



After the life sciences strategy: managing science-based R&D collaborations

Notes from the event at NESTA, Friday 27th January 2012

A reminder: this event was conducted under the Chatham House rule, so remarks are not attributed to attendees or speakers. These notes form a summary of the main points of discussion from the various speakers and the questions.

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Agenda

10:00 – 10:05 Introduction – Louise Marston, Lead Policy Advisor at NESTA

- 10:05 10:20 Simcha Jong, UCL
- 10:20 10:50 Panel One: Transferring research from the lab and organizing R&D in start-up firms;
 - David T Phillips, Partner at SR One (The corporate venture capital arm of GlaxoSmithKline)
 - Harren Jhoti, President and founder of Astex Pharmaceuticals
 - John Sinden, CSO and founder of ReNeuron
- 10:50 11:10 Questions for panel one

11:10 – 11:40 Panel Two: Challenges in using R&D relationships with academic partners to enhance the firm's innovative capabilities:

- Dave Tapolczay, CEO of MRC Technology
- Mike Wood, Director of R&D at Vernalis
- Richard Storer, CSO of Summit Corporation.

11:40 – 12:00 Questions for panel two

Main points and topics

The industry environment is changing

Large pharmaceutical companies are undergoing significant changes: restructuring R&D, reducing R&D budgets. Industry R&D is facing pressures to reduce costs, to identify return on their investments (ROI) and to reduce risk, especially risk of costly late-stage failure.

A failure at Phase II is a catastrophic failure for a researcher that has spent years on the compound, but highly significant for the CEO as well – especially if it's a blockbuster replacement. <u>Pfizer lost 11%</u> of its value, \$12 billion, in a day when the failure of Torcetrapib at phase III was announced in <u>December 2006</u>.

In the last 10 years or so, pharma has also become more like biotech in culture, somewhat more entrepreneurial and responsive to new technologies and opportunities. Some ideas which once would have spun out from large pharma can now be developed in-house.

The changes in Big Pharma create opportunities to exploit, as well as challenges. If you're looking to collaborate, you often never talk to the same person twice – reorganisations, site closures, and turnover of people all make it hard to maintain relationships.

There was general approval from the speakers of the improvements in government infrastructure. NIHR and NOCRI are helpful and are making it easier to get R&D and regulatory approvals.

Technology Transfer Offices have broadly developed in the right direction. They used to be really difficult to deal with, and IP was always an issue. In the last 5 years or so, there have been a lot of new people added to those offices, and there has been a readjustment of thinking.

Role of informal

A lot of the good ideas that arrive at a large company are informally introduced – how can those informal touchpoints reach the right person to make a decision. How do we capitalise on the informal?

To get things started, you need to encourage people to talk– forums for that are scarce. Meetings are important and are where many projects get started – but one of the first things to go when R&D gets cut is the travel budget.

Some tech transfer offices and companies have a specialist team of people to make informal contacts in universities and research charities, both in the UK and overseas. Cutting travel makes it harder to make these informal contacts. There is a need for the R&D department to impress on Finance the importance of the informal, face-to-face contacts. Merck a few years ago appointed 500 scientists as network agents, to go out and find interesting ideas. Glaxo used to have a milkround system where every university in the UK had a representative inside the company, and they got to know the research of that university in detail, giving access to lots of early-stage work.

In the research phase, you might be more interested in serendipity, as opposed to venture funding and acquisition searches, which are more focused on a specific need. Ultimately, it means making the investment of time and money, putting it into people's objectives, to make sure space is created for informal interactions.

Responsiveness can also be an issue. Ideas can get squashed by lengthy committee processes. Small businesses have the advantage of being able to get things going in a few days, and are better able to keep the momentum going. It's hard to get a quick answer from large companies –that's not a criticism, just a fact. Taking away some of the approval process, and trusting in scientists to make good connections is a way to become more responsive to opportunities.

There's a fear that you'll only have one good idea in your life – a fear about giving ideas away by sharing them. If you can get away from that fear you can co-operate with others to develop them. Great ideas only become great once a significant number of people have been involved in shaping them. You might need permission to get away from creating immediate value for the company, especially at a small company – that's a very difficult thing to balance.

Advantages of academic collaborations

Most big pharma companies are not doing fundamental research in house any more. For example GSK had a hundred people sequencing genomes ten years ago. Not anymore. Failures in later stage trials can sometimes be traced to a lack of fundamental understanding of the pathways, or the absence of biomarkers to subdivide responders from non-responders. These are areas where the academic community can play an important role.

