The changing pharmaceutical industry and the opportunity for precision medicine

March 2013

Report of FORUM Annual Lecture delivered by Dr Ruth McKernan, Senior Vice President at Pfizer and Chief Scientific Officer at Neusentis and Panel Discussion chaired by Professor Sir John Tooke PMedSci
The Academy of Medical Sciences

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Report overview

On Wednesday 20 March 2013, the FORUM annual lecture was delivered by Dr Ruth McKernan, Senior Vice President at Pfizer and Chief Scientific Officer at Neusentis, on 'The changing pharmaceutical industry and the opportunity for precision medicine'. In her talk, Dr McKernan highlighted the current need for change faced by the pharmaceutical industry and the opportunities provided by 'big data' and 'precision' medicine. She concluded her talk by outlining her vision for how healthcare may work in the future.

The lecture was followed by a lively discussion regarding the 'Attributes of good academia-industry-NHS collaboration models' led by a panel comprised of representatives from academia, industry, the NHS and research funders.

This report is in two sections. The first summarises the key insights presented by Dr McKernan in her lecture. The second outlines the issues surrounding collaborative models raised during the extensive panel discussion, capturing the views of panel members and the audience from academia, industry, the NHS, medical research charities, regulators and government departments.

The event was chaired by the Academy President, Professor Sir John Tooke PMedSci.
Introduction to the FORUM Lecture and panel discussion

Professor Sir John Tooke PMedSci opened the event by explaining that linking academia, industry and the NHS, and facilitating their engagement with regulators, is a core part of the Academy’s strategy. The FORUM Lectures of the Academy provide an opportunity for FORUM members, Fellows and other invited guests to hear from leaders in biomedical science and discuss important issues of common interest to stakeholders of the life sciences sector.
Lecture summary

Critical challenges to the pharmaceutical industry – and the factors driving them

Dr McKernan began her talk by reminding attendees of critical challenges currently facing the pharmaceutical industry. The development pipeline is faltering, compounded by the looming expiration of patents for many of the block buster drugs previously relied upon to generate revenue, while few new blockbusters have been launched over the last decade to replace this lost revenue.¹ The efficiency of R&D spending has been on the decline, including for Pfizer: increased investment in pharmaceutical R&D over the last few decades has not been reflected in the number of new drugs approved.² These challenges have driven consolidation across the sector: 10 companies dominate the sector today, whereas 57 existed in 1990 (see Figure 1).³,⁴

Dr McKernan proposed that this downward trend in R&D efficiency (number of molecular entities per $ investment) can be explained by three factors common to all pharmaceutical companies: the increasing regulation of clinical trials; a tougher reimbursement climate; and the failure of clinical trials - particularly that of large and expensive late stage clinical trials. The final costs of successful products must take account of investments in both successes and failures. To contain the cost of developing a new medicine, which is now in excess of $2 billion⁶,⁷, it is important to try to minimise the failures. Dr McKernan identified diverse reasons for failure, such as the following:

- Sub-optimal clinical trial design, where efficacy is difficult to track or patients are not treated early enough in their disease progression;
- Over-reliance on poorly-predictive animal models;
- Changes in the regulations and standards required for approval;
- Poor brain penetration (where applicable); and
- Lack of perceived cost-effectiveness over existing standards of care, despite efficacy in trials.

The pharmaceutical industry must change to try and address these challenges.

⁵ http://www.afgventuregroup.com/dispatches/afg-venture-group-newsletter/what-is-the-future-for-the-big-pharma-model/
Figure 1 The decline in R&D efficiency and the number of pharmaceutical companies

Source: Diagnosing the decline in pharmaceutical R&D efficiency, Jack V. Scannell, Alex Blackey, Helen Botton & Brian Warnongton, Nature Reviews Drug Discovery, March 2012
**Change in structure: the Pfizer example**

Like others, Pfizer’s R&D efficiency has been affected in recent years. Pfizer’s previously increasing R&D spend has plateaued, and the number of novel drugs/small molecular biologics being produced has been declining.

