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Ensuring UK leadership in experimental medicine

A report from the joint meeting of the ABPI and BPS, October 2014

Executive summary

Recent years have seen a surge of interest in translation, with a strong focus on the first translational gap identified in the landmark 2006 Cooksey Report.[1] This is the territory of experimental medicine – broadly speaking, studies of disease processes and responses to developmental medicines in humans. Advances in this area are widely believed to be central to the more efficient development of medicines.

Experimental medicine is an area in which the UK has undoubted strengths, with strong academic and industrial sectors and growing collaboration between the two. Yet there are considerable challenges, not least concerns about skills gaps and the need for even greater connections between academia and industry. These were among the themes explored in a one-day meeting in October 2014 jointly organised by the Association of the British Pharmaceutical Industry (ABPI) and the British Pharmacological Society (BPS).

Alongside presentations from leading figures from academia, industry and funding bodies, the meeting also included discussion sessions dedicated to two key areas of experimental medicine: training in clinical pharmacology and pathology and National Institute for Health Research (NIHR) Translational Research Partnerships.

[1] *A review of UK health research funding*, 2006 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/228984/0118404881.pdf)

Introduction

Experimental medicine encompasses research at the critical interface between laboratory and clinical science. Initial studies involving human participants are challenging to conduct, and have been a bottleneck in the translation of promising lines of research.[2]

Experimental medicine is an area of extensive overlap in the interests of academic researchers and industry, and hence offers scope for fruitful collaborations between the two sectors. Many initiatives have been launched to promote greater interactions and joint work towards shared goals.

The future of experimental medicine is likely to be shaped by wider factors influencing medicines development, including the continuing evolution of stratified medicine. Medicines development is also likely to become more 'patient-centric', with trial methodologies more reflective of patients' needs and wishes.

Equally importantly, medicines development will be based on ever-growing scientific understanding of disease. This will come largely from collaboration between industry and academia, working in pre-competitive space, although there is also a need to ensure that academia can work productively with industry on commercially oriented projects.

Experimental medicine is heavily dependent on skills in clinical pharmacology and pathology. Indeed, there is an urgent need for more clinical pharmacologists and molecular pathologists with a broader training in the new tools of experimental medicine and a sound understanding of the pharmaceutical industry.

Central to the delivery of experimental medicine in the UK is the need for a skilled workforce able to design and lead early clinical studies, as well as the infrastructure and personnel required to deliver high-quality studies to industry-relevant timescales.

Both the Medical Research Council (MRC) and the Wellcome Trust have launched training schemes to attract high-calibre physicians into clinical pharmacology and translational medicine. These schemes introduce clinical fellows to a wide range of methodologies in academia and industry, to boost the skills base in clinical pharmacology and to enhance translational medicine capacity in traditional medicine disciplines. The schemes are addressing an important need. However, it remains too early to evaluate their lasting impact. Furthermore, they are relatively small-scale schemes, and continued support to increase the numbers of participants is therefore essential.

A further innovative initiative promoting interactions between industry and academia is the Translational Research Partnership (TRP) scheme, managed by the NIHR Office for Clinical Research Infrastructure (NOCRI). TRPs provide access to national networks of academic expertise and clinical resources in key areas of medicine, with NOCRI acting as a single point of contact for potential industry partners.

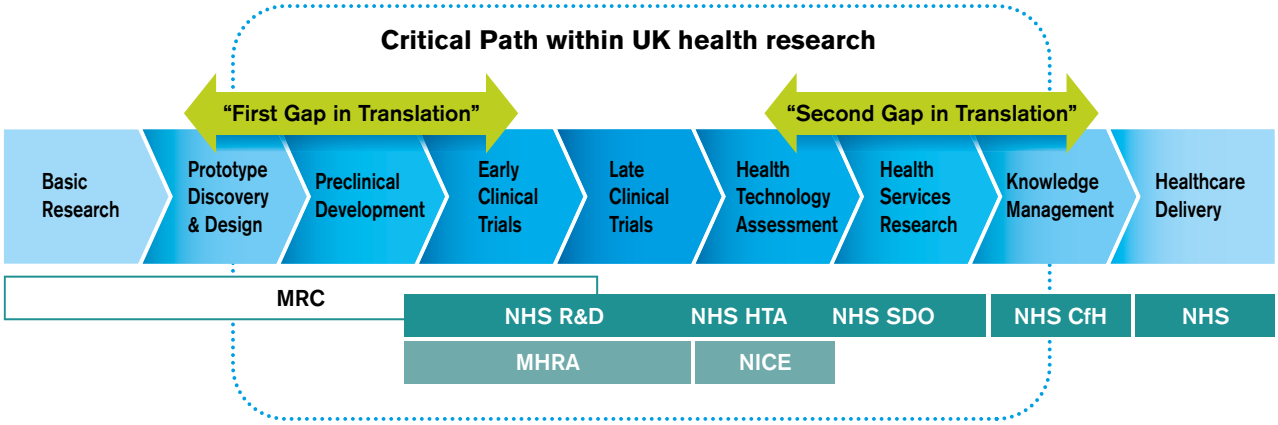
TRPs were established as a new model for industry–academia interactions during early clinical development, based on collaboration and joint development. Around 20 projects have been initiated at the two TRPs launched in 2012. TRPs have made a promising start, but there may

