, compared to €17.61 in the US, and well above the European average of €3.42. In part, this reputation is built on the unusually strong links formed between academics and clinicians in the UK cancer research community, supported by 20 years of relationship development. This expertise is critically dependent on strong relationships between funding bodies, researchers, clinicians and industry funders, such as the collaboration between cancer research funders and industry through the National Cancer Research Institute (NCRI). The NCRI was the first national umbrella organisation to bring together government, charity and industry funders. The National Cancer Research Network served as a model for the National Clinical research networks that followed.

1.3 We underuse the resources we have

The UK has a number of characteristics that give us this international advantage. These include: our world-leading universities; an established cohort of clinical academics, who pursue a clinical career as well as doing research; and a large and diverse population, with a good standard of medical care, making the UK a suitable site for clinical trials; and a diverse system of public research funding through the National Institute of Health Research within the NHS, and the Research Councils.

However, there are significant assets that differentiate the UK, and which could be better exploited to support the industry. At a time when the industry is moving to a new model of research, with much greater use of external partners, the system also needs to adapt to new ways of working. We don’t yet have a joined-up system to do this. It took a long time to build the relationships and networks that make the oncology research system work well, so the difficulty of this task shouldn’t be underestimated. These underexploited research assets include:

- The NHS
- Research excellence within universities and research institutes
- Large medical charities
- Large pharmaceutical companies
- Communities of smaller companies

The NHS

The interaction between the biomedical industry and the NHS should be a productive one for both parties. However the NHS is often perceived as a reluctant partner in healthcare.

Box 1: Developing specialist centres with a disease focus – Cancer Research UK Centres

Cancer Research UK has established a national network of cancer research centres in a major strategic initiative. Cancer Research UK Centres are partnerships working on a local level with universities, NHS Trusts, cancer networks and other charities, and on a national level with government and industry.

The Manchester Cancer Research Centre (MCRC) is a multi-million pound partnership founded by The University of Manchester (which includes the Paterson Institute for Cancer Research), The Christie NHS Foundation Trust and Cancer Research UK. The MCRC is a world-class centre of excellence for research, with ambitions to more than double the level of cancer research activity in Manchester by 2015.

Additional partners, including industry, have been attracted to the concentration of expertise and infrastructure in Manchester that is enabling cancer research to flourish. Extensive collaboration with industry involves many different pharmaceutical and bioscience companies. AstraZeneca has a long-standing and successful strategic partnership with Manchester, providing significant investment against areas of mutual scientific interest. Areas of interest include biomarker identification and validation, biobanking, imaging, radiation combinations and clinical research training.

research. Research is seen as a peripheral activity in most parts of the health service, approvals for clinical trials are slow to obtain and little thought is given to the research services and resources the NHS could offer.

The system is moving in the right direction. A considerable investment in new research infrastructure has been made since the ‘Best Research for Best Health’ report in 2006 and the creation of the National Institute for Health Research (NIHR).11 This recognises the importance of health research to both the economy and the nation’s health. Investment has been put into research centres and facilities, new clinical academic career paths and reforms to make it easier for researchers to gain permission to work with NHS patients.

This commitment has been maintained by the coalition government, who have preserved NIHR and MRC budgets, amidst cuts in other research areas.

The change goes beyond the NHS Trusts and large research universities. All Trusts are now required to report the number of patients recruited into clinical trials in their quality accounts, putting the issue on the desk of every Trust Chief Executive.12 What effect this will have remains to be seen.

Research excellence within universities and research institutes

The UK has an international reputation for research excellence – the key driver of industry when seeking out research partners. The UK has four universities in the global top ten for Clinical, Pre-clinical and Health research13 and is second in the world in its output of clinical and health-related research papers and citations.14 Half of the MRC’s spending goes to its research institutes, such as the internationally recognised Laboratory of Molecular Biology in Cambridge.

Clinical academics are an important part of the UK research system. They make up between 5 and 10 per cent of the UK medical workforce.15 Most are employed by a university, contributing to undergraduate teaching and curriculum, post-graduate medical training, and practising medicine for around half the week. The UK has around 3,000 clinical academics, a figure that has been increasing since 2006.

Connecting the worlds of research science and clinical practice is critical for innovation. Biomedical innovation is not a linear process, with basic science being refined through trials until it reaches clinical practice. Rather, it relies on a range of feedback loops to ensure that research is connected to clinical need and patient experience. Clinical academics can provide this feedback.

Bridges between research and clinical practice can also be built at the institutional level. In 2008, five Academic Health Science Centres (AHSCs) were created in the UK, to bring together leading research universities with NHS Trusts. These have been modelled on examples of similar institutions in the United States as institutions to integrate research, education, and clinical hospital practice.

Large medical charities

The UK is a major location for charitable investment in biomedical research. Charities contribute approximately one third of all public expenditure on medical research in the UK, over £1 billion in 2009/10.

Clinical Medicine research in universities is even more reliant on charities – it is funded 46 per cent by charities, 41 per cent by government or research councils, and 9 per cent by industry. Charities provided £834 million of university research funding in 2008/09.16

The Wellcome Trust is an international exemplar for charitable funding of basic research. With a science budget of around £590 million in 2008/09, it has huge influence on the sector, and often leads the way in new models of supporting research. There are many other large medical charities in the UK, such as Cancer Research UK, The British Heart Foundation and Arthritis Research UK, who have a combined research budget of over £400 million.17 They provide important perspectives on the prioritisation of research for patient benefit, but can also connect research to patient groups more directly, involving them with trial design and implementation. This strength is recognised by the UK public who are more generous in their donations to medical research charities than people in most other countries. Seventy per cent of the UK public say they have donated money to medical research campaigns, a figure that is second in Europe, and well above the EU27 average of 39 per cent.18

Research by the Office for Health Economics describes the complementary role that public and charitable research funding has in stimulating private sector R&D investment. The report states: “A £1 increase in UK government or charity spending on medical research could
lead to an increase in private research spending from the pharmaceutical industry of between £2.20 and £5.10."\(^{19}\)

### Large pharmaceutical companies

Two of the top ten pharmaceutical companies by market capitalisation are based in the UK – GlaxoSmithKline and AstraZeneca. The pharma industry is unusual among high-tech industries in having large active companies based in the UK. The electronics industry frequently complains about a shortage of large companies to invest in acquisitions, training and development. It also means that when smaller companies are acquired, there is a good chance that they can remain in the UK. However, historically, UK stock markets have been a less favourable exit route for small biotechnology companies, affecting venture funding for these companies at the early stages. The UK also attracts large amounts of inward investment in pharmaceutical R&D, £1.6 billion in 2009. Unfortunately, the vulnerability of this investment has been underlined by Pfizer’s decision to close its Sandwich site, its only R&D facility outside the US. This and other R&D site closures have underlined the global nature of these companies and the mobility of their research activities. A UK headquarters is not enough to guarantee UK R&D activity for these companies, who must compare the UK with universities, workforces, tax regimes and health institutions worldwide. Moreover, large R&D facilities are less relevant to the new model for pharmaceutical R&D. The last thing we need is a ‘big pile of bricks with air-conditioning’.”\(^{20}\)

### Small company communities

In addition to the large pharmaceutical companies, there is a strong community of smaller companies in the UK, those developing pharmaceutical compounds, as well as biotechnology companies and those developing devices and diagnostic technologies. A 2009 report\(^{21}\) highlighted the importance of the wider community of biotechnology and medical technology companies. These companies are almost all SMEs, have a combined turnover of £14.8 billion compared to pharmaceutical companies’ turnover of £15.6 billion per year, and employ over 75,000 people. As pharmaceutical companies increasingly look to external sources for new ideas and technologies, a healthy small company community is important for the health of the sector.

### 1.4 Collaboration mechanisms can improve the industry

The question of how the NHS works with the pharmaceutical industry has been addressed by a number of reports in recent years, including those by Sir David Cooksey,\(^{22}\) the Office for Life Sciences,\(^{23}\) the Academy of Medical Sciences,\(^{24}\) the National Institute for Health Research\(^{25}\) and the Royal College of Physicians.\(^{26}\) Recommendations emerging from these reports can be grouped into a number of high-level themes:

- **Institutions**: Recommendations around the budgets and goals of key ‘vehicles for change’ such as NIHR, UK Clinical Research Collaboration (UKCRC), the Office for Strategic Coordination of Health Research (OSCHR), the Medical Research Council and the Super Cluster.
- **Regulation**: changes in the regulation of clinical trials and pricing regulation.
- **Funding**: improving access to funding for biotech and Pharma companies; preserving public funding for areas of need.
- **Skills**: ensure the supply of skilled individuals, and make it easier for doctors and other healthcare professionals to acquire research skills.
- **Collaborative mechanisms**: fora, incentives and metrics that promote interactions between the various players.

While the other four areas are important, this report seeks to examine the potential of collaborative mechanisms for improving the UK’s biomedical industry. We aim to provide practical recommendations on how collaboration can be encouraged, as a cost-effective way to make the most of our biomedical science assets.

The 2010 Academy of Medical Sciences ‘Reaping the Rewards’ report\(^{27}\) highlighted the need to:

- Encourage alliances between the NHS, universities and industry to share the risk and reward associated with generating more cost-effective and novel therapeutics, diagnostics and devices.


Similarly, the Royal College of Physicians\textsuperscript{28} recommended that they would:

- Work with the DH [Department of Health] to devise incentives for NHS bodies and doctors to take part in research.

These are valuable goals. We aim to show how these goals can be achieved through specific incentives and by removing or mitigating blockages to such alliances.

1.5 Motivations for change

This report comes at a critical time for the industry. All parts of the system must change the way they work to survive in the future. Public budgets are being squeezed in both healthcare and research. At the same time, an ageing population will increase demand for healthcare as the latest research equipment and healthcare treatments become more specialised and more expensive.

Pharma has seen a decline in research productivity in recent years – it costs more and more to get a drug to launch, as the number of potential compounds falling at each trial stage increases. New compounds must also prove they exceed the performance of existing therapies, as many diseases already have licensed treatments which would be displaced by new ones. This reflects a more competitive marketplace and more stringent regulatory requirements. To improve productivity, pharma companies are now sourcing ideas and research capacity from external sources, often reducing in-house R&D capacity as a result. Patrick Vallance of GlaxoSmithKline says that they now do 50 per cent of their drug discovery externally – a significant change from just a few years ago. This pool of outsourced R&D presents a significant growth opportunity both for universities and small companies in the UK.