In response to this, Pfizer evolved in a manner akin to that of many technology companies. They moved away from a consolidated model, in which the majority of functions are provided internally, to a more distributed model, whereby most functions beyond the core expertise are contracted out to external companies (see Figure 2).

This change required significant restructuring of multiple sites and reductions at the Sandwich site in the UK to approximately 700 staff from approximately 2,400 in 2011. The site has been sold to a new company called ‘Discovery Park’ and is now in multi-use with a number of spin-out/start-up companies already - or anticipating - working there. Pfizer research is now structured into ten smaller research units that work on particular therapeutic areas and are located in cities of academic/biotech excellence. More work is done in partnership with other organisations, such as Evotec for screening. Although the company may be more reliant on external partners than before, they consider this to be a more economically sustainable arrangement. However, because of the importance of proximity to successful partnerships, location has become a critical factor for the smaller partnership-intensive, biotech-style units such as Neusentis in Cambridge.

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8 For example, see http://www.discovery-park.co.uk/news-item/items/new-tenants-join-the-growing-success-at-discovery-park and http://www.discovery-park.co.uk/news-item/items/new-tenants-join-the-growing-success-at-discovery-park

9 For example, see http://www.evotec.com/archive/en/Press-releases/2002/Evotec-OAI-Expands-Long-Term-Screening-Technology-Alliance-with-Pfizer/1684/1

10 http://neusentis.com/
**Figure 2** The changing structural models of pharmaceutical companies

### Old Model
Vertically Integrated Large Sites

**Internal**
- Regulatory
- Pharmacovigilance
- QA/QC
- Development Ops
- Clinical Dev
- Experimental Medicine
  - Supply Chain
  - Final Manufacturing
  - Bulk Synthesis
  - Drug Safety
  - Tableting
- Metabolism
- Screening
- Biologic Target Validation
- Medicinal Chemistry
- Exploratory Research

**External**
- Research Grants
- In-License & M&A

### A New Model
Externalization of Non-Core Functions

**Internal**

**External**
- **Clinical trials** – Paraxel, Quintiles
- QA/QC – Paraxel, Quintiles
- Dev Ops – Paraxel, Quintiles
- Experimental medicine – Tassella, Pivital, Imanova, Cantab
- Supply Chain – Fisher
- Final Manufacturing – Lonza, Aptuit
- Bulk Synthesis – Peakdale, Lonza
- Drug Safety – Huntington Life sciences, Covance, Chantest
- Tableting – AMRI, aptuit
- Metabolism – Quotient, York, Covance
- Screening – Wuxi, Galapagos, Evotec, Essen
- Med Chem – Wuxi, Peakdale

**Legend**
- Development Functions
- Enabling Lines/Functions
- Research Functions

**Spin-outs**
LECTURE SUMMARY

Change in approach: precision medicine

A data-driven approach
Dr McKernan highlighted how improvements in the molecular understanding of disease - which rely on the rapidly expanding wealth of data originating from electronic health records, biobanks and genetic sequence repositories - will ultimately enable precision and personalised medicine (see Box 1) approaches. In some areas it is already possible to stratify patients on the basis of their likely response to a particular treatment.

These developments present opportunities not only for improved health benefit to patients, but also for faster and cheaper drug development: the collection and analysis of this rapidly expanding data is creating new opportunities for the pharmaceutical industry. For example, Pfizer has made use of resources such as the Clinical Practice Research Datalink (CPRD)\(^\text{11}\) and UK biobanks. Such emerging resources can contribute to the drug development pipeline for the following:

- Identification of novel drug targets, such as rare gene or protein variants;
- Optimisation of drug trial design; and
- Post-filing evaluation, such as understanding drug repurposing and health economics, for which electronic health records are particularly informative.