[2] *A review of UK health research funding*, 2006 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/228984/0118404881.pdf)

be scope to enhance their interactions with industry to raise awareness of their existence and 'unique selling points', and to ensure their activities are fully aligned with those of potential commercial partners.

The 2006 Cooksey Report[3] identified key bottlenecks in the translational medicine pathway, one of which was at the point at which potential new therapies make the transition to studies in humans. This focus has stimulated much interest in experimental medicine studies in which humans are the major focus, and the objective is to gain insight into disease mechanisms or to explore the early potential and safety of new treatments.

Figure 1: Translational gaps. The 2006 Cooksey report identified gaps in the translation of health research into healthcare improvement, as shown[4]



Interests in experimental medicine span both academia and industry. Moreover, with the growing awareness of the need to base medicines development on a better understanding of disease processes, such studies are increasingly carried out through collaborations between industry and academia with information freely shared in the public domain. Increasingly, growing scientific understanding is informing early decision-making in drug development, to reduce the risk of failure.

The UK has traditionally held a strong position in experimental medicine. In part, this has reflected the exceptional academic biomedical research base in the UK, as well as strong pharmaceutical and biotech sectors. The past decade has also seen concerted efforts from Government and funders – public and charitable – to encourage collaboration in order to accelerate translation and the development of new medicines for patient benefit.

[3] *A review of UK health research funding*, 2006 (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/228984/0118404881.pdf)
[4] Reproduced from the report: *A review of UK health research funding*, Sir David Cooksey (Crown copyright, 2006).

The MRC perspective

Opening the meeting, Sir John Savill, Chief Executive of the MRC, described how experimental medicine and encouraging academic collaboration with industry have become major themes for the MRC. This is reflected in the MRC's new Research Strategy 2014–19 ('Research Changes Lives') and dedicated funding for experimental medicine studies, as well as support through other funding routes.

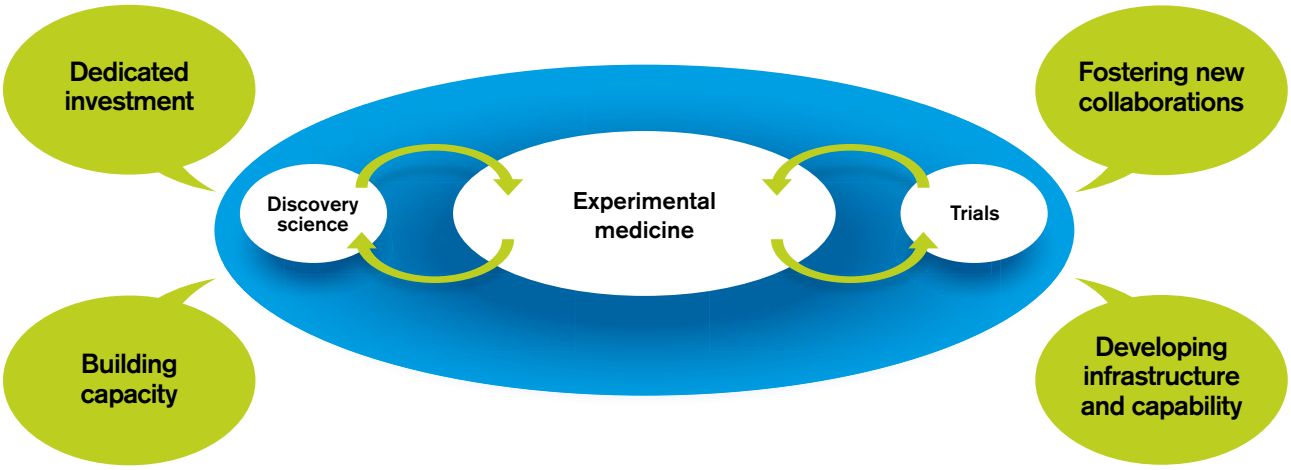
Echoing Sydney Brenner, Sir John suggested that humans were the definitive experimental model of the 21st century. However, he also acknowledged that human studies were difficult to do well, and the field had plenty of scope to develop. He pointed to examples such as the partnership between the Wellcome Trust Sanger Institute and GlaxoSmithKline (GSK) on the Centre for Therapeutic Target Validation as an example where academia and industry can work together to mutual benefit in the early development of medicines.