There are also advantages for companies in engaging in academic collaborations:

• It is easier to attract high-quality scientists to join a Scientific Advisory Board (SAB) if you have built up a scientific reputation.

- You have an advantage in recruiting PhDs that can amount to a 25% discount in hiring costs. In addition, publications act as an advertisement for the company. Allowing researchers inside the company to publish creates a scientific reputation for leading-edge science, as well as attracting people who read the papers to work for you.
- Some translational grant funding, such as EU FP7, is easier to attract with a link to academic research.
- Firms that publish have a higher R&D productivity over those that don't. In fact, an analysis of the R&D productivity of UK biotechnology firms highlights that for each article firm scientists publish in a scientific journal, the firm typically enjoys a 5% jump in R&D productivity measured in terms of clinical compounds in the pipeline and a 9% jump in R&D productivity measured in terms of clinical compounds in the pipeline that are new chemical entities.
- Making academic and university links both in the UK and overseas can also be important for funding. The National Cancer Institute (NCI) in the US and NCIC in Canada are sources of funding for oncology trials.

Making academic and industry collaborations work

Conducting research within the firm makes it easier to build links with academics.

Different priorities, pressures and timescales can make direct collaboration between companies and academics fraught with tension. It's important to recognise and then respect the different priorities and objectives that each side has, and to establish ground rules and expectations upfront.

Working with industry won't work for every academic – some need to focus on the blue sky research, and the teaching that are at the centre of universities. If you want to work together with academics, there is a need to be sensitive about the different environment academics work in. For example, trying to get academics to work on industry timescales is bound to lead to problems.

Academic quality for regulators

Academics generally don't work under the same conditions that regulators require. To do this sort of work, you can try to put a quality system in place in the academic lab that will cover documentation, writing up procedures and address the need for auditable data required for regulatory submissions. Funders could get involved to advise on these systems.

However, it may be that this work is better done within a company, rather than an academic lab: this is not always the best way to use their expertise. You are taking a bigger risk when you are reliant on the data coming out of academia for a regulatory submission.

Sometime you might do work inside the company to support what the academic wants to do, where that is the most efficient way to make progress – in the same way you might use CROs. In this way, you use academic collaborations to push the boundaries of what you're doing, rather than just an extended resource. Academics are looking for a new challenge in their collaborations –making a thousand analogues, for instance, would be a misuse of the academic's time.

Timescales

Small companies in particular have strict timelines to stick to, and little room for serendipity. Academics have an environment of licensing and committees for trials and research that can be slow for a small company. On the other hand, even when both parties are enthusiastic about collaboration, the time taken to negotiate the contract terms can mean a loss of momentum.

Most academics are driven to be first to publish in competitive fields, and work hard to make sure they are at the cutting edge. Academics can be enthusiastic and keen to work to industrial timescales, but very few are able to focus all their time on your project, as you could inside a company or CRO. Managing collaborations alongside teaching duties, administration and other research is something few can achieve.

Incentives for academics

Academics do get incentives in the form of share options or shares in spin-out companies.

Some technology transfer offices, such as Isis, market their academics as consultants, in which case they receive a consulting fee. <u>http://www.isis-innovation.com/consulting/</u>

The MRC runs a number of schemes for working in partnership with companies. These have a 35% success rate, compared to 20% for normal grant applications.

The REF (Research Excellence Framework) now provides incentives to create impact – both social and economic – with research.

It is important that we allow people to get on with blue skies research as well. There has to be significant effort on areas where the application or impact is very hard to see at the start.

Technology transfer and licensing

Technology transfer offices need highly professional people who can work with big companies. There are still pockets that are driven to bring in more short-term revenue (often from the vice chancellors office). Even if the academic is enthusiastic, if the TTO is unrealistic it may be best to stop the discussion early on, rather than try and persist.

Industry also needs to be clearer to TTOs about what they are looking for. Hopefully they can then filter out much of the stuff that is not relevant.

Spinning out

It's important to have someone on the team from an industrial background. They will bring a network that starts to build the personal connections for collaboration. You also need the experience of moving a programme from early stage to late-stage.

Some other factors for success:

- A clear shared vision across all of the team
- A culture of collaboration that avoids knowledge silos
- Choose and reward the best people but also reward appropriate risk taking
- Balance fixed and variable costs 80% internal, and 20% managed CROs outside. This gives you some flexibility to reduce external expenditure.