Box 1 Definitions: precision medicine, stratified medicine, personalised medicine

(sourced from the European Science Foundation report, ‘Personalised medicine for the European citizen: towards more precise medicine for the diagnosis, treatment and prevention of disease (iPM)’\(^\text{12}\))

Stratified medicine “refers to the identification of subgroups of patients with a particular disease who respond to a particular drug or, alternatively, are at risk of side effects in response to a certain treatment”...“At present, the term is largely applied to the use of treatments with companion, disease pathway specific diagnostics in order to determine whether a patient is likely to respond to a given therapy. Nevertheless, the concept need not be restricted to such approaches and can equally be applied to risk stratification for prevention.”

Precision medicine – “providing the right medicine to the right patient at the right time” – “encompasses the use of tools for stratification and takes into account the myriad factors that can influence the development of disease in a given individual, including not only genomic and biological factors but also environmental and lifestyle influences”

Personalised medicine – “customisation of healthcare that accommodates individual differences as far as possible at all stages in the process, from prevention, through diagnosis and treatment, to post-treatment follow-up”.

\(^\text{11}\) http://www.cprd.com/intro.asp
\(^\text{12}\) European Science Foundation (2012). Personalised medicine for the European citizen: towards more precise medicine for the diagnosis, treatment and prevention of disease (iPM). http://www.esf.org/index.php?eID=tx_nawsecured8u=0&file=fileadmin/be_user/CEO_Unit/Forward_Look/iPM/FL_2012_iPM.pdf&it=1365525879&hash=e198ec6cc99b122df05c0ece6c9e016e95634946
Use of these data could also support better disease modelling and pre-competitive partnership. For example, consortia with on-going registries have been established for tracking Alzheimer’s disease. Such resources could enable trials requiring fewer patients to reach firm conclusions about treatment efficacy, and are particularly valuable in diseases where the timing of treatment is crucial.

Dr McKernan emphasised the importance of cross-sector contributions to data repositories and welcomed new initiatives in this area, such as the UK Government’s recent announcement to sequence the whole genomes of 100,000 NHS patients with cancer or rare diseases.

Although genetic information may reveal the most opportunities to develop precise therapeutics, non-genetic markers can also be utilised in certain conditions. Levels of proteins can be measured, such as Tumour Necrosis Factor (TNF) levels in inflammatory conditions. Furthermore, phenotypic markers could be used, such as the diagnosis of depression in suspected sufferers by assessing their emotional responses.

**Using a data-driven approach in pharmaceutical development: the example of crizotinib**

Using the example of crizotinib, Dr McKernan illustrated how the identification of key genetic mutations has defined disease subtypes, revealed new molecular targets and ultimately improved R&D efficiency (see Figure 3).

In 2007, a published study reported the presence of an EML4-ALK fusion gene in about 5% of non small cell lung cancer (NSCLC) patients. Pfizer discovered that one of their drugs in clinical trials for NSCLC at that time targeted this mutation. The ongoing trials were subsequently expanded to include patients presenting the ALK translocation, and this subpopulation went on to show dramatic response rates. This approach led to faster drug approval and an accelerated treatment being available for seriously-ill patients (see Figure 3).

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Figure 3 The transformative impact of using patient data in pharmaceutical development: the example of crizotinib

Typical Tumor Response In All-Comers Vs ALK Patients

The reduced speed, cost and improved patient benefit

- Less than 400 patients in total to registration
- 8 year development
- Substantially reduced costs of development
- Fast approval

43-yr Old Male Non-smoker With NSCLC ALK Fusion
**Using a data-driven approach to personalise risk-benefit balance**

The potential of a data-driven approach to minimise adverse drug reactions can be illustrated by the opportunities for tailoring the treatment options for patients at risk of gout, a painful condition caused by elevated concentrations of uric acid. By interrogating existing electronic health record databases, Pfizer has found that drugs commonly used to treat unrelated diseases have now been shown to also change uric acid concentrations, both negatively and positively. Uric acid increases could be tolerated by many patients, however new information on the additional effects of drugs generated from real world data and electronic health records could improve selection of therapy for those predisposed to developing gout – perhaps because of familial genetics. Other examples of patient stratification generated by the CPRD include subdividing patients given HRT into groups with very different risk/benefit ratios. We can expect to see greater use of existing patient responses to guide prescribing in the future.

