COMMERCIALISING RESEARCH: Tensions between academic research and commercialisation

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There is increasing interest in the commercial translation of fundamental academic research. I will explore the tension between the role of the academic research world and the need for commercialisation of outputs. This highlights key issues in the development of academic research towards commercial outcome and point to solutions to the problems when commercial and academic worlds meet.

THE ROLE OF MRC TECHNOLOGY

MRC Technology is the technology transfer organisation for the Medical Research Council and is responsible for the Intellectual Property (IP) and commercialisation of research done at the MRC's Units and Institutes around the UK. MRC Technology activities include: filing patents, licensing technology to companies, spin-out creation from IP developed at the MRC and organising contracts for collaborations with industry.

Unlike other technology transfer offices we also have in-house development labs creating new early stage medicines. This was started to bridge the gap between MRC researchers, providing knowledge about the biology of disease, and the development of new drugs and chemistry. This now provides access to all researchers in the UK. MRC Technology bridges the gap between innovative biology and the point at which companies are able to take on projects for further development. We leverage our expertise in antibody engineering technology developed at the MRC.

MRC work on therapeutic humanised monoclonal antibodies, pioneered by Sir Gregory Winter, has resulted in major therapeutic advances and the introduction of a new class of therapeutics. Work done by MRC Technology, to create such antibodies in collaboration with pharmaceutical companies, has produced two medicines that are now having a significant impact in the treatment of MS and rheumatoid arthritis.

We also offer services to medical charities in the UK to help them get most out of their research funding: to monitor how their funding is used to develop treatments and expertise in assessing translation and commercial and development opportunities.

MRC Technology is positioned between industry and academia to deliver new technologies but also to develop technologies with academia and collaborating with other institutions to provide new medicines.

COMMERCIALISING ACADEMIC RESEARCH

Research provides insights into potential new products. The UK remains at the forefront of efforts to commercialise academic research.

The challenge is – what can be protected, what is worthwhile protecting and, crucially, will that protection aid the development of the technology or medicine. This is a crucial test in publicly funded research that would not apply in a business context. In patenting we are not simply looking for a monopoly position that can be exploited – that monopoly position should be to benefit the development of the technology. We don't assume "blocking positions" simply to corner a market.

For academia there may be an opportunity to bring in industry funding and achieve cash returns from the sale or licence of technology. This has advantages as an opportunity for re-investment but can be a two-edged sword: Industry partners often cite over-valuation by academic technology transfer organisations as a barrier to co-operation with academia. There is potential for poor communication and conflicting goals and perceptions. Valuation

. . . labs creating new early stage medicines . . .

. . . Academia contributes to product development . . .

is only one potential area for conflict.

TENSIONS AND POTENTIAL CONFLICT

Realising commercial end-points is not the prime motivation for academic research. Academic research doesn't start from the premise "what product does the market need". Academia contributes to product development but we need to understand how such interactions are best managed.

One of the prerequisites for academic scientific research is the requirement to publish. In a commercial environment there would necessarily be much tighter control of publication and indeed the need for secrecy. Often a source of friction, the requirement for publication may seem very strange to industry partners who may be paying for the work and have to forego control over it.

Academia produces

. . . requirement for publication may seem very strange . . .

technology at an early stage in development. In the pharmaceutical industry the certainty of bringing a product to market will be at best poorly understood and very risky – there is a huge attrition rate. Further, in the protection of IP we have to balance the need to publish with filing patents. Patents arising from academic research must be filed at an earlier stage, often before the full development of the invention, and this can compromise value.

The collaborative nature of academic research can make IP ownership complex which implies a cost to manage such interactions. This is sometimes a huge frustration for industry partners as they end up dealing with a multitude of parties and can provide for complex diligence processes.

In licensing technologies to companies there are significant barriers to overcome

- **Not invented here –** companies may be resistant to taking on a technology they have not invented, it increases risk.
- **Investment will be high with an unproven market,** with very new products there may not be a developed market so difficult to assess the reach, impact and value of the potential product.
- **The risk may be too great** and the product development may languish.

