
Royal College of Physicians: Physicians and the Pharmaceutical Industry Working Party**Response by the Wellcome Trust**

April 2008

Introduction

1. The Wellcome Trust is pleased to respond to the Royal College of Physicians consultation on physicians and the pharmaceutical industry. The Wellcome Trust is the largest charity in the UK. It funds innovative biomedical research, in the UK and internationally, spending around £650 million each year to support the brightest scientists with the best ideas. The Wellcome Trust supports public debate about biomedical research and its impact on health and wellbeing.
2. Clinical research can often be enhanced by collaboration between physicians and the pharmaceutical industry, for example in clinical trials or in earlier stage physiological studies to test drug pathways. Our response concentrates on the collaboration between physicians and industry in clinical research. As stated in the Wellcome Trust policy on relationships between Trust-funded researchers and commercial organisations¹, the Trust views it as desirable to encourage, where appropriate, scientifically productive relationships between Trust-funded researchers and commercial organisations. At the same time, the Trust wishes to ensure that the intellectual integrity of Trust-funded researchers and their freedom to carry out curiosity-driven research are not compromised by such relationships.
3. As a prerequisite for productive physician-industry collaboration in research, it is important to encourage physicians to engage in clinical research in the first place. Recent efforts have strengthened clinical research in the UK, for example the establishment of the UK Clinical Research Collaboration (UKCRC) – which includes industry representatives. UKCRC developed the ‘Research Passport’, which streamlines the process for academics to conduct research in the NHS, and is working to further streamline the regulatory and governance environment to facilitate clinical research. Outcomes of the Cooksey Review are expected to further enhance clinical and translational research. Still, there is a need to continue improving support for physicians conducting research in the UK and in the NHS in particular.
4. Although this consultation focuses on the pharmaceutical industry, we would also encourage the Royal College of Physicians to consider collaboration between physicians and the medical devices and biotechnology industries.

Question 1: What should be the nature of the ideal relationship between the pharmaceutical industry, the NHS, and academic medicine?

5. There should be a collaborative relationship between the pharmaceutical industry, the NHS and academic medicine to ensure translation of research to benefit patients. The most fruitful research partnerships include exchanges of knowledge and collaboration between

¹ This policy is available at: <http://www.wellcome.ac.uk/About-us/Policy/Policy-and-position-statements/wtd039176.htm>

personnel in academia and industry, not just funding passed from industry to academic clinicians.

6. Research cooperation between the pharmaceutical industry and physicians working in developing countries is also important. This is particularly relevant as many clinical trials take place in developing countries.

Question 2: What are the current political, economic, commercial, organisational, professional and public barriers to creating this kind of relationship?

7. There remains a level of scepticism among some academics about working with industry – due to negative public perceptions of pharmaceutical companies – as well as some scepticism in industry about working with academics. Actors on both sides need encouragement to overcome any initial reluctance to work together, as well as professional assistance from their respective legal and administrative services to ensure that appropriate. For academics, partnerships with industry can bring access to a variety of research resources such as high throughput technologies, diagnostics, small molecule libraries, manufacturing, medicinal chemistry and GMP facilities. It is important for partners from academia and industry to understand and respect each others' driving ethos and economic positions.
8. In the past research has been under-emphasised within the NHS, making it more difficult for physicians to engage in research at all. The NHS R&D strategy, which led to the establishment of the National Institute for Health Research (NIHR), offers a good opportunity for encouraging research in general as well as collaboration with industry. NIHR's establishment of disease specific networks, building on the successful NCRI cancer network, is a key step in providing rapid access to a valuable patient resource for clinical research. The Office for Strategic Coordination of Health Research (OSCHR) – as well as the Health Innovation Council (which includes industry representatives) – will also help facilitate clinical research.
9. Recently there have been suggestions from HMRC and the Charity Commission that collaboration with industry may make universities liable for corporation tax. This could make it more difficult for academic physicians affiliated with universities to work with industry partners. The significant public benefit arising from academic-industry collaborations needs to be emphasised and understood.
10. The Lambert Report on Business-University Collaboration (2002) focused on the most common barriers to efficient cooperation. Many of the key points expressed in that report are relevant here. One concern is that both industry partners and academics (in this context academic clinicians) must understand each others' constraints in order to proceed with fruitful partnerships. For example, the obligation for academics to publish their results may conflict with the commercial need of the industry partner to maintain confidentiality so as to maximise its competitive advantage. It is important that both parties understand that it is possible to reconcile these two positions and to agree on publication rights in advance through intelligent drafting of the collaboration agreement - a critical step in the negotiation process preceding the collaboration. In addition, industry partners may be unwilling to share important pieces of information with academics due to concerns about competition. There is a need to build trust between partners to manage this type of secrecy, which again can be addressed through appropriate confidentiality clauses in the terms governing the partnership, as can the ownership and rights of use relating to result arising from the research.
11. Beyond issues of IP and confidentiality are the occasional frustrations arising from different cultures: academic clinicians tend to want freedom to explore their ideas in an unrestricted research environment, whilst commercial partners look for targets and deliverables by