The UK biomedical research system

Figure 1 is not intended to be a comprehensive view of the entire UK system, but rather an indicator of the key elements. Funding bodies...
Box 2: Structure of the UK biomedical system and some terminology

There is a defined series of development stages involved in drug development. Although it is not a purely linear process, there is a series of stages associated with approval milestones that will be referred to in this report.

Basic biological research leads to applied research, done on human cells or cultures with a clinical need or disease target in mind. Translational or experimental medicine are terms applied to the boundary between research and clinical application. This often takes the form of very early experiments on patients, often to establish a ‘biomarker’ or indicator that the treatment is operating in the expected way.

Clinical trials are numbered from I to IV, with phase I first-in-human trials usually done on healthy volunteers. Experimental medicine experiments on patients, using micro doses of the treatments, may be termed phase 0. Phase II seeks to establish the effective dose (phase IIa) and measure efficacy (phase IIb), so are conducted on small groups of patients.

Phase III trials are large-scale patient trials to assess efficacy with as much certainty as possible. Phase IV trials are post-approval and provide surveillance of usage, looking for long-term effects and rare side effects or interactions.

are arranged at the top of the diagram, with research and clinical practice arrayed lower down. Some bodies span both areas – medical schools being an example of an institution conducting research as well as clinical practice.

The figures indicate some of the funding flows referred to later in the report. These figures are based on 2008/09 figures for consistency.

For more detail on some of the acronyms in this report, see the Acronym Soup appendix on page 44.
Part 2: How much improvement could we see in UK collaboration?

In this chapter, we set out to quantify the UK’s current performance in biomedical collaboration, and compare it with other countries. Existing data on collaboration is limited, so the conclusions below are necessarily incomplete; we hope that future research will improve the available data. We have also examined the ‘size of the prize’ – the potential opportunity for the UK that could be unlocked. Later chapters examine ways to access this opportunity.

2.1 About the data

We have worked with Thomson Reuters and the Higher Education Statistics Agency (HESA) to compile data on the UK’s biomedical collaboration performance. The countries we profile include the largest pharma players as well as smaller nations such as Singapore and Finland that are growing in importance. Figures throughout this report can be accessed along with the underlying data at http://www.nesta.org.uk

Box 3: Definition of biomedical research

For data sourced from Thomson Reuters (Scientific) Inc., the journal categories representing biomedical research were agreed after consultation with NESTA and include all those in the following Thomson Reuters Essential Science Indicators research fields. These research fields encompass 71 journal categories from the 251 used in the Web of Science classification scheme:

- Biology & Biochemistry
- Clinical Medicine
- Immunology
- Microbiology
- Molecular Biology & Genetics
- Neuroscience & Behaviour
- Pharmacology & Toxicology

For the Higher Education data, subject areas were selected for analysis from the categories used for university financial returns to HEFCE:

- Anatomy & Physiology
- Biosciences
- Clinical Dentistry
- Clinical Medicine
- Pharmacy & Pharmacology
- Veterinary Science
Figure 2 illustrates the output volume, citation impact and growth in output of biomedical papers for the countries within our analysis. The US obviously dominates publication volumes. The UK, Germany and Japan come next with broadly similar levels of output, but with very different levels of citation impact from the work. Growth in the number of publications is broadly similar for the US, UK and Germany, with Canada and Singapore growing faster, and Finland and Japan showing slower growth. The chart illustrates the point that the UK is a significant source of biomedical research, producing highly cited work, but with growth slower than countries like Canada, Germany and the US, that position is vulnerable.

2.2 Benefits of collaboration

Before looking at the status and the future opportunities for the industry, we need to examine why collaboration is important, and the benefits that might be expected from increasing it.

Collaboration produces more advanced innovations

Innovation is brought about by the recombination of knowledge and resources from different parts of the system. Connected systems, where this knowledge flows to where it can be applied, trump disconnected systems. We know that firms that introduce ‘new to market’ innovations are more likely to co-operate with external partners for innovation than those who introduce more incremental ‘new to firm’ products or services. Those who introduce these more advanced forms of innovation are twice as likely to use universities as innovation partners, in addition to suppliers and customers, compared to those pursuing incremental innovations.

New and advanced technologies require many types of expertise, which are hard to assemble in one firm or organisation, so external partnerships are necessary to bring in the range of knowledge needed for a ‘new to market’ innovation. Innovation results from the “clash between different modes of behaviour and habits of thought”.

Collaborative research has greater impact

A new analysis of UK biomedical publications shows that our impact in biomedical sciences is high relative to other countries, and that collaborative papers have a greater citation impact than purely academic papers.
Science has some well-established metrics for quality of research, often focusing on how frequently a paper is cited by other authors. This is not a perfect measure of a work’s importance, but it is widely used by funding bodies and research institutions.

To review whether collaborations between academic and industry researchers are more impactful than when working alone, we examined the citation impact of all biomedical papers published in these three groups. Citation rates vary between research fields and with time, consequently, analyses must take both field and year into account. In addition, the type of publication will influence the citation count. For this reason, only citation counts from reviews and articles are used in calculations of citation impact. The standard normalisation factor is the world average citations per paper for the year and journal category in which the paper was published, which is rebased to 1. The citation impact in this analysis is the overall average for the ten-year period.

The evidence from this data is firstly, that UK citation impact in biomedical sciences is high relative to other countries, but papers with both academic and industry authors are even more impactful than either purely academic or purely industry-based publications. An analysis conducted by Pfizer of their co-published work confirms that the average impact of research co-published with European authors has risen above the average impact of research with North American co-authors (although the European volumes are smaller).

This analysis supports other work that has demonstrated a link between interdisciplinary and inter-institution collaboration and increased citation impact. It is not possible to completely rule out the influence of self-citation on these figures (where authors cite their own work in later papers), but equally there is no reason to suppose that the level of self-citation is greater in one part of the data (either by sector or by country) than in another. Other research investigating the impact of this effect has found it to be small,


Figure 3: Relative citation impact of biomedical papers across seven countries

![Figure 3](image_url)
and that it does not affect the conclusion that collaborative papers have greater impact.\textsuperscript{35} The consistent difference between sectors in different countries also reinforces this conclusion.

Although it is hard to measure the degree of genuine collaboration that lies behind these co-published papers, these data seem to refute any perception that research done with industry is of lower quality, damages academic status or can be considered as less serious. It also demonstrates that increased collaboration could benefit not only income levels but also the citation impact of research.

**Further benefits of collaboration: better use of resources, better insights**

Collaboration brings together those with complementary skills to produce more effective teams and greater insights. A study of academic organisational structures in the universities of Northern California describes how those with a problem-focused structure and many different disciplines in the same team were better at generating spin-out companies and industry links.\textsuperscript{36} These case studies suggest that university spinoff networks can provide valuable expertise back to universities, and industry links can highlight their current problems as areas for new research. Such links bring together basic and applied researchers; create connections to industry to ensure that research links to problems relevant to industry; and provide space for organisational experimentation and rewarding entrepreneurship.

Collaboration also allows researchers greater access to resources, whether those are proprietary compounds from pharma companies or imaging facilities for industry researchers.

**Measuring collaboration**

We have seen the advantages of collaboration. So how does the UK compare internationally? We use co-publication rates, research income and clinical trials as three metrics to assess this. Data on collaborative research and innovation is scarce, especially within sectors. A true collaboration requires elements of shared risk and reward, as well as parallel (rather than sequential) efforts by the collaborators. These are not factors generally measured in innovation surveys or financial accounts. The indicators for collaboration we have used attempt to provide a proxy for true collaboration rates, and are used because they can be compared internationally. These data are new and we think provide important new insights, however, for those reasons, the conclusions should be treated with some caution. We would welcome efforts by those in the sector to expand and improve upon metrics for collaboration.

2.3 Co-publication

Co-publication is simply the creation of a scientific paper with multiple authors, usually from different institutions. Academic-industry co-publication, where at least one author is from a university, and one from a corporation, is a metric of collaboration that allows international comparisons to be made easily, due to the availability of data on scientific publications. It also seems to be a good indicator of a genuine scientific collaboration, where the authors named are likely to have worked together.

We chose seven countries for this analysis, including the top four locations for business expenditure on pharmaceutical R\&D (US, Japan, UK and Germany), and smaller but growing locations of Singapore, Finland and Canada.

The UK’s publication of biomedical papers (see Box 3) makes up around 40 per cent of the national research base, a similar proportion to the US and Germany. The UK publishes 8.5 per cent of the world output, and all the countries we studied have grown their biomedical publication output in the past decade, the UK slightly less than Germany or the U.S.

Of the total UK academic output, 30 per cent are co-authored with external partners. Academics collaborate not only with industry, but also with other academics, and external organisations when doing research, and this is reflected in those with which they co-publish articles. Around 18 per cent of the academic output is published with a health organisation and 6 per cent with industry researchers. Roughly half of UK industry papers have an academic co-author.

**The UK has high rates of academic-industry collaboration, but other countries are improving**

The UK produces the greatest number of academic-corporate papers after the USA. The UK also has the highest proportion of academic-industry co-publication, relative to academic output, of the countries we looked


at: 6 per cent of all academic publications were co-authored with industry over ten years. This compares with just 3 per cent in Germany and Japan.

In all countries except Japan, the number of academic-corporate collaborative papers has increased over the period, Germany’s recent increase being particularly rapid.

The UK’s academic-industry co-publication rate, as a percentage of academic output, has remained fairly steady over the last ten years, while other countries have increased their rate towards the UK level. This is a common theme in the data – the UK does well, but as other countries invest and improve, our historic strengths are no guarantee of future success.

There is no reason to believe that 6 per cent is a ‘natural’ limit to this activity. As pharmaceutical companies continue to become more comfortable with publications, and as budgets are squeezed, there is scope to increase the share of biomedical work involving industry researchers even further.