Development programmes can be long-term and the early stage nature of academic IP also contributes to differing views on value – clearly a source for conflict between University and industry partners.

Conducting research at universities can be expensive. For SMEs the costs can be prohibitive and this discourages interactions between smaller companies and universities. For larger companies it discourages research with universities outside business critical areas.

POTENTIAL SOLUTIONS

Differing views on publication have to be managed; we work towards managing the requirement for publication to ensure adequate time to protect valuable IP. This can be limiting but it is necessary to balance the requirement to publish and commercial considerations. There will remain a potential challenge to realise the full potential value of academic research.

- Reduces costs, and risk, for the company.
- Co-development can overcome "not invented here" syndrome.
- The university is able to call on the market and commercial focus of the company which gives confidence to the funding agency.

Valuation is a negotiation, but both sides need to understand how the technology will

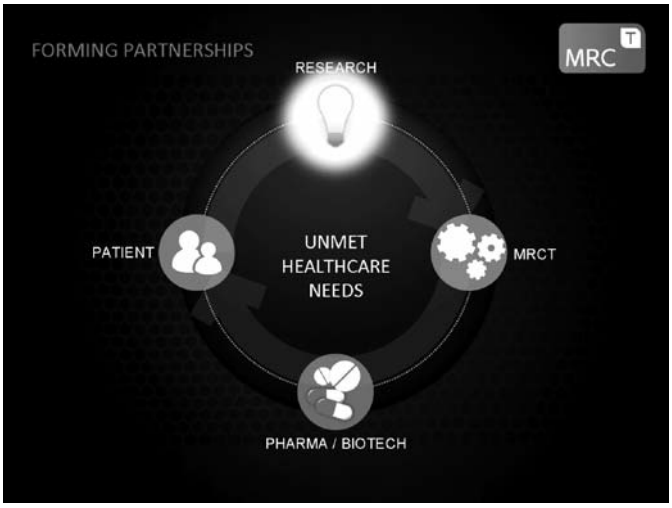
. . . research at universities can be expensive . . .

There are various initiatives to grow interactions and relationships and exchange ideas (for instance the MRC's and the Technology Strategy Board's Biomedical Catalyst schemes) and to overcome a number of the issues:

- Allow companies and universities to work together within a framework developing the partnership, fostering interaction between people.

generate value and work towards a fair share for the academic partner. The university needs to understand how the business will profit from the new technology and the business needs to help this understanding.

The key focus is providing environments both physical and funding in which industry and academia can interact. This not only promotes exchange of idea but exchange of working practice and engagement.



MRC Technology seeks to deliver new medicines and new medical technologies, commercialising academic research and partnering with industry.

COMMERCIALISATION OF RESEARCH

Dr Louise Leong and Dr Bina Rawal
Association of the British Pharmaceutical Industry

With the creation of the UK Strategy for Life Science under the sponsorship of the Prime Minister, the Government clearly sees the Life Science industry as a key sector underpinning long term economic growth for UK plc, as well as a key contributor to the wellbeing and health of the nation.

The biopharmaceutical industry is the industry sector that invests most heavily in R&D – £4.85 billion in 2011 [1], is the largest investor in health research [2], provides 67,000 highly skilled jobs, brings life-saving medicines to society, and generates over £6billion trade surplus annually [3].

In this article we focus on gaps in the translation of biomedical research towards effective treatments for patients, how this can be bridged, and what more needs to be done.