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**Box 2 Induced pluripotent stem cells: a system for investigating the molecular basis of neuronal disease *ex vivo***

Neuronal diseases are an important area of study: for example, persons with a variant of the gene SCN9A that encodes a non-functional version of the sodium channel NaV1.7 cannot feel pain.17

Whereas researchers often isolate and study patient cells to investigate the molecular basis of disease, this is not possible for neurones. The development of techniques for differentiating embryonic stem cells into sensory neurones, *ex vivo*, is providing a new system for the study of molecular mechanisms of disease in these cells. StemBancc, one of the projects of the Innovative Medicines Initiative, is generating up to 500 new iPS lines for research use and a follow on initiative will establishing a repository of up to 10,000 induced pluripotent stem cell lines for use by academia, biotech and Pharma.18,19

These developments enable new questions to be addressed, such as identifying which drugs reverse disease phenotypes in vitro and whether the activity of existing drugs is consistent across all receptor variants.

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**The future taxonomy of disease**

The abovementioned developments in the molecular understanding of disease are also driving fundamental changes in the way disease is perceived and classified.

Dr McKernan highlighted cancer taxonomy as a case in point: classification criteria are shifting away from classical organ and histology based features, to oncogenic ones. She also highlighted how the classification of central nervous system (CNS) disorders, such as epilepsy and migraines, is evolving. This is due to rapid expansion of research into the genetics of ion channel variants over the last decade, which has enabled CNS disease taxonomy to expand beyond behavioural and neural characteristics to incorporate genetic

18 [http://stembancc.org/](http://stembancc.org/)
19 [http://www.imi.europa.eu/content/stembancc](http://www.imi.europa.eu/content/stembancc)
factors. Pfizer are active in this research field: they recently contributed to a collaborative project investigating the genetic aspects of CNS disorders using innovative stem cell differentiation methodology (see Box 2). In some cases these developments are creating opportunities for improved therapeutic treatments through a precision medicine approach.

Figure 4  Precision approaches that are bridging the gaps

![Precision approaches diagram]

Healthcare in the future

Healthcare is currently reactive: it is based on symptomatic management, episodic care and therapeutic intervention. Dr McKernan outlined her vision for a future precision healthcare system in which data derived from diagnostic technologies – such as genetic information – is routinely used for the benefit of patients. Such data will permit the selection of the most effective intervention for their condition from a range of small molecules, antibody and even stem cell therapies, by improving the understanding of risk factors and their quantification. Such precision approaches are already bridging the gaps in some areas of medicine, particularly in oncology and viral infection (see Figure 4).

Dr McKernan stressed that the increasing use of precision medicine is reliant on molecular pathology and biomedical informatics expertises, which must be taught in medical schools, and the facilitation of innovative companies by future funding through the support of schemes such as the MRC/Technology Strategy Board’s Biomedical Catalyst Fund.20

Precision medicine has the potential to deliver better patient stratification, more efficient clinical development and greater value due to the improved certainty of an effective response in the patient. However, there are many uncertainties; most notably what proportion of drugs will be developed for more precise patient populations, how this will

20 https://www.innovateuk.org/competition-display-page/-/asset_publisher/RqEt2AKmEBhi/content/biomedical-catalyst-1
change over time, and the impact upon R&D costs, health benefit for patients and the size of target markets.

Summary

Dr McKernan outlined how the pharmaceutical industry is becoming more flexible and nimble in changing to reflect challenges in product development.

Structural changes to functional capacity have been necessary for improved economic sustainability at Pfizer, who have moved their core functions from a consolidated model to a distributed model involving many more partnerships.

Precision medicine presents opportunities for novel approaches to product development, and the improving of patient care, by bridging the gap between the data and the patient. Two elements will be critical to the success of this approach: leveraging innovative methodology and the wealth of data from the Human Genome Project, biobanks and health records; and facilitating collaborative partnerships, such as those that Pfizer has both with academia and small biotech companies.
Panel discussion summary

The FORUM Lecture was followed by a panel discussion session chaired by Professor Sir John Tooke PMedSci, which considered "Attributes of good academia-industry-NHS collaboration models". The members of the panel included representatives from industry, academia, the NHS, a funding body and one of the two UK Life Sciences Champions.