2.4 University research income

The second source of data we have used is the research income received by universities, recorded on finance returns sent to the Higher Education Statistics Agency.

Sponsorship of university research by companies is just one form of academic-industry collaboration, but the availability of university finance data allows this measurement to be examined in some detail, at least in the UK. Universities and companies interact in many ways, including consultancy, contract research, licensing of intellectual property, provision of training, industry placements and collaborative research. Therefore, these figures will not represent the full extent of industry spending with higher education institutions, and in-kind industry contributions such as access to equipment or compounds are not included. It also excludes income from research institutions such as the MRC institutes.

UK universities received a total of £2 billion in research funding for biomedical disciplines in 2008-09. Most of this money came from charities and from government, via the research councils, central government spending and local authorities; 9.7 per cent, or £200 million was from UK and international companies.

Of the £200 million spent by industry on academic research funding, £129 million was from UK industry, and the remainder, around a third, from overseas sources. The majority of this was for funding in clinical medicine.
Figure 5: Co-publication trends over time

Source: Thomson Reuters (Scientific) Inc.

Figure 6: Sources of university biomedical research income

Source: Higher Education Statistics Agency (HESA)¹⁷

³⁷ It should be noted that a change in categorisation in 2007/08 allowed the contribution of EU and international companies to be captured for the first time. Before that date, this income is shown on the chart above as ‘Other’.
disciplines – £138 million (this is also the subject area that receives the majority of government research funding).

It is worth noting that UK industry income for university research has grown more slowly than other sources over the past ten years – 4 per cent per annum compared to 10 per cent growth in government funding, and 7 per cent by UK charities. Some have speculated that the impact of full economic cost pricing may be responsible. This costing model was introduced in 2006 to ensure that universities calculate the full costs of each piece of work, including overheads. It has sometimes meant that the full economic cost is then charged to commercial funders, making the UK a less competitive place for research, when compared to costs of equivalent work in Europe or the US (which may not incorporate full overheads into their pricing).

This metric can also be examined from the other side, as expenditure on R&D by industry. An international comparison shows that business enterprise expenditure on all forms of R&D in the pharmaceutical industry increased by 5.3 per cent per year between 2002 and 2006 in the UK, by 28.7 per cent in the US and 12.6 per cent in Germany. These rapid increases in pharma’s R&D spending, as well as government’s investment in biomedical research in the UK, mask some more worrying trends.

Industry-funded research has been falling relative to government and charity funding, although this could equally reflect a rapid increase in government funding in this area. The comprehensive spending review has largely maintained funding to the sector, through the science budget and the NIHR allocation from the Department of Health, although universities will have other funding cuts that may impact their ability or willingness to collaborate. However, university funding has also fallen as a share of industry spending on external R&D. Where industry once spent around 9 per cent of their external R&D budget with UK universities, they now spend closer to 5 per cent. This suggests that although industry is spending more on external R&D, they are looking less and less to UK universities as a research partner.

International comparisons of university income from industry
US universities do not collect data on income by subject area or department, so it is

![Figure 7: Industry funding for university research = £200 million](source: HESA)
impossible to produce a comparable breakdown of the respective contributions made by government, charities and industries for those institutions. We can, however, make some comparisons by looking at pharmaceutical company R&D spending with universities over a similar period.

While directly comparable data on US biomedical research income is not available, the data on pharmaceutical company spending in Table 1 suggests that the UK gains a greater proportion of university income than the US from industry. The UK average industry income of 14 per cent of total university research funding, compared to 9 per cent for the US institutions. Restricting the US dataset only to those institutions with at least 50 per cent of their invention disclosures in therapeutics (i.e. with a focus on biomedical) gives an average of 11 per cent.

While directly comparable data on US biomedical research income is not available, the data on pharmaceutical company spending in Table 1 suggests that the UK gains a greater proportion of university income than the US from industry. The UK average industry income of 14 per cent of total university research funding, compared to 9 per cent for the US institutions. Restricting the US dataset only to those institutions with at least 50 per cent of their invention disclosures in therapeutics (i.e. with a focus on biomedical) gives an average of 11 per cent.

Table 2 compares institutions, grouped by their total research income for the subject. For clinical medicine subjects, where the majority of industry spending goes, there is

Table 1: Pharmaceutical industry R&D funding, US and UK

<table>
<thead>
<tr>
<th></th>
<th>Pharma industry R&amp;D spend (BERD)</th>
<th>Extramural R&amp;D spend by pharma industry</th>
<th>Higher education income from pharma industry</th>
<th>Ratio of higher education spend to all extramural R&amp;D</th>
</tr>
</thead>
<tbody>
<tr>
<td>UK</td>
<td>$6.18 billion (OECD)</td>
<td>£2.48 billion (ONS)</td>
<td>£84 million$^a$ (HESA)</td>
<td>3.4%</td>
</tr>
<tr>
<td>US</td>
<td>$69.5 billion (NSF)</td>
<td>$17.1 billion (NSF)</td>
<td>$469 million (NSF)</td>
<td>2.8%</td>
</tr>
</tbody>
</table>

Source: OECD, NSF, ONS, HESA – for 2008/09
no obvious link between the ability of high-income institutions (those in the top quartile) to raise industry funding and those with lower incomes until you reach the lowest quartile. This relationship does not hold as true for biosciences, although the lower quartiles are dominated by institutions with very small research income levels, and where a few institutions have 100 per cent industry funding, presumably for a one-off project.

Finally, we have compared the proportion of research income that is industry-funded with the corresponding RAE assessment for that subject area (Figure 9).  

Figure 9 confirms that there is little correlation between research quality ratings and percentage of industry income. In other words, the ability to work with industry is independent of research quality or funding quantities, above a certain threshold. This implies that other factors play a greater role, and we can speculate that these might include the amount of outreach work the university does, or the organisational structure of the research departments, and that some universities have significant capacity for improvement. It is also possible that the balance of basic and applied research work is a determining factor, but we have not been able to examine that with the available data. By using just the clinical medicine subject area, we have attempted to minimise the influence of this factor on the analysis.

If all institutions that already receive some amount of industry funding for research were to reach the benchmark set by the better performing institutions of 15 per cent industry funding (from both UK and international sources), there would be an additional £118 million of research funding available to the academic community, an increase of 60 per cent over current levels, and a return to 2002 levels of industry funding, as a share of pharma’s external R&D spend. Additional income is by no means the most important benefit of collaborative research, and industry representatives are at pains to be regarded as research partners and not as simple funding sources, but the figure is illustrative of the potential for increased collaboration. This could provide significant resources at a time when government research funding, though protected in real terms, is unlikely to increase during the UK Government’s Spending Review period through to 2014-2015.

Learning from Scotland

Scotland represents an interesting case study for industry collaboration. In 2006 the

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**Table 2: UK universities – comparison by quartile of research income**

<table>
<thead>
<tr>
<th>Quartiles by total clinical medicine funding (n=39)</th>
<th>Average research income</th>
<th>Average percentage of industry funding</th>
<th>Average industry research funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Top quartile</td>
<td>238,915</td>
<td>10.3%</td>
<td>24,334</td>
</tr>
<tr>
<td>2nd quartile</td>
<td>83,357</td>
<td>9.1%</td>
<td>7,262</td>
</tr>
<tr>
<td>3rd quartile</td>
<td>28,264</td>
<td>12.3%</td>
<td>3,580</td>
</tr>
<tr>
<td>Bottom quartile</td>
<td>2,248</td>
<td>3.6%</td>
<td>119</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Quartiles by bioscience funding (n=99)</th>
<th>Average research income</th>
<th>Average percentage of industry funding</th>
<th>Average industry research funding</th>
</tr>
</thead>
<tbody>
<tr>
<td>Top quartile</td>
<td>48,224</td>
<td>5.5%</td>
<td>2,436</td>
</tr>
<tr>
<td>2nd quartile</td>
<td>9,334</td>
<td>10.0%</td>
<td>988</td>
</tr>
<tr>
<td>3rd quartile</td>
<td>1,566</td>
<td>14.5%</td>
<td>230</td>
</tr>
<tr>
<td>Bottom quartile</td>
<td>97</td>
<td>22.7%</td>
<td>30</td>
</tr>
</tbody>
</table>

**Source:** HESA

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39. Note: 4* rated research was calculated from the weighted average by staff numbers of 4* ratings across 5 Units of Assessment in the 2008 RAE: Cancer Studies, Cardiovascular Medicine, Other Hospital Based Clinical Subjects, Other Laboratory Based Clinical Subjects and Infection and Immunology. This was compared to the industry funding for Clinical Medicine subjects obtained from HESA.
Percentage of research that is 4* rated is a weighted average (by staff submitted) across the medical subjects of cancer studies, cardiovascular medicine, infection and immunology, other hospital based clinical subjects and other laboratory based clinical subjects. This is based on publicly available 2008 data from the Research Assessment Exercise.

Source: HESA, HEFCE (RAE)

Figure 9: Link between research quality ratings and industry income

Figure 10: English and Scottish industry income

Source: HESA
Translational Medicine Research Collaboration (TMRC) was formed between four Scottish universities, their corresponding NHS trusts and Wyeth, now merged with Pfizer. Through this agreement, £50 million was invested in research across the universities and hospitals, £33 million of this from Wyeth/Pfizer.

This investment has significantly increased Scottish university income from industry overall, as Figure 10 shows. Industry income increased by more than two and a half times in the first three years of the collaboration, compared to the previous three years, and total clinical medicine funding went up by 45 per cent. However, the original five-year TMRC agreement is due to expire next year, and Pfizer says: “this has prompted the founding partners to revisit the organisational structure for the collaboration to consider how to make it less complex and to more flexibly accommodate translational projects of varying scope and scale given the challenges to R&D investment for all companies, including big pharma.” Pfizer is not alone in indicating that it is likely to shrink its overall R&D spending in coming years.