The research and development of new medicines for unmet medical need is a long, complex and risky process that takes on average 10-15 years, and costs £1billion per medicine [4]. Industry funds much of this upfront and bears the risks. This underlies some of the key barriers to commercialisation of research. Other factors influencing biomedical innovation and their desired state include:

- Intellectual capital: The desired state would be a talent pool of researchers with access to funding schemes and excellent technology transfer offices.
- Research and development: Support for biomedical clusters; flexible collaborations between businesses; more industry-academic-NHS collaborations.
- IP: Appropriate protection of intellectual property in line with risk and cost of development.
- Clinical and regulatory: Continued streamlining and harmonisation of research and governance processes; new approaches for cost and risk sharing attempted.
- Market incentives: Incentives for both incremental and radical innovation; matching schemes for public and private investment; leveraging charitable investment and other capital.

Much of fundamental science underpinning our understanding of health and disease, and early discovery research using disease models, is carried out in academia. Target identification and validation, preclinical safety, early and late phase trials and meeting regulatory requirements for marketing authorisation (ie for a new medicine to be licensed for use in patients) is conducted in industry, whether in-house in pharmaceutical companies or outsourced to CROs.

A substantial part of today's health burden is in complex chronic and heterogenous disease or syndromes, such as diabetes and metabolic disease, inflammatory disease whether respiratory, joint, or neurological, and dementias. Industry has therefore sought to overcome scientific and technological challenges through greater precompetitive collaboration, both between companies, as well as across sectors with academia and health service clinicians. This larger R&D ecosystem includes the medical research charities and patients.

. . . £6billion trade surplus annually . . .

The translational gap that was the focus of a recent meeting of the Parliamentary and Scientific Committee was in the commercialisation of academic research beyond proof of concept, ie the "valley of death". This may involve the funding of proof of concept studies from discovery, to the point where a potential medicinal candidate is of interest to a drug developer to take on and pursue further clinical development. Investors in such translational research face similar pressures to industrial R&D as outlined above, such as the risk of candidate attrition and long timelines of development impacting on their return on investment. Investors are now investing at later, more mature stage of development, requiring greater proof of concept. In many cases, early assets from academia may not be validated, or the potential market misunderstood. Despite big strides being made in the UK in the last decade, the academic-business cultural divide as well as university technology transfer barriers can lead to overvaluations of assets. Investment is often serial, with a chain of investors each building on the asset, and with exit-oriented objectives.

How might this translational gap be bridged? A diversity of funding sources to plug the gap sees an increasing role for charitable organisations and public funders (eg US National Institutes of Health, and Wellcome Trust's *Seeding Drug Discovery*), while traditional investors have included business angels and small investors, venture capital and independent corporate venture arms, and public markets. Investor education and engagement on the medicine development process and perceived risk is important. Actions to reduce risk can be useful, to increase knowledge and confidence in assets. Examples of such initiatives in the UK include the NIHR Translational Research Partnerships; academic-industry research consortia; innovative development/licensing approaches (eg adaptive licensing); and retaining the value of exploitation in the UK

. . . increasing role for charitable organisations . . .

by improving the clinical research/trial environment. Commitments in the Life Science Strategy have been helpful, such as the Biomedical Catalyst fund, and fiscal measures such as the Patent Box and R&D tax credits.

The UK possesses historical strengths that we should capitalise and build on:

- High public sector investment in the life science research talent pool
- A cultural willingness to take risks and accept failures
- Mobility of people between research organisations and industry
- Availability of specialist, early-stage capital
- Structured networks and communication forums to connect researchers with businesses
- Meaningful incentives for research organisations and researchers as well as companies
- Geographical proximity between research organisations and SMEs, eg incubators
- Fiscal and regulatory environment, such as the protection of IP, taxation and regulation
- The unique feature of "cradle to grave" continuum of care through the NHS for the majority of the population

At the same time, there are also increasing pressures in life sciences to address. For example, the decline of the UK's global share of clinical trials (including for performance reasons) [5], a weakening commercial environment in the UK in terms of usage of innovative medicines, uncertainty around the pricing framework which traditionally has been perceived as stable and predictable, and an understanding of the link between the commercial environment and R&D investment particularly in clinical research. For example, the UK is now the lowest and slowest adopter of new medicines in the EU [6]. The UK Life Science Strategy has sought to address some of these barriers – government's commitments are welcome, and success is contingent on competing globally.