specified dates. Furthermore, in industry resources and personnel are usually available to do things very quickly, while in academia, processes and resource limitations mean that things take more time. On the other hand, if industry partners decide that a scientific question is no longer of high priority, they are likely to cut it very quickly and move on, which can be frustrating and difficult for academic partners. Regulatory concerns can also make pharmaceutical industry partners averse to even very remote risks in study protocols that academics might propose, as companies seek to avoid any possibility of adverse events being recorded on their products. This can make them less attractive research partners from the academic perspective.

Question 3: What changes within industry, the NHS, research, undergraduate and postgraduate medical education, professional and pharmaceutical regulation, and the wider UK political environment would augment and protect the relationship you are describing?

12. Improved career mobility between industry, academia and the NHS would build better opportunities for collaboration. Individuals with experiences in multiple sectors are able to understand and adapt to partners' constraints when undertaking industry-academic research collaboration. Industry also offers the potential for unique training environments for clinicians.
13. Facilities that support research by both academics and industry also encourage cross-fertilisation of ideas and collaboration. The UK Centre for Medical Research and Innovation will be one such institution. The Wellcome Trust Clinical Research Facilities (CRFs) also host industry research studies; the Trust has designed its agreements with the CRFs to make them as accessible to industry as possible. Based at Birmingham, Cambridge, Edinburgh, Manchester and Southampton, Wellcome Trust Clinical Research Facilities (CRFs) provide much-needed space in a hospital setting for research involving people. The Department of Health played an important role in helping to develop the CRFs as well.
14. Electronic patient records – currently being developed in the UK through Connecting for Health – will be able to serve as a rich source of data for biomedical research, in addition to directly improving patient care and patient safety. This will be a tremendous resource for academic researchers, industry researchers, and academic-industry research collaborations.

Question 4: How can doctors – and specifically the Royal College of Physicians – help to advance an ethical and productive relationship between industry, the NHS, and academic medicine to improve the overall health of the UK population?

15. The RCP could perform a very useful role by engaging with doctors to convey the importance of clinical research in the first place, as well as the value of collaborating with industry. Recognising that academic clinicians can and should derive important scientific benefits from collaborating with industry – and that it is not just a source of funding – is important to emphasise. It is, of course, essential to ensure that collaborative research is undertaken with the highest ethical standards. A small number of bad examples can have a disproportionate effect on perceptions of working with industry.

Can you give any examples of good practice relating the above?

16. The Wellcome Trust has sought to promote collaboration between academic clinicians and the pharmaceutical industry through a number of funding initiatives, including:
 - Wellcome Trust Clinical Research Facilities. As mentioned above, a number of the Clinical Research Facilities have served as platforms for research collaboration between academics and the pharmaceutical industry.

- Interdisciplinary Training Programmes for Clinicians in Translational Medicine and Therapeutics. This Wellcome Trust funding scheme aims to encourage UK academic institutions and the pharmaceutical industry to form training partnerships to develop individuals with a firm grounding in the principles of basic and clinical pharmacology as well as the most modern research technologies to address complex (patho) physiological questions. Applications from academic-industry consortia are currently being considered.

17. We are also aware that the Translational Medicines Research Collaboration² in Scotland, a partnership between the Scottish Executive and Wyeth pharmaceutical company, has been well received as a mechanism for promoting research partnerships between academic clinicians and industry.

² www.tmrc.co.uk