The collaboration is one part of a Scottish drive to become more competitive in biomedical research, building on existing research excellence and the assets of the Scottish NHS structure. This wider initiative has encouraged Scottish universities across a range of subject areas to pool resources and work more collaboratively, driven in large part by the Scottish Funding Council. The collaboration continues to be successful, and has led to the creation of a broader partnership, the Scottish Academic Health Science Collaboration (SAHSC) which works with other companies. Funding from the TMRC has been allocated on project terms to the SAHSC, and this funding rewards collaboration. The creation of the SAHSC included the setup of the National Research Scotland Co-ordinating Centre (NRSCC), a single portal for multi-centre trial approval. NRSCC now turns around approval (from receipt of the full application pack) in under 20 working days.41 The challenge for Scotland now, as elsewhere in the UK, is patient recruitment (see Clinical trials below).

2.5 Clinical trials

Clinical trials conducted in the NHS require the involvement of both the sponsor of the research and the health service. In later stage trials in particular (phases IIb and III), this is likely to be a transactional relationship – one provides the protocol that the other follows. Earlier trials and translational medicine research are more likely to involve true collaboration. A 2008 report estimated that the pharmaceutical industry spent £1 - £2 billion per year on clinical development in the UK.42 This funding is not included in the university income data.

The approval processes required to start a trial are a frequent source of complaint by pharmaceutical companies and researchers. But an analysis of the number of clinical trials approved to go ahead suggests that the registration of trials in the UK is holding up despite these problems. The number of trials approved in the UK has increased (Figure 11) and its share of all global trials has also gone up. While some other countries are improving more rapidly, the UK seems to be holding its position, at least in relation to Europe.

The number of individual trial sites has declined a little, in the face of strong growth from places such as Germany. This is perhaps an indication that companies prefer to add UK sites as just one of many other options.

However, these data only tell us about trials approved, not whether they were completed or whether patients were successfully recruited. When examining patients enrolled in clinical trials, it is clear that the proportion of patients remains small, even for earlier phase II trials.

The report for the Ministerial Industry Strategy Group (MISG) on Commercial Clinical Research in 200843 highlighted that the UK had 6 per cent of patients enrolled into clinical trials worldwide in 2000, but by 2006, this figure had declined to 2 per cent. We have used the same data source44 to generate a more recent picture of patient enrolment in clinical trials (Figures 13 and 14).

The UK’s share of patient enrolment has declined over this four-year period from 2 per cent to 1.4 per cent for both phase II and phase III trials. This does not appear to be solely the result of increased trial volumes from cheaper locations such as India and China; Germany and Japan have both grown their share of patients in the most recent period. If the capacity and expertise for these trials erodes, it will be hard to recover the attention of global companies for the UK as a location for trials.

This data is obtained from a panel of subscribing companies, so it is possible that it does not represent the global picture. However, given the coverage of patient numbers, it
Figure 11: Clinical trials approved per year, as a percentage of global total

Source: Thomson Reuters (Scientific) Inc.

Figure 12: Clinical trial sites approved, as a percentage of global total

Source: Thomson Reuters (Scientific) Inc.
Figure 13: Share of global patients enrolled in phase II trials

Source: CMR International – a Thomson Reuters business

Figure 14: Share of global patients enrolled in phase III trials

Source: CMR International – a Thomson Reuters business
Figure 15: Recruitment performance of all closed commercial studies with NIHR Network support

Research that requires clinical subjects necessitates collaboration with hospitals and health centres. One indicator of the extent of such collaboration could be an analysis of levels of trial activity in each trust. However, NHS Trusts have not previously had to publish their industry income levels or trial activity. There is a new requirement introduced in 2010 for NHS Trusts to publish the number of patients recruited into clinical trials in their quality accounts. This will hopefully increase the attention that this form of collaboration receives.

2.6 How big is the opportunity?

If the collaborations between the pharmaceutical industry and universities and between pharma companies and start-up companies could be improved, this would have healthcare benefits as well as boosting both the private and public research sectors.

This improvement would come from two sources:

- Private sector company growth – improved return on investment, opportunities for small companies, greater research capacity.

- Public sector income – to universities, public research institutes and the NHS.

If all universities improved to the level of the top quartile, in terms of the percentage of research income from industry, a 60 per cent increase in industry funding could be available.

As the pharmaceutical industry continues to grow external R&D spend, there is huge potential for growth by small companies as well as universities. At current growth rates of almost 15 per cent per annum, by 2015, there could be an additional £3 billion in external R&D funding available.

NHS participation in trials

UK patients enrolled in phase II and III clinical trials, as a percentage of worldwide patients and in total figures, have fallen since 2004. If we recovered the UK share to 3 per cent for both phase II and III, this would represent approximately an additional 3,000 patients per year with access to trials. Kinapse estimated in 2008 that the pharmaceutical industry spent between £1 and £2 billion per year on clinical development in the UK. Comparing the rates of trial approval with the decline in patients indicates that there is vast scope for improvement here. Given the National Institute of Health Research budget of just under a billion, any change in this figure could make a material difference to research and trials funding in the UK.
Collaboration is both important and necessary for biomedical science. We have shown it can improve the impact of research. The size of the prize for the UK is big, and will affect not just research income, but the quality of treatment and opportunities for patients.

But those at the sharp end have identified some real barriers to such collaboration. The UKCRN Directors Forum held a meeting between representatives of the NHS, academics and industry in 2009\(^4\)9 where perceptions of working together were discussed.

Academics and NHS participants expressed their need for ‘true collaboration’ with industry; access to industry knowledge on clinical pharmacology, regulation and project management; and partnership rather than service provision. Industry’s concerns were for faster contracting and better delivery by academics, along with metrics to assess these; more accurate feasibility assessments; and access to knowledge and patients.

These issues aren’t just about money or intellectual property ownership, which are commonly cited as barriers to collaboration – they are frustrations of process, and of understanding each other’s priorities. Interventions which make it easier for those involved in the process of biomedical discovery to appreciate other perspectives should help to address these areas.

This chapter addresses the specific incentives that could address these concerns, successfully creating alliances between the NHS, universities, charities and industry at the levels of departments and individuals. It also looks at barriers that currently limit collaboration in these areas. These represent both specific areas for improvement and general principles of successful collaborations.

Successful collaboration cannot be mandated. It works best when created from the ground up, with willing participants; imposing them from above can be counter-productive. That said it is possible to create conditions that make it easier, encouraging the first conversations to take place. Mutual respect for other skills and expertise is critical. Relatively simple measures that improve understanding can help these peer relationships to be created.

The recommendations are divided into three areas: infrastructure, people and processes.

3.1 Create the right infrastructure

NHS research infrastructure has changed significantly in the last five years. The National Institute for Health Research (NIHR) was created in 2006, and has brought in more competitive funding structures and significant investment in new facilities such as Biomedical Research Units and Biomedical Research Centres based in research hospitals. Clinical Research Networks have also been established to co-ordinate access to the research infrastructure. Those in the industry seem united in supporting the direction in which NIHR has travelled.

However, the NIHR is the first to acknowledge that it needs to join up these pieces of infrastructure, to make better use of existing resources and make them more accessible to industry. It has established its Office for Clinical Research Infrastructure (NOCRI) to ensure coordination of NIHR-funded infrastructure.
and to provide a navigation and collaboration service for potential research customers including industry. There is also a vast investment that has been made by the research councils, major medical charities and by industry in UK research infrastructure. Linking these pieces up into a coherent system is much more challenging, but could make the system as a whole much more effective.

Beyond this major challenge, there are further steps that could improve the national research infrastructure.

Deploy electronic patient records to support research
The UK should exploit its potential to be a world-leader in the use of electronic patient records to support medical research. So far, research has been an afterthought in the design of English electronic patient records. This is missing a major opportunity to improve the competitiveness of England for research, and to encourage public participation and awareness. Scotland has made much more progress than England in this area (see Box 5).

Electronic medical records make aspects of the research process much easier and more accessible, and create new opportunities for innovation. Electronic patient records have become a highly political and controversial issue, at least in England and Wales. A recent review of public engagement by the New Economics Foundation50 shows that the public want to be better informed about the system and its potential benefits. The huge cost of the National Programme for IT (NPfIT), along with uncertainty about which data would be stored, has made many people wary, if not actively hostile, to the idea. However, the research opportunities represented by a national records system are significant, and the public are generally supportive of other efforts to improve care through research. For example, the UK Biobank has now recorded data and clinical samples for half a million volunteers, as a data resource for long-term research.

By restricting the Summary Care Record to a very minimal set of information, reinforcing the right to opt-out and requiring opt-in before additional information is stored, the current government hopes to draw a line under the controversy. These changes are likely to make the records less useful for research. Nevertheless, it will be important to inform patients of the possible research benefits, and provide simple ways for them to allow their data to be used for research. In the New Economic Foundation research, 74 per cent of adults supported the use of electronic patient records for research purposes, although a majority also believed that specific consent should be given.51

An electronics records system can contribute to research and patient care, both in improving recruitment for clinical trials, and as a research tool in its own right. When designing a clinical trial, especially an early-stage trial, a researcher will have a target number of recruits to ensure that the results are statistically valid. If these patients cannot be recruited in the time needed, the whole trial will become an expensive failure. Knowing which patients with the right profile are available in a certain area is crucial to designing the trial and choosing where to run it.

Box 4: Electronic medical records as a research resource – the Mayo Clinic

A group of researchers from the Mayo Clinic used the electronic medical records accumulated by the clinic to conduct an association study on those diagnosed with peripheral arterial disease. The authors observed that the data provided them with “a scalable solution for clinical research, providing comparable and consistent data that can be employed in comparative effectiveness studies, outcomes research or translational research”. With patient consent, the health records were used to confirm cases of the disease, in this case Peripheral Arterial Disease, and extracted demographic data and laboratory values. Information such as smoking status was derived from natural language processing of the clinical notes. These approaches simplified logistics, costs and timelines relative to more traditional genomic studies.52
With a large record set and detailed data, genetic association studies can be performed, comparing links between symptoms, treatments and genetic results, just by analysing the records (see Box 4).

The UK could lead the world in electronic patient records. As a country with cradle-to-grave NHS care, simply recording all of a patient’s interactions with the NHS effectively provides a complete medical history. One of the main requirements for a successful national records system, a unique patient identifier, already exists as the NHS number – although it is not widely used, so at this stage cannot be effectively used to connect multiple episodes of treatment without the paper records being sent back to the GP.