WHAT MORE CAN BE DONE?

- Leading edge R&D relies on a healthy science base and **continued public sector investment** into science and research, and graduates with right mix of talent that modern drug development requires;
- **Stronger collaborative culture** across industry, academia, NHS
  - NHS understanding of translational barriers and how new medicines are developed
  - More partnership working with shared common ambition
  - People **mobility** – more is needed across sectors
- **Biomedical catalyst fund** welcomed – but its scope should be widened beyond SMEs – as pump-prime to overcome risk barriers. For example, as a vehicle to ensure there is funding aligned with large national initiatives when created, particularly the Translational Research Partnerships
- **Culture of research** to be embedded in the NHS
  - Trial recruitment targets hit at pace and scale – time, quality, cost
  - Investment in Clinical Research Networks is sustained for them to deliver
- **Health Data initiative** – investment in **CPRD** for staff, capabilities and technology

We see a number of potential measures to facilitate knowledge exchange, with cross-sector involvement:

- Mentorship from industry clinical pharmacologists and preclinical development experts in drug discovery
- Mentorship from clinical and biology experts from NHS and academia respectively for industry teams
- Sharing of training resources
- Sponsored innovation briefings

Ideas for sharing the risks and costs of innovation include:

- Enlarging the pre-competitive space
- Adaptive licensing as a flexible and iterative approach to drug development
- The ability to more efficiently answer research questions, develop personalised/stratified medicine or monitor drug safety through access to anonymised health data and data linkages
- Use of worldwide data and observational studies to improve understanding of use of medicine in a global setting

How will we know when success has been achieved? Some quantitative metrics may include growth in R&D investment (new bioscience clusters/parks, manufacture facilities for high value products, pipeline growth and product launches, trade balance), increase in clinical trials activity. While qualitative measures may include reputational perception (UK as a preferred partner/location), uptake of ideas by others, and the shaping of policy.

The ABPI is actively engaged on much of the above, to improve the environment for R&D in the UK. We will continue to:

- Engage a broad network of stakeholders across industry, government, academia, the third sector, NHS, and patient groups;
- Be a trusted broker for a range of R&D collaborations;
- Maintain a reputation for knowledge sharing and future-proofing of the skills base;
- Provide rational, well-supported and authentic input into policy debates and new regulation;
- Champion the UK as a highly conducive environment for R&D.

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COMMERCIALISATION OF RESEARCH
Realising the commercial potential of university research

Professor Stephen Caddick
Vice-Provost, Enterprise, UCL

If we are to unleash the potential of our academic entrepreneurs, government, universities and the business community need to remove the barriers to commercialisation of research.

THE PURPOSE AND IMPACT OF UNIVERSITIES

Universities carry out three core activities. Firstly, education: to enable students to develop a deep understanding of their subject of choice and acquire relevant skills. Secondly, fundamental research: to create new knowledge and insight. Thirdly, impact: to apply knowledge outside academia for the good of society.

UK universities do an exceptionally good job at the first two. While there is much exemplary achievement in the third element, universities need a supportive environment to boost their academic endeavours.

Academic research has the power to change lives through broader application, and the major challenges we face – climate change, food security, health, digital innovation – will need a combination of curiosity-driven and applied research to develop solutions.

We know that many transformational findings are likely to emerge from unfettered research. Research Councils UK estimates that £45bn of current economic value in the UK accrues as a consequence of investment in fundamental research. As President Obama noted in his 2013 state of the union speech, "Every dollar we invested to map the human genome returned $140 to our economy." Sustained investment in 'blue skies' research will create discoveries and new knowledge that will drive innovations and industries.