Opening comments from the panel

Panel members introduced the discussion topic by briefly offering their perspectives on collaborative partnerships.

**Dr Chris Streather, Managing Director of the Academic Health Science Network (AHSN) for South London**, spoke of cross-sector collaborations historically being too transactional, and how AHSNs could support collaborations by assisting in researcher access to NHS data and providing methodological expertise to inform the design and interpretation of clinical trials.

**Professor Sir John Bell FRS HonFREng FMedSci, UK Life Sciences Champion**, stressed the importance of adjacent innovation - both in terms of physical proximity and inter-disciplinary co-operation - and brought to attention the obstacles currently facing collaborative interactions.

**Professor Peter Downes OBE FRSE FMedSci, Principal and Vice Chancellor at the University of Dundee**, spoke of the benefits of partnerships with industry to Higher Education Institutions (HEI), the need for HEIs to put innovation at the heart of their culture and recognise their position in the innovation chain, and how successful collaborations require efforts amongst partners to deliver what they promise and create mutual advantage.

**Dr Declan Mulkeen, Director of Research Programmes at the Medical Research Council (MRC)**, outlined the increasing complexity of working in partnership, spoke of the importance of flexibility, and warned how easily ill-informed stereotyping of one sector by another precludes collaboration.

**Dr Ruth McKernan, Senior Vice President at Pfizer and Chief Scientific Officer at Neusentis**, highlighted that determination to achieve a common goal is the key to collaboration, which helps navigate challenging bureaucratic obstacles that may be encountered.

Key factors in good collaborations

**Physical proximity**

The panel discussion identified physical proximity of collaborating parties as key to developing successful partnerships: Dr Ruth McKernan spoke highly of the vibrancy of Pfizer Neusentis’ collaboration with local academic groups and biotechnology companies in Cambridge. It was noted that such proximity can be difficult to achieve within the pharmaceutical industry, due to its global nature and the associated long-distance travel.
**Mutual benefit and trust**
The discussion highlighted mutual benefit and trust as critical requirements for successful partnership. All parties should have a clear understanding of what they hope to achieve, and deliver in their role within the collaboration.

The Division of Signal Transduction Therapy at the University of Dundee, established by Sir Phillip Cohen FMedSci, was widely acknowledged as a good example of productive industry-academia collaboration.21 The University’s appreciation of the non-financial benefits of such partnerships - including access to the assets of industrial partners such as knowledge, complimentary IP and infrastructure – has led them to place translation at the heart of their institutional strategy. This aim is reflected beyond their collaborations, in their teaching and research activities.

Dr McKernan’s experience at Neusentis also echoed comments made regarding the importance of openness and understanding between collaborating partners.

**Obstacles to good collaborations**
The main obstacles articulated during the panel discussion were those that interfere with the interpersonal relationships and momentum that drive collaboration. The process of developing contractual relationships and - sometimes - the unrealistic expectations of financial gain were highlighted as two of the primary obstacles to successful collaborations.

It was thought that success is based on getting the science done. However, the time, skill and sustained commitment needed by the academic developing a partnership – sometimes without enough support – can be considerable. Therefore university technology transfer offices must be structured to provide appropriate support and not unintentionally hinder collaboration. Although contracts need to be produced to formalise partnerships, at Dundee care is taken to ensure that this process does not interfere with the interpersonal relationships of the collaborators or impede the momentum of collaborations. Dr Ruth McKernan stated that Pfizer also supported this perspective, and cited the Pfizer-UCL collaboration to develop a cell therapy for macular degeneration as an excellent example.

**Solutions for encouraging good collaborations**

**Changing technology transfer functions**
It was suggested that diverting the responsibility for much of the administration of collaborations away from the researchers and clinicians involved should be a principal function of technology transfer offices.