In contrast, other countries face significant difficulties in implementing electronic patient records. The US does not have a national patient identifier, which hinders the use of electronic data for research.53 Some private hospital groups such as the Mayo Clinic and Kaiser Permanente have implemented electronic records very successfully, but the systems are not necessarily interoperable. A survey in 2009 found that only 17 per cent of US physicians were using either a basic or comprehensive electronic records system.54 The closest the US has come is the Veterans’ healthcare system, which uses a widely praised electronic records system called VistA. The system provides electronic records, and order entry for the US Veterans Health Administration’s eight million patients across 153 hospitals and many more clinics.55 The open-source software has been credited with some of the dramatic improvements in healthcare quality at the VHA at a time when costs have been kept down. The software has been adopted by many other institutions across the world.

In the international market for trials, this is an area where the UK could show a real competitive advantage. A few countries have successfully implemented a national system, among them Denmark, Finland and Sweden, but they do not have the genetic diversity of the UK, or the same breadth of university research which makes the UK such an attractive location for clinical trials.

### Box 5: Electronic patient records in Scotland

Scotland has an electronic patient records system, where everyone registering with a GP is given a unique number that is used in one system to link clinical records from GPs, outpatient appointments and other interactions. In practice, records are not yet fully electronic, with some paper records still in use, but also using the patient number. However, in certain areas, coverage is excellent – for instance, Dundee has led the way with its diabetes population. This makes that group an attractive population for research, and potentially gives access to clinical trials that they may not have otherwise been able to participate in.

The Scottish Diabetes Research Network (SDRN) was commissioned in 2006 by the Chief Scientist Office (CSO) of the Scottish Government to improve the quality and increase the quantity of diabetes research in Scotland. The network has developed a National Research Register for patients wishing to take part in research. With pre-obtained consent to contact patients about research studies, it is hoped that this will make recruiting for research more focused and easier to conduct.

The Scottish system does not allow companies to access the patient records data directly. Dundee has a good health informatics centre which can extract information out of the NHS systems, and package it in an anonymous way for researchers to work on. NHR Ayrshire & Arran is piloting a Patient Portal for diabetes and COPD patients to access and update their own records electronically.

“The biggest value of this service for the pharmaceutical companies that use it is in being able to link the results of tests on clinical samples to other characteristics of the patient cohort. In a system where basic patient information is not linked to test results, this form of analysis is not possible.” Pfizer Scotland
It is not necessary for a single system to be put in place in one go for this to be useful. It could be introduced gradually so long as common standards are used for identifiers, information exchange and regulation. Scotland is already using a single patient identifier and electronic records successfully (see Box 5).

**Share resources and services between institutions**

Funders and public institutions should prioritise opportunities to share resources and services. Sharing resources can save money by cutting costs or spreading them over time, and reducing duplication. Universities are more used to competing with each other for funding than collaborating with each other. Such competition can raise standards, but can also lead to duplication of effort and costs, and sub-scale resources. These savings will become increasingly important in enabling more research, and the behaviour of universities and funders will need to change.

Better shared access to resources can also affect the science. A recent study showed that the number of papers linked to 108 cell lines increased by more than 50 per cent when they were transferred to biological resource centres that made them easier to access.56

Biomedical science is an expensive enterprise. Unlike a web start-up, each enterprise has a high degree of technical risk as well as a long development timeline that includes extensive safety testing. Producing the right molecule or protein, and proving it efficacious and safe, involves a lot of trial and error. Running costs are also greater: an office in a business centre isn’t enough for a bioscience start-up – the equipment to kit out a company is expensive and improving rapidly. And before tests can start, there is often a long period required to grow cells, generate compounds and reagents, followed by time to develop indicators to discover if the treatment has been effective.

All these contribute to high risk in bioscience investment, and this has led to a fall in venture funding, as investors move to industries that are ‘safer’ bets. This is not just a problem for small companies, although it is most acute there: as pharmaceutical productivity has declined,57 large corporations as well as university departments face squeezes to research funding, and are looking for more efficient ways to operate.

One way to lower costs is to share services to make better use of them. This is true of equipment such as imaging centres; laboratory services; data and test results; and expertise (see Box 6).

Universities have not only bioscience facilities, but also chemistry and physics departments with equipment which can be made available more widely, with benefits to the company by expanding their range of partners, and the sources for their pipeline (see Box 7).

The NHS is generally not good at thinking of itself in terms of the resources and services it could offer to companies. Although the NHS has vast resources and expertise that could be used for research, this is often seen as a

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58. See http://cic.gsk.co.uk/
separate activity, or something done under contract when a request is made, rather than something to be sought out. There are exceptions – Academic Health Science Centres in particular have built links between hospital trusts and research universities to bring research up the priority list. But there is significant opportunity for more collaboration here, without damaging patient care.

Data can also be shared in a model of ‘open innovation’ or ‘open science’. Patents already provide a way of sharing data, so that, for example, universities can reproduce compounds for research purposes from the patent descriptions. Open innovation is leading to greater sharing, but principally in areas such as infectious disease, where Third World markets are the target, and for pre-competitive information such as verification data and biomarkers (see Box 8).

A recent joint statement by some of the largest bioscience funding bodies sets out a vision “to increase the availability to the scientific community of the research data we fund that is collected from populations for the purpose of health research, and to promote the efficient use of those data to accelerate improvements in public health”.


Box 7: Open access to testing services - Lilly Phenotypic Drug Discovery initiative

In an example of sharing corporate services with external partners, Lilly is offering to test compounds for free under their PD-squared initiative. Researchers submit electronic structure descriptions; those that pass are invited to submit a sample for screening against an assay. The IP of the submitted structures remains with the researcher. If it is of interest, Lilly has the rights to negotiate a deal. If the talks break down, IP and the testing data are retained by the owner. Despite the potential of this, there remains a perception that the motives for these offers may be opaque, and a fear of being taking advantage of by a corporate giant. The imbalance of risk and resources between large and small organisations is a frequent problem faced in collaborations.

Box 8: Sharing research data as it is created - Alzheimer’s Disease Neuroimaging (ADNI) project

The ADNI project practises open science by asking researchers to share their data as soon as it is generated, rather than waiting for publication. Funded by the National Institutes of Health in the US, the project focuses on establishing biomarkers to indicate Alzheimer’s progression from neuroimaging and other testing. The aim of identifying these biomarkers is to find suitable surrogate endpoints that can be used when testing new treatments. As Alzheimer’s typically has a slow, degenerative development, testing potential treatments by monitoring symptoms is problematic. Finding new indicators could allow the disease to be identified earlier, and for the disease progression to be tracked more accurately.

The researchers across the US are creating a public domain resource, combining images, clinical data, biological samples and neuropsychological data. Public and charitable funders, the Federal Drug Administration, pharmaceutical companies and academics are all collaborating on this project, aiming to reduce the time and cost of phase II and III trials.
Reform the VAT system to encourage collaboration

Intellectual Property is an example of where sharing services could give universities access to more expertise, by sharing costs with other institutions. Value Added Tax (VAT) is a key obstacle here: as charities and universities cannot recover VAT on their purchases, there is a strong disincentive to collaborate or share services through irrecoverable VAT, preventing potential economies of scale.

A zero VAT rating for new buildings for charities can only be maintained if the building is used 95 per cent for non-business charitable purposes. This has the effect in Clinical Research Facilities funded by the Wellcome Trust that biotech and pharma partners cannot be brought in to develop new products without the building becoming subject to VAT at the standard rate even though the output of the research is for the public benefit. It has also had an influence on the legal structure, and restricts the strategy for collaboration, on the UK CMRI campus planned for North London.

In order for charities to collaborate, in some cases a new charity or organisation will be created in order to maintain zero-rating status. However, this is only worth doing for large projects, and restricts collaboration with organisations outside the original agreement, as well as restricting any translational activities.

Irrecoverable VAT for charities sharing services has been the subject of an ongoing campaign by the Charities Tax Group, with successive Chancellors promising a review. With this obstacle removed, more options to improve efficiency and expertise would be opened up. The June 2010 budget announced that “the Government has started discussions with charities and other affected sectors to consider options for implementing the EU cost sharing exemption. It will continue those discussions and launch a formal consultation in the autumn.” At the time of writing, no such consultation has been launched.

Develop more specialist research support

Those working in the biomedical system often play more than one role. Most obviously, clinical academics need to balance both a clinical workload and time for research. Research scientists also spend a good deal of time developing their tools and reagents before beginning their experiments.

There is a general trend in science and medicine towards greater specialisation. This can mean more efficient use of time – where researchers are able to spend more of their time on tasks that make greatest use of their specific expertise, we get the most value from them. Separating some of the specialist research support tasks into centres of expertise can improve the quality of support as well as freeing up researchers or clinicians to focus on their specialism (see Box 9).

Specialisation as a way to improve the capacity of limited resources can also be applied to clinical trials. Although overall capacity for clinical trials in the UK is good, the same small

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**Box 9: Developing specialist support services - Division of Signal Transduction Therapy, University of Dundee**

Professor Sir Philip Cohen established a collaboration with industry based on his kinase research that has now been running with different companies, for 12 years. Each company participating ‘buys in’ with £10.8 million of funding over four years.

Forty per cent of the funding for this collaboration goes to a service facility. This has 25 staff in a series of ‘backup’ teams that support the 14 research groups, including a DNA cloning team, and a kinase profiling service. This is staffed mostly by technicians, with some post-docs, and they provide services to the companies, providing reagents and chemicals which generate a further £4 million per company over the four-year period. The support teams are incredibly useful to the academic teams as well. It is possible for an organised programme leader to have all the reagents ready for a new research to start their experiments on the day they arrive, rather than spend months on cloning and making reagents before they can get underway.
number of centres and investigators attract a large number of the industry requests, and there can be delays in starting trials because of this workload. Pharma companies are often reluctant to use new, untried investigators because of the higher cost in time and money bringing them up to speed – they need more support than those they have worked with before. But the most popular investigators have limited time and often find it hard to recruit for multiple studies within their patient population.

Ensuring that trial investigators are provided with effective support, to enable their time to be used most efficiently, should make the most of the capacity available. Changes to the trial approval process may help – the Academy of Medical Sciences has conducted an independent review of clinical trial regulation procedures in the UK, and recommended a more proportionate and symmetrical system that would streamline approvals procedures.