• Do no more than you can afford to do: don't collect stamps – it's tempting to get just one more piece of data. You may not need it.

Funding for life sciences

There is money out there for good companies. Imperial Innovations launched a £100m fund, GSK created a £50m UK fund. Good projects will find money at the end of the day.

The single most important factor for UK biotech is a lack of appetite in the public markets in London for biotech stocks. Around 2004 the markets started to dislike research. Now they hate it, there is no interest in the research phase as adding value to the company. There is no simple answer but this is the single most important challenge.

Charities can play a critical role in supporting research, through to trials – especially for rare or neglected diseases.

Alternative sources of funding: R&D tax credits can be helpful, but can also make it difficult to get grant funding. It might not be cost-effective in terms of time or returns for a small company.

SROne is considering putting a small amount of seed money into companies that aren't yet commercially fundable to finance key experiments that they need to do, as well as providing some coaching and mentoring.

Small companies working with academics

Small companies without the clout of 'big pharma' aren't able to enter into the long-term multimillion dollar funding relationships that are becoming more popular with large companies. Instead, they need to pick small targeted pieces of work – a specific piece of data, access to patient samples or a particular technique. Doing these small pieces of targeted work quickly is quite hard because TTOs can still take a long time to get contracts signed.

Small companies have a key position between academia and pharma, as pharma takes on more of a development role, with less focus on discovery. As mergers continue, and R&D groups get larger, spread across more sites it is hard to maintain relationships. This creates opportunities for small companies but also challenges – they still need funding to provide the bridge that advances early stage research and maintains the flow from academia into the marketplace.

Links and further reading:

Simcha Jong paper – Nature Biotechnology "Commercialising a disruptive technology" <u>http://www.nature.com/bioent/2011/110601/full/bioe.2011.6.html</u>

"New modes of innovation" project webpage: <u>http://www.esrc.ac.uk/my-esrc/grants/RES-598-25-0032/read</u>

NIHR – National Institute of Health Research

A special trust within the NHS charged with funding health research and infrastructure.

http://www.nihr.ac.uk

NOCRI – NIHR Office for Clinical Research Infrastructure

An office set up to help public, charity and industry research funders work in partnership with NIHR infrastructure, including Biomedical Research Centres, and Units, facilities and networks.

http://www.nihr.ac.uk/infrastructure/Pages/nocri.aspx

Translational Research Partnerships (formally Therapeutic Capability Clusters)

These bring together investigators in the academic and NHS centres to support collaboration with industry in early and exploratory development of new drugs and other interventions. There are two partnerships currently running: Joint and related inflammatory diseases and Inflammatory respiratory disease.

http://www.nihr.ac.uk/industry/Pages/translational_research_partnerships.aspx

Christoph Westphal and Verastem:

Serial entrepreneur and industry insider Christoph Westphal has recently led another IPO in the US.

http://www.fiercebiotech.com/story/westphal-pulls-rare-stunt-55m-verastem-ipo/2012-01-27

Survey of academics – 40% don't want to be involved:

http://www.timeshighereducation.co.uk/story.asp?sectioncode=26&storycode=418784&c=1

"About 40 per cent of the researchers questioned who were working with the university to commercialise their work said they felt they had been "forced" to do so, Ms Miller told *Times Higher Education*.

"They didn't really feel like it was part of their job - their job was teaching and research," she said, quoting one interviewee who said they "didn't know how to sell".

GSK Academic superstars programme

Dr Mark Pepys and Pentaxin: <u>http://www.uclb.com/news/ucl-professor-mark-pepys-hailed-as-an-academic-superstar-by-glaxosmithklineucl-professor-mark-pepys-hailed-as-an-academic-superstar-by-glaxosmithkline</u>

MRCT – Development gap fund

Pre-seed translational research fund for scientists in MRC units and institutes. Covers proof of concept studies, target validation components of drug discovery, assay development and device/diagnostic prototyping. Typical awards are £20-200k over two years, for salaries and consumables.

http://www.mrctechnology.org/commercial-opportunities/funding-translation

MRC Award To Inventor scheme

A financial scheme where the researcher will receive a significant financial share in the IP. <u>http://www.mrctechnology.org/information-for-researchers/protecting-your-ip/awards-to-inventors</u>

MRC Fellowship scheme

Encouraging placements with industry for a year to develop skills.

http://www.mrc.ac.uk/Fundingopportunities/Fellowships/PEP/MRC006237