**Developing education, training and infrastructure**
Translating new knowledge and innovations into healthcare, including the development and adoption of precision medicine, will increasingly require collaborative working. Developments in education, training and infrastructure - across academia, industry and the NHS - will be required to develop the skills and collaborative cultures necessary for such partnerships.

21 [http://www.lifesci.dundee.ac.uk/research/dstt](http://www.lifesci.dundee.ac.uk/research/dstt)
For example, there is a need to improve training in bioinformatics and healthcare data analysis across all sectors in the UK to develop the partnerships and skills required to develop and adopt innovative technologies. It was stated that the AHSNs will likely facilitate these improvements.

The requirement for infrastructural changes to facilitate collaboration was outlined. One issue considered was how changes to the culture of higher education institutions might ease the formation of collaborative partnerships. A further issue considered was how the NHS could link and improve access to its data: although this data is essential for the monitoring of healthcare, it is siloed within the NHS, and inaccessible to researchers in academia and industry developing new healthcare products. It was felt that this challenge could be overcome through improved inter-sector communication and collaboration.

**Improving permeability between sectors**

It was felt that more sustainable mechanisms to encourage collaboration are required, to avoid the development of laboured relationships overly concerned by contractual concerns. Partnerships based on scientific curiosity and a deeper mutual understanding of all the parties involved show more promise of being effective and productive. The discussion highlighted that greater permeability between sectors should be ensured to achieve this aim, involving temporary movement of individuals between sectors, or between institutions or companies of different sizes.

Many of the FORUM Lecture attendees relayed anecdotes of positive experiences of secondments and short placements of post-docs and academic students in industry settings. Attendees also heard how work by Pfizer Neusentis on retinal pigment epithelial cells was critically informed by attendance of their researchers at meetings of a local academic research group where they heard about cutting-edge research. The success of a recent technology transfer venture at the University of Oxford was also described as relying on individuals who were invited from industry into academia.

The discussion saw many suggestions and thoughts from the floor on how best to implement increased flexibility and flow of individuals and knowledge between academia, industry and the NHS. Many comments outlined the need to professionalise inter-sector collaborations by funding exchanges of individuals between sectors. However, one of the problems lie in encouraging clinicians to work in industry to experience how clinical trials work in a pharmaceutical setting: it was suggested that pharmaceutical company-based elective placements for medical students could be promoted.

Although the systems and mechanisms required for permeability are not widespread, it is possible to learn from and adopt current best practice at those establishments which already have successful models of movement between disciplines. For example, the experience at the University of Dundee is that the learning environment is a crucial factor. They have found that although training individuals with the skills needed to engage with different sectors is a starting point - for example taught modules on collaborative environments - practical training in an environment where collaborations are taking place provides countless advantages over theoretical education.

It was felt that development of permeability initiatives will require a lot of experimentation during the next few years, and that such experimentation will need an approachable interface between the collaborating parties to be maintained. It was noted that AHSNs could play an important role, for example, by establishing secondments between industry and AHSNs, initially in low risk ventures as a means to focus the current culture on increased permeability.
Summary

As highlighted in Dr McKernan’s lecture, the ability to translate data into health benefit will depend more and more on the success of collaborative partnerships: innovation will arise from novel perspectives gained through cross-disciplinary interactions. The culture of collaboration must change to develop mutual respect for the roles played by all actors in the innovation cycle.

Good collaborations are built on good interpersonal relationships and informed by common scientific goals and clinical need. These relationships depend upon physical proximity and trust between collaborators, which can be developed through the education, training and cross-sector placement (‘permeability’) of researchers. These activities could be facilitated by increased professional incentives and flexibility in career pathways.

Higher education institutions and technology transfer offices could facilitate collaboration most effectively by considering how to minimise the interference of bureaucracy, and other factors such as contractual negotiations, with the developing inter-personal relationships that drive good collaboration.
### Annex I Delegates

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<tr>
<th>Name</th>
<th>Position/Title</th>
<th>Affiliation</th>
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<tbody>
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