Internships, training and placements could also be an effective way of providing additional resource to these investigators, while training up new ones, and building relationships between companies and new investigators (see below).

3.2 Support people who move between sectors

The best collaborative work arises from intersections between disciplines – people with different but complementary knowledge coming together to solve problems. Those critical to bringing these ideas together are often ‘boundary spanners’ – those who work or have worked in different areas, and can spot opportunities for collaboration, as well as understanding the perspectives of both groups.

There is little data available on the career paths of those in the biomedical industry (this would be another area where new data would be welcome). Anecdotally, however, the migration appears to take place more often from academia to industry than in the other direction, and those with pharma industry experience can be valuable staff for small bioscience companies, as they ‘speak the same language’ as potential pharma partners.

Increase the number of industry placements

Temporary industry placements, whether undergraduate or post-graduate placements, training schemes or later career secondments, can all contribute to greater understanding by building contacts and introducing researchers to the reality of industrial life. What is especially valuable is their temporary nature, enabling participants to bring an industrial perspective back into academic and clinical environments.

But such interactions are on the decline. The Association of the British Pharmaceutical Industry (ABPI) reports a 33 per cent decrease in industrial placements since 2007, 84 per cent of which are provided by just three companies (from 530 to 355). Although PhD studentships and postdoctoral grants have increased since 2007, even these numbers are still below the figures for 2003. There is also a trend towards more overseas placements: over 25 per cent of all postdoctoral research was in conjunction with institutions outside the UK – in 2007, the figure was just 10 per cent.

These decreases in overall placements are not just a missed opportunity to develop industry skills in students and academic researchers; they also reduce opportunities to develop collaborative links between universities and companies.

Knowledge Transfer Partnerships (KTPs) are run by the Technology Strategy Board (TSB) in a range of industries, and allow small companies to benefit from academic placements. The TSB’s strategic review of the scheme called it: “an important tool to help academics engage with business and a key vehicle to develop their understanding of industry.” However, very few of these placements are currently made within the life sciences sector. Recent changes to the scheme, allowing post-doctoral students to take part, should make KTPs more attractive to life sciences companies, and will hopefully lead to more widespread take-up of the scheme.

Industry has a role to play in providing more placement opportunities, cultivating the trained staff they need. Funders and higher education institutions should also be more pro-active in requiring external experience for applied research roles.

Structure careers to enable working across boundaries

Those who work in several different parts of the system have an especially important role in spotting opportunities for collaboration and bringing different perspectives together. Universities’ knowledge transfer offices span university-industry boundaries; clinical academics are often employed by both an NHS
Trust and a university; and some academics also own spin-out companies.

Clinical academics are a particular strength of the UK research system. In 2002, the Academy of Medical Sciences published ‘Clinical academic medicine in jeopardy: recommendations for change’.64 Between 2000 and 2006, the number of UK clinical academics declined steadily from just over 3,500 to less than 3,000 full time equivalents (FTE). This led to a series of changes in the support for clinical academics and clinician scientists that have largely been effective – 2007 saw an increase in numbers which has continued in subsequent years, although figures are still below those in 2000.65,66

One or two figures have made significant moves from clinical academia into industry – Patrick Vallance and Keith Peters have both moved from senior academic positions into GSK, for example. However, revolving doors are rare: industry and academic structures are not conducive to moving in and out of industry. There is an assumption that clinician scientists moving to industry ‘go native’ after six months, and never return to academia. In practice, the requirement to publish regularly can make it effectively impossible to return to an academic career after a break. Creating realistic career options for those who would like to transition in both directions should be a priority for both universities and large companies – seeing a career move as a one-way decision is bound to limit the potential pool of candidates.

At the same time, academic research can lead to greater commercial applications with the right support. There are a number of schemes that aim to bring relevant industry experience into departments, and provide a degree of advice and mentoring that helps provide feedback to academics. Through advisory panels, or ‘entrepreneurs in residence’, they can bring in ideas about current clinical and industry needs, explain how to shape a proposal that is commercially attractive, and highlight which aspects of the research have the greatest commercial potential – areas with which the academics may not be in close enough contact to assess easily (see Box 11).

Hugh Laverty at the MRC Centre in Drug Safety Science at the University of Liverpool co-ordinates industry interactions for the centre, and recognises the importance of his biotech background in those discussions. Although it is still hard to get companies to agree to share data for pre-competitive collaborative projects, “it helps you understand where they are coming from”, he says.

Recognise the importance of co-located facilities and clusters.

Clusters are a familiar idea when considering policy to support specific industries or technologies. There is a good deal of evidence that some elements of clusters – ability to share inputs, easy transfer of labour, and knowledge spillovers – are linked to geographic proximity.

The Office for Life Sciences (OLS) announced the introduction of Therapeutic Capability Clusters in 2010 as part of a Life Sciences super-cluster. These are to be virtual clusters, linking together therapeutic expertise from

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Box 10: Industry training for clinicians - Wellcome Trust Translational Medicine and Therapeutics scheme

The Wellcome Trust has funded four research training programmes for clinicians in translational medicine and therapeutics. These programmes are based at University of Cambridge, University of Newcastle, Imperial College and the Scottish Consortium.

Programmes are developed around academic and industrial partnerships. Industry partners have agreed to match the £11 million of Wellcome funding, and include GlaxoSmithKline, Wyeth (now Pfizer), Roche, AstraZeneca, Sanofi-Aventis, Sirtris and PTC Therapeutics. This initiative aims to train early-stage academic clinicians and familiarise them with industry problems and ways of working. The aim is to produce a cadre of clinicians with the expertise to design and conduct studies for developing and evaluating novel therapies in humans.

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64. See http://www.acmedsci.ac.uk/p99puid25.html
centres across the UK, in order to make access easier for companies. They also represent an important attempt to link industry, academia and the NHS in a three-way relationship, where most collaborations operate primarily as industry-academic or industry-NHS partnerships.

While these linking initiatives are helpful, some would argue that they are not true clusters. The geographical basis of clusters is important and simple factors such as the ability to walk down the hall to chat with a colleague and sit in on research meetings and talks, make collaboration easier. It is often these informal unscheduled interactions that generate the personal relationships that are so important to successful working together.

When GlaxoSmithKline was developing its research facility in Cambridge, the company found that having an impenetrable facility with many security locks and passes limited its ability to interact with academics in the same building. It has since become much more open. Pfizer chose to locate its regenerative medicine research facility in Cambridge as well, precisely because it wants to be close to the researchers, rather than locating close to Pfizer’s other R&D facilities.

Box 11: Bringing an industry perspective into academia – Edinburgh and Birmingham medical schools

The Edinburgh medical school entrepreneur-in-residence scheme was created in 2006, with the appointment of a serial biotech founder, and is now funded by the MRC. The scheme is modelled on entrepreneurs-in-residence at venture capital companies. Along with a number of other changes, including implementing an interdisciplinary structure, the department went from no start-ups in five years to four in one year, disclosures increased five-fold in a year and consulting to industry doubled.

Birmingham school of medicine employs an external commercialisation board that meets every six months. Academics bring forward ideas, and the board gives feedback on what they need to think about, and what to do next. This often raises ideas that they hadn’t even considered doing, and provides a friendly source of challenge and feedback to help shape early ideas.

Box 12: Investing in a cluster through co-location - Pfizer Regenerative Medicine

Located at Granta Park, Cambridge, the UK arm of Pfizer Regenerative Medicine operates as an independent Research Unit. Its US counterpart centre is located in Boston.

In choosing the site of the centre, a range of factors led Pfizer to Cambridge. The company wanted a site with academic and biotech excellence, and a place where the future of stem cell research was relatively assured. In Cambridge, it also had a high density of biotech companies, a couple of existing stem cell companies, and a number of institutes working in adjacent areas, such as the Babraham Institute.

The centre has attempted to integrate with the academic community as much as possible. Staff attend Stem Cell Network meetings in London and Cambridge, and they are building a PhD programme where students attend lectures within the university and do research work in the Pfizer lab. The local links help with understanding the academic landscape – you can often get the unwritten opinion from a face-to-face, informal meeting. The head of the centre, Ruth McKernan, sits on several scientific advisory boards, which creates a dialogue between the research groups and the industry perspective.
Clusters generate a level of cross-fertilisation between industry, academics, biotech companies and clinics that is evident in the highly successful Boston cluster. This has simple effects, such as the ability to move jobs without moving house or schools. It also enables large collaborations to be created amongst local institutions.

Unfortunately, how you identify and support a cluster is still far from clear. In many cases, a trade association, university or other intermediary has provided a relatively small amount of resources to help co-ordinate activities. The Center for Integration of Medicine and Innovative Technology (CIMIT), a non-profit consortium of Boston teaching hospitals and engineering schools, fosters interdisciplinary collaboration among experts in medicine, science and engineering, and has done a lot with a relatively small amount of co-ordination money (see Box 13). The Massachusetts Medical Device Industry Council was formed as a trade association after identifying that a large number of medical device makers were already clustered together without a co-ordinating body.

Create organisational structures that support applied work and collaboration

Organising research around problems rather than disciplines can help academic departments to engage with industry. Dr Simcha Jong examined the organisational structures at Stanford, Berkeley and the University of California at San Francisco (UCSF), and the impact they had on the spin-out and industry activity of these academics. In contrast to the other schools, UCSF’s open, interdisciplinary research community, organised around complex human biology problems, better positioned UCSF scientists to identify new opportunities in therapeutic markets within their research, and to pursue these opportunities through industrial biotech companies. UCSF scientists were central to the foundation of a large proportion of the early biotech companies in the region, including Genentech.

Jong argues that these cases “highlight the important role that integrated interdisciplinary basic research communities in scientific fields of direct practical relevance play in supporting the growth of science-driven industries.”

In 2008, five Academic Health Science Centres (AHSCs) were created in the UK, to bring together leading research universities with NHS Trusts. These have been modelled on successful examples in the United States, where the concept is fairly widespread. Professor Dzau at Duke Medicine argues that these centres can “promote interdisciplinary collaboration and efficient use of common resources” by integrating the discovery to care continuum. However, although one AHSC (Imperial)

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Box 13: Focusing on a clinical need: MIMIT – Manchester Integrating Medicine and Innovative Technology

MIMIT has been operating for two years as the only international affiliate of CIMIT in Boston. Although its aims are similar, the different systems in the UK required a complete revision of CIMIT processes to work. The MIMIT innovation development pathway that has been developed is therefore unique to them.