Our universities contribute substantially to the economy. The UK HE sector employs more than 650,000 people and, according to a study by Universities UK in 2009, generated more than £59bn per annum in the economy. Many universities are their region's largest employer and most play a key role in attracting overseas investors.

THE KNOWLEDGE EXCHANGE LANDSCAPE

The commercialisation of research has, over the last few decades, become an important element of knowledge exchange (KE). This is the process by which we enable the communication, translation and application of knowledge between academic and non-academic communities. There are many forms of KE, among them consultancy, continuing professional development, and collaborative and contract research (see panel). These generate £3.3bn per annum, income which universities reinvest in students, staff and our communities, to fuel education, research and innovation.

New inventions or discoveries made in academic laboratories have the potential to be converted into a commercial product. Although such ventures can generate a financial return for universities, this may not be the primary driver. Data show that income derived by UK universities directly from IP is around £70m per annum, approximately 1.1% of research income, whereas in the USA it exceeds £1.1bn, more than 3% of research income. Nevertheless a commercial approach is pursued because it is the most effective method for maximising the impact and benefit of academic research.

COMMERCIALISATION IS A KEY INSTRUMENT FOR EFFECTIVE KNOWLEDGE EXCHANGE AND IMPACT

How have universities evolved their approach to commercialisation?

The most common approach is for universities to establish technology transfer offices (TTOs), dedicated to the

commercialisation of research. Typically, their mission is aligned with the core values of the university rather than oriented toward profits. They seek to maximise the impact of the knowledge created through commercialisation and to reinvest any surplus in the academic mission.

TTOs work to take promising ideas through proof-of-concept and into the early phases of commercialisation. The business managers need to be skilled in working with the academic community and balance academic imperatives with commercial considerations.

However, it is still relatively difficult for academic entrepreneurs to successfully spin-out companies in the UK. The most significant barrier is the lack of financial capital available for long-term development work and to maintain the costs of patents. Inventors and universities often find themselves "diluted out" before the enterprise reaches a significant value. There is pressure to seek capital overseas, where a healthier, less risk-averse investor community exists. Until we make it easier for entrepreneurs to access local capital, their bridge across the 'valley of death' will take them overseas.

The relative inaccessibility of finance might explain the strong preference within the UK to progress innovation through partnering and licensing. In such cases a third party organisation takes the lead in development phases and the inventors are rewarded through a revenue sharing arrangement.

BUILDING ON OUR SUCCESS IN KNOWLEDGE EXCHANGE AND COMMERCIALISATION

The UK is far better at KE and commercialisation than is often recognised, but we can, and must, do better. If we are to do so we must be more ambitious, so that the individual entrepreneurs and innovators can realise their potential. There are some specific actions that universities and government can take.

WHAT CAN UNIVERSITIES DO BETTER?

Universities need to do more to foster a culture of entrepreneurship within their academic and student communities. This means re-examination of their policies, promotion criteria and reward structures, and the provision of time to pursue innovation.

UK's knowledge exchange contributes more than £3bn to the economy

	2003-04	2006-07	2010-11
Collaborative research	645	736	872
Contract research	688	862	1,053
Consultancy	251	317	370
Facilities and equipment-related services	95	102	129
Continuing professional development and Continuing Education	352	534	606
Intellectual property	46	64	69

Income generate by UK universities in 2011 through services to business, including commercialisation of new knowledge, delivery of professional training, consultancy and services amounts to more than £3bn – SOURCE HEFCE

Key facts on commercialisation of UK HEI's intellectual property from 2010/11 HEBCI survey

- 268 new businesses were set up based on research from UK universities.
- More than 1250 active spin-off companies employing 18,000 people with a turnover of £2.1 billion
- UK universities formed one new company per £24 million of research funding during 2010-11, compared with £56 million in USA
- Graduates established more than 2800 new enterprises
- UK universities made 2,256 patent applications with 757 patents granted
- Intellectual property income for UK universities was £69M in 2010/11