MIMIT has seven partners: six NHS trusts and the University of Manchester. Each partner has appointed Site Miners – senior clinicians, in some cases with a research nurse or nurse practitioner. They seek out the clinical needs within each partner. They have a wide range of backgrounds, but share a real desire for change and to facilitate innovation, and importantly, are dedicated to these roles. It makes a significant difference having the work prioritised as someone’s main role.

They generate two or three unmet needs per month. These are validated for commercial feasibility, the existing IP landscape and to see whether there is a procurement pipeline for it. If the idea is successfully validated, then it will be disseminated to those who can provide solutions: academics, clinicians, industry reps, SMEs in any field or industry. Ideas are submitted, and the best are selected to receive funding for 12 months, typically around £50,000. So far 70 per cent of the projects have leveraged further investment at the end of the first year.
has a shared NHS Trust Chief Executive and principal of the Faculty of Medicine at Imperial College, these centres continue to straddle the boundary between the university and the NHS system. A Joint Research Office at Imperial can negotiate contracts on behalf of either the College or the NHS Trust but the AHSC itself is not a legal entity. There are examples, such as Johns Hopkins School of Medicine, that have a more integrated organisation.

Sir David Cooksey’s review of UK health research funding in 2006 noted that the AHSC proposal “which promises to deliver greater integration of not only research strategies, but vital underpinning human resources and capital assets, should make for a more effective approach to health research and patient care at these institutions.” More is still to be done to deliver this greater integration.

Organisational structures within pharma are also resistant to change. In 2008 GSK re-organised into smaller drug discovery units in an attempt to be more agile and to provide each unit with a degree of autonomy in their approaches, a move that others have also made. Moving from a large internal R&D organisation to a more collaborative model will be a challenging transition.

For small companies, fragmented structures and unclear lines of responsibility can be very frustrating when attempting to engage with a large organisation, whether that is a Trust, a university or a large pharmaceutical company. Providing simple entry points that will help guide potential partners to the right person can go a long way.

3.3 Get the right processes in place

The most frequent complaint about the UK as a location for biomedical research is the process of approving clinical research. This is the subject of the Academy of Medical Sciences review published in January 2011 and an area which the NIHR is clearly focused on, so we will not review the issues in detail here. A great deal of effort has been put into easing some of the procedural problems, although significant issues remain, with the UK’s share of patients in clinical trials continuing to decline.

The main issues are speed of setup, the number of different permissions and delays in the system, and consistency and reliability. Variability between applications and between one trust and another are very high, making it hard to predict when the status of a research application will be determined, and causing problems with planning. This puts the UK at a particular disadvantage when multi-centre trials are commissioned, and centres outside the UK can start recruiting much earlier.

**Encourage universities to use standards common to industry to make collaboration easier**

Trial approvals are not the only process that could be improved within UK biomedical research. The set up of a commercial laboratory and an academic one is very different. The researchers within them can also be expected to operate to different standards – the requirements of scientific journals, patent offices and drug regulators can all be very different. Having common standards and expectations for work can make collaboration easier, and help researchers to speak a common language.

Laboratory notebooks are one area of variable standards. US patents are granted on the basis of first to conceive an idea, not first to register a patent. This means that keeping accurate laboratory notebooks and having them signed off, which may not be normal practice in every university setting, is critical to the future commercial value of the work. Finding out during an IP negotiation that these standards have not been considered from the outset can immediately damage the commercial value of the work, and its potential for further development.

Performing laboratory tests and reagent services to industry standards means they could be offered to companies but also raise the credibility of the academic work. For example, DNA cloning can be done by sequencing one or both DNA strands. Companies often insist on the latter, which is more costly but more accurate and not standard practice in academic labs. In Dundee, one of the partner companies in the Kinase collaboration will re-sequence any samples they receive and come back to complain if they find mistakes.

Professional project management is a frequent area of discontent for companies and charities working with universities. The Association of Medical Research Charities report ‘Ways and Means’ quotes one respondent saying that researchers may “promise everything and don’t do anything”. Simple, but hard to get right skills such as meeting predicted milestones and providing good communication about progress...
can go a long way to improving trust and co-operation in collaborative work, or in more transactional contract research (see Box 14). It is also important for clinical trials recruitment – being able to provide an accurate feasibility assessment of expected recruitment figures and timelines improves the ability to meet these targets, and allows companies to plan their trials on the basis of realistic forecasts.

Government research funding should remove indirect penalties for collaborative research
The public research funding infrastructure is not well set up for industry-academic research collaborations. The Wellcome Trust’s Translational Awards is one of very few schemes specifically aimed at research proposals with an industry partner (most research councils now offer some follow-on funding for pursuing translational work, but can’t fund companies). Biomedical science suffers from not having an obvious applied science counterpart, as engineering is applied physics, for example.

The evidence in this report is that collaborative research with industry is not only as impactful, but can have greater impact than academic work. However, the translational work that is most accessible and relevant to industry is a peripheral activity for many universities. Communication of research through publication and teaching takes precedence over implementing research findings through knowledge transfer and collaborative research.

The current funding structures do not provide enough opportunities to work with companies. It’s easier to get research council funding for an academic project than an industry collaboration project. Research councils are not permitted to place grants directly with for-profit companies (unlike the NIH). Promotion and assessment criteria in life sciences departments emphasise publication results, not putting research into practice.

The attempt to factor impact into the Research Excellence Framework, which will direct a significant proportion of funding, is a useful intention, but will need to be structured carefully to avoid unintended consequences. Focusing on licensing and income values, although relatively easy to measure, can be counterproductive for encouraging collaborations. The results of the REF pilot are encouraging, and indicate that behavioural change may be created simply by the exercise of requiring academics to think about their research impact, in the widest sense, when preparing submissions.

A range of impact assessment metrics exist already. Charities develop their own to monitor whether their funding is reaching their intended charitable goals; many other countries have considered similar schemes to incorporate impact measures into university funding, and a summary of some of these is given in HEFCE’s report ‘Capturing Research Impacts: A review of international practice’.70

In the biomedical sphere in particular, the MRC has been capturing a range of impact measures using their e-Val system for some time, which captures collaborations and partnerships, effects on policy, dissemination to non-academic audiences and development of new

Box 14: Transferring Industry skills – Bioprocessing Research Industry Club
The BBSRC’s Bioprocessing Research Industry Club (BRIC) is a group launched by BBSRC, EPSRC, bioProcessUK (originally a TSB-funded Knowledge Transfer Network, and now part of the HealthTech & Medicines Knowledge Transfer Network) and industry to strengthen the UK research base in the area of bioprocessing and improve academic-industrial links. The club bridges the gap between Research Council responsive mode funding and the TSB CR&D funding.

A key activity of the club is industry relevant training at all levels. The club has been able to open up in-house company training to the young academic researchers taking part. Previously provided only to employees, these training courses provide an opportunity for academic researchers to acquire industry-relevant ‘employability’ skills, but also to see inside industry and make contacts.
research measures and tools, amongst other factors. This survey shows that 13 per cent of MRC funded principal investigators have productive collaborations with industry.

Although surveys like this and the RAND system used by the Arthritis Research Campaign, and profiled by HEFCE, help to raise awareness of impact levels, without some form of feedback into funding decisions, the incentives for greater collaboration are still not embedded into the system.

Above all, academic researchers should be recognised for trying to build collaborative links with other institutions, whether public or private. Activities such as long-term industry secondments can impact negatively on academic careers and research groups. The current assessment framework penalises interdisciplinary, translational and collaborative work when compared to ‘pure’ science and blue-sky research. Both are important, and the funding system should aim to reflect this.

University intellectual property policies should be more consistent to enable successful collaborations

There is still a perception that universities generally overvalue intellectual property (IP) and their contribution to a drug discovery process. The relative time and cost involved in negotiating IP agreements are often disproportionate to the likely value of any IP that might emerge. Even the most basic, pre-competitive research needs to be protected, although both sides recognise that commercial results are highly unlikely. Pressure from Vice-Chancellors or departmental heads to bring in up-front licensing payments, and maximise short-term income can cause discussions to break down, especially with smaller companies.

Within the NHS, the policy is that all IP relating to inventions by NHS employees is owned by the Trust, which doesn’t provide a significant incentive to clinicians to spend time on developing research.

Where broader collaborations have been created, with ‘umbrella’ agreements that set out the basic rules of engagement, the overhead is greatly reduced, as many projects can use the one agreement, and the negotiation costs are spread out. Some Clinical Research Organisations (CROs) are able to provide a valuable service to companies, simply by constructing such umbrella agreements, and thereby removing the ‘headache’ of individual negotiations.

IP negotiations also need to recognise the value of contributions in kind – not just financial remuneration, but also the provision of reagents, compounds, facilities and expertise. It also needs to function more as a support service to allow research to take place, rather than the sometimes adversarial barrier that sometimes occurs.

The situation is especially complicated in biomedical science, as there is almost always at least one university and NHS Trust involved. If there are multiple funding bodies, and multiple sites, it becomes even more intractable. This complexity extends across a continuum of research, from investigator-led discovery through to phase IV trials. Much of this work is iterative, and moves back and forth between universities and industry. The translational stages – pre-clinical experimental medicine and phases I and IIa – are where a large proportion of the UK work lies.

Templates for collaborative research have been developed by a working group co-sponsored by NIHR and the MRC that includes academics, clinicians and industry participants. These are based on the Lambert agreement templates, but will specifically aim to accommodate the tripartite relationships needed for collaborative research. These are referred to as the NIHR/MRC model Industry Collaborative Research Agreement (mICRA), and were launched in February 2011.

The UK needs to provide much greater consistency and alignment between universities and the NHS across the UK on what the norms should be for IP agreements, so that companies can receive a more consistent experience. Academic Health Science Centres could provide a useful lead on this matter. There should still be room for institutions to experiment, such as Glasgow’s experiment in releasing unused IP for free, but the objective should be to simplify engagement wherever possible, and make best practices more widespread.