Source HEBCI survey – 2010/11

Selected commercial successes from UK academic research

Company or Product	Academic Researchers	Outcome
Biovex - cancer vaccines	Coffin / Latchman (UCL)	$1bn (2010)
CAT - antibodies	Winter (LMB, Cambridge)	$1.3bn (2006)
CDT – polymer bases LED'S	Friend / Holmes (Cambridge)	$170M
Domantis – domain antibodies	Winter / Tomlinson (Cambridge)	£230M (2006)
MTEM – hydrocarbon detection	Zielkowski (Edinburgh)	$275M (2007)
Renovo – wound healing	Ferguson / O'Kane (Manchester)	£275M (2007)
Solexa – DNA sequencing	Balasubramanian / Klenerman (Camb)	$600M (2007)
Simulect - antibody	Akbar, Amlot / Janossy (RF, UCL)	>$500M

Universities need to tear down bureaucracy within their organisations and be less risk averse. Universities need to invest more in innovation within their organisations and be more explicit about both its value to society and its role in enhancing the university mission. Finally, universities need to get better at working with business, seeing long-term collaborations as an investment, rather than a source of short-term income.

WHAT CAN GOVERNMENT DO?

Government has a key role. Firstly, it needs to recognise our universities' strengths, rather than simply assuming that all good innovation happens overseas. Secondly, we need continued investment in translation and innovation, but not at the expense of funding for basic research. We have a wide range of effective instruments in place: HEFCE, Research Councils, the Technology Strategy Board (TSB) and Capital for Enterprise, so let us use them rather than invent new ones. Thirdly, government needs to focus on policy initiatives that will benefit the UK, rather than those – such as IP giveaways and ill-considered open access requirements – that will benefit our competitors' economies. Fourthly, we need a coherent and modern approach to industrial strategy, and we need to create the conditions for individuals to succeed: backing, not picking, winners. Our business community needs a simpler approach to regulation, improved infrastructure, a skilled workforce and an attractive tax environment. Finally, we need to make it clear we are open for business, and that means competing effectively for global talent and making the UK the destination of choice for world-class innovators, entrepreneurs and employees wherever they come from.

SUMMARY

Commercialisation of the intellectual property generated through research is an important part of the knowledge exchange landscape in the UK. Despite this, at present there are significant barriers, which impede the UK's academic entrepreneurs. If we are to unleash the entrepreneurial spirit and potential of the academic community, we need concerted effort from universities, from government and from business partners.

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SIN: Overseas Champions of UK Science and Innovation

Sam Myers

In today's competitive and evolving global marketplace for science and innovation, the Government's global Science and Innovation Network (SIN) is harnessing opportunities for the UK through international partnerships. In this article, Sam Myers explains how SIN is championing UK science and driving growth through collaboration and influence overseas. Sam has worked for SIN since 2007, establishing the strategy for Britain's engagement with Southeast Asia and now leading the Asia Pacific region from Beijing, China.

The international marketplace for science and innovation has never experienced such competition and upheaval as in recent years. Established players in Europe and the USA have been challenged and in many cases displaced by newcomers in the Gulf, South America and Asia Pacific. Despite the excellent funding settlement secured for the UK science budget, our proportion of GDP spent on R&D stands at 1.8% (£26bn), less than half that of Finland. China's growth in science demonstrates the challenge facing the UK: Chinese R&D investment has increased 20% annually for over a decade, reaching £100bn in 2012. This has propelled them into second place globally by research publication volume.

. . . China's growth in science . . .

However, it is not time to hang up our British lab coats yet. Our scientific heritage continues to serve us well: with just 1% of the world's population, we publish 14% of the world's highest impact science, and are home to a fifth of the world's top 20 Universities. Pound for pound British researchers are the most efficient in the G8, and this attracts more foreign-funded R&D to the UK than any other country.

So Britain is in the global innovation race. But how do we make sure we lead the pack? And how do we support UK companies to source the best technologies and attract further