The NHS and universities should adopt a more flexible and strategic approach to pricing

True collaboration requires shared risk and reward and working in parallel. Without these elements, there is a transactional relationship of outsourced services. This concept has consequences for both NHS and university contract guidelines.

Full Economic Costing (FEC) was introduced to university research costing in 2006. FEC is
defined as “a price, which, if recovered across an organisation’s full programme, would recover the total cost (direct, indirect and total overhead) including an adequate investment in the organisation’s infrastructure”. Researchers are usually encouraged to minimise the gap between direct costs and FEC when considering external funding. In fact, as the earlier chapter shows, industry research funding has grown more slowly than other sources in recent years.

The effect of FEC is most obvious when comparing costs internationally. FEC can make the UK relatively uncompetitive compared to other research locations. European and US academics are sometimes much cheaper, simply because they don’t charge full overheads. Linked to the expectations of IP ownership, it has also created the absurd situation of some universities quoting full commercial rates for providing research services, and then also asking for a share of any IP resulting from the work. This is not shared risk and reward, but reward for no risk.

A more strategic approach would take into account the potential gains from the collaboration, as well as in-kind contributions, such as access to equipment and resources on both sides, and choose an appropriate pricing scheme. For genuine collaboration, it is important that the academic party has some ‘skin in the game’ – a vested interest in the success of the project. For transactions where FEC is applied, delivery to agreed timelines and meeting industry-standard delivery practices should be expected.

For clinical trials costs, the NIHR has introduced a costing template to make pricing more consistent across the NHS, which has started to improve the predictability of Trust responses. However, some Trusts are now charging a setup fee for work that has not been ‘adopted’ into the NIHR portfolio. Again, this fee has no link to the actual recruitment performance of the Trust – if industry pays for these services, it should be able to expect professional standards of performance and delivery.

71 See http://www.admin. ox.ac.uk/fec/background. shtml
Part 4: Conclusion and further work

The overall picture of collaboration in the UK’s biomedical research system is one of pockets of excellence within a relatively fragmented patchwork of organisations, infrastructure, programmes and initiatives. The approach of universities to collaboration is inconsistent, as is the approach of individual NHS Trusts. The autonomy and independence of these institutions has created a confusing and complicated set of processes for anyone who attempts to interact with more than one of them. Autonomy is an important attribute for successful management in this area, but greater agreement on the norms and expected practices would enhance the competitiveness of the UK as a whole.

There are fundamental benefits to collaborative research – it has greater impact as research, but it also generates important personal links between institutions, reduces duplicated effort, makes better use of different people’s expertise, creating a more rounded team. And yet, the UK system is set up as though industry research is a trading subsidiary of ‘proper’ academic work. This distinction is unhelpful and significantly restricts funding and facilities for work which has the best chance of leading to improvements in care. Recognising the importance of collaboration to both research and innovation should mean changing the way we think about funding, incentives and career paths in the biomedical sector.

The onus is on all those involved in supporting biomedical research to enable effective collaborations to take place, whether it is in the incentives in government funding, the restrictive charging policies of universities, the development of NHS electronic records or the facilitation of more industry placements. There is a wealth of opportunity available if we can do so – we have identified the potential for universities to increase their industry research funding by 60 per cent, simply by lifting the degree of engagement among those least involved in industry collaborations. While other countries’ biomedical industries have received a boost from recent stimulus spending packages, these short-term investments will soon come to an end, presenting a renewed opportunity for the UK to compete for talent and investment.

The ideas in this report have implications for not only the biomedical sector, but for many other areas. Innovation is the process of collaboration between people who often belong to different social systems: in this case, the realms of science, universities, clinical care, business and investment. Some attributes are shared, and some are at odds with one another. The diversity of perspectives and organisational systems is vital to innovation – if everyone worked in the same way, these collaborations would be much less valuable. But the barriers of mindset and incentives can be modified to embrace collaboration.

4.1 Further work

There are a number of areas where we hope to see further work. Data on collaboration is hard to find. Improved measures of bibliometric and financial collaboration would be welcomed. There is also a paucity of data on scientific career paths. A survey of transitions between academia and industry would be useful in a number of ways.
Acronym Soup

Many of those outside the biomedical community (as well as some within it) complain of the huge number of acronyms used for the bodies and organisations. Here is a guide to some of them:

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<tbody>
<tr>
<td>ABPI</td>
<td>Association of the British Pharmaceutical Industry – an industry body representing pharmaceutical companies.</td>
</tr>
<tr>
<td>AHSC</td>
<td>Academic Health Science Centres – five collaborations between hospital trusts and universities.</td>
</tr>
<tr>
<td>BBSRC</td>
<td>Biotechnology and Biological Science Research Council – funding body for bioscience research.</td>
</tr>
<tr>
<td>BIA</td>
<td>BioIndustry Association – a trade body for innovative bioscience enterprises.</td>
</tr>
<tr>
<td>BRC</td>
<td>Biomedical Research Centres – 12 centres within partnerships between academic and NHS resources. Setup up by NIHR. Funding is awarded to NHS partner.</td>
</tr>
<tr>
<td>BRU</td>
<td>Biomedical Research Units – 16 units for translational research in priority areas that are underrepresented in the Biomedical Research Centres. Part of NIHR Infrastructure.</td>
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<tr>
<td>BIGT</td>
<td>Bioscience Innovation &amp; Growth Team – produced the Bioscience 2015 paper.</td>
</tr>
<tr>
<td>CRUK</td>
<td>Cancer Research UK – major charity funder of medical research, spending around £300m in 2008/09.</td>
</tr>
<tr>
<td>CEDD</td>
<td>Centre for Excellence in Drug Discovery – a GSK unit usually composed of many DPUs.</td>
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<tr>
<td>CRF</td>
<td>Clinical Research Facilities – 11 Wellcome Trust and NHS-funded facilities for scientists to work closely with clinical researchers.</td>
</tr>
<tr>
<td>CSO</td>
<td>Chief Scientist’s Office.</td>
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<tr>
<td>CSP</td>
<td>Comprehensive System for NHS Permissions.</td>
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<tr>
<td>DPU</td>
<td>Drug Performance Unit – a GSK team of researchers.</td>
</tr>
<tr>
<td>GMEC</td>
<td>Global Medical Excellence Cluster – a not-for-profit body bringing together universities, companies and NHS Trusts. Programmes aim to share knowledge and improve collaboration.</td>
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<tr>
<td>HIECs</td>
<td>Health Innovation &amp; Education Clusters – created in 2009, 17 formal partnerships sponsored by SHAs, aimed at improving education and training to support innovation.</td>
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<tr>
<td>INVOLVE</td>
<td>National advisory group, funded by NIHR, to support and promote public involvement in healthcare research.</td>
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<tr>
<td>IRAS</td>
<td>Integrated Research Application System – a central system for NHS research applications.</td>
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<tr>
<td>MHRA</td>
<td>Medicines and Healthcare Products Regulatory Agency – responsible for ensuring that medicines and devices work and are acceptably safe.</td>
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<tr>
<td>MRC</td>
<td>Medical Research Council – the funding council for medical research.</td>
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<tr>
<td>NIC</td>
<td>NHS Innovation Centre – manages the innovation process for ideas in the pre-market stage that address a clinical need, as well as gathering need statements from clinicians.</td>
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<tr>
<td>NHS Institute for Innovation &amp; Improvement</td>
<td>Supporting staff innovation and service innovation.</td>
</tr>
<tr>
<td>NHS Life Sciences Innovation Delivery Board</td>
<td>Objective to improve the relationship between the NHS and the Life Sciences industry. Work programme is to be established in Spring 2010.</td>
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<tr>
<td>NICE</td>
<td>National Institute for Clinical Excellence – the regulatory body that approves treatments for prescription on the NHS, and provides broader healthcare guidelines.</td>
</tr>
<tr>
<td>Acronym</td>
<td>Description</td>
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<tr>
<td>NIHR</td>
<td>National Institute for Health Research – main funding body for NHS research.</td>
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<tr>
<td>NIHR CRN</td>
<td>NIHR Clinical Research Network – English component of the UK CRN.</td>
</tr>
<tr>
<td>NOCRI</td>
<td>NIHR Office for Clinical Research Infrastructure – a co-ordinating unit within NIHR.</td>
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<tr>
<td>NRSCC</td>
<td>National Research Scotland Co-ordinating Centre – a single portal for multi-centre trial approval in Scotland.</td>
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<tr>
<td>NTAC</td>
<td>NHS Technology Adoption Centre. Works with the NHS to overcome barriers to adoption of proven new technologies.</td>
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<tr>
<td>OLS</td>
<td>Office for Life Sciences – established in 2009 to address issues raised in the Refresh of Bioscience 2015.</td>
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<tr>
<td>OSCHR</td>
<td>Office for Strategic Coordination of Health Research – jointly set up by DH and DIUS to take an overview of the budgetary division and research strategy of both the MRC and NIHR.</td>
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<tr>
<td>SAHSC</td>
<td>Scottish Academic Health Science Collaboration.</td>
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<tr>
<td>SHA</td>
<td>Strategic Health Authority – there are ten in England and they provide local NHS management (although have relatively little budget).</td>
</tr>
<tr>
<td>SMC</td>
<td>Scottish Medicines Consortium (equivalent to NICE in England).</td>
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<tr>
<td>TCC</td>
<td>Therapeutic Capability Clusters – part of the Life Sciences Super Cluster announced in 2010.</td>
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<tr>
<td>TMRC</td>
<td>Translational Medicine Research Collaboration – a partnership between Pfizer, Scottish Enterprise, four Scottish universities and four NHS Trusts.</td>
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<tr>
<td>UK CRC</td>
<td>UK Clinical Research Collaboration – a partnership between the key players that influence clinical research.</td>
</tr>
<tr>
<td>UKCRN</td>
<td>UK Clinical Research Network.</td>
</tr>
<tr>
<td>Wellcome Trust</td>
<td>Largest charitable funder of medical research in the UK. Spent over £470m on science funding in 2009, plus £78m on technology transfer.</td>
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