Sir John identified a number of MRC initiatives promoting experimental medicine and interactions with industry. These include the Experimental Medicine Challenge Grant Programme, which has committed £24.5 million to date, and deprioritised compound-sharing agreements pioneered with AstraZeneca and now extended more widely. Further important partnerships include a £60 million stratified medicine initiative[5] and the UK Dementias Platform,[6] aiming to leverage the power of population cohorts to develop a deeper understanding of neurodegenerative diseases.

Sir John also acknowledged the importance of capacity-building and addressing skills shortages. Research training for clinicians is a priority and currently being reviewed, while targeted initiatives have addressed the clinical pharmacology and molecular pathology skills base. Medical bioinformatics is a further critical area receiving major MRC investment, for example with the multi-centre Farr Institute and other support. A network of MRC Hubs for Trials Methodology Research and the Regulatory Support Centre will provide additional resources to support research on human participants. The £150 million funding in clinical research infrastructure complements the important role played by other funders, particularly the NIHR, in developing the infrastructure to support studies on humans.

[5] Medical Research Council; Our Research (http://www.mrc.ac.uk/research/initiatives/stratified-medicine/background/)
[6] UK Dementias Platform (http://www.dementiasplatform.uk/)

Figure 2: Inputs needed to drive success in experimental medicine



Sir John also drew attention to the 'proximity to discovery' initiative, which is providing seed funding to enable universities to attract large or small companies to locate close to academic centres or otherwise engage with academia.

In terms of skills shortages, Sir John highlighted the relative dearth of molecular pathologists. In the future, he suggested, with the emergence of new technologies, the field was likely to expand to include researchers from multiple other disciplines.

The future of medicines development

Having held joint positions at the University of Manchester and AstraZeneca, Professor Andrew Hughes is well placed to comment on the evolving relationship between the two sectors. He briefly summarised key trends shaping the future of experimental medicine.

The first key theme, he suggested, was the relentless growth of 'precision medicine' (stratified or personalised medicine). Many new technologies that are being developed to stratify patients are currently being evaluated by multiple centres. The field would benefit from a smaller number of specialised National Qualification Centres to standardise and streamline processes.

Professor Hughes also foresaw greater use of multi-arm clinical trials. With stratification, profiling of patients for entry into trials is costly; it would be more cost-effective if test results could guide entry into multiple trial arms. This would require greater collaboration and inter-sponsor agreements (with reworking of contract principles) but would be consistent with moves towards open innovation.

A third important area within personalised medicine is the emergence of 'niche populations'. While 'lung cancer' may be a common disease, its molecularly defined subtypes are not. Hence there is a need for greater collaboration between centres to create patient cohorts of sufficient size to adequately characterise the clinical benefits of new drugs. The Experimental Cancer Medicine Centre network is a start but needs to be expanded and enhanced, to promote collaboration and shared practices.

The second key theme identified by Professor Hughes was 'patient-centricity'. Patients are increasingly seen as active participants, shaping how studies are designed and run. One recent example has been the use of smartphones to enable patients to provide informed consent and to self-report information to trial organisers. 'Real-time' information, such as the time-course of minor adverse events, could be of benefit to other participants. This kind of approach requires dialogue and engagement with ethics review boards and legal advisers.

Similarly, new technologies are providing greater scope for real-time monitoring of patients. New visualisation tools are providing insight into ongoing physiological function and opportunities to integrate data from multiple sources. This approach could also help to identify rare adverse events before data analysis at the end of trials (although the issue of blinding naturally remains important). Dialogue with regulators will obviously be essential. There is also a need for innovative software to analyse, integrate and communicate data.

Patients themselves have the potential to input more into clinical studies and regulatory decision making. One possibility would be a 'Chief Patient Officer' representing the patient view at a senior level within companies.

The final theme identified by Professor Hughes was scientific understanding. Human physiology and pathology is massively complex, and a deeper understanding of key disease processes is urgently needed to ensure drug development has the soundest possible intellectual basis.

One focus could be on ‘inquisitive phenotyping’, with greater exploration of the effects of experimental drugs by academic partners, in order to gather new information. Greater porosity, or exchange between academia and industry, would again encourage the accumulation of knowledge. Data interoperability will also be a key issue, with data and assay standardisation assuming a central position, alongside patient consent and associated governance issues.

This new way of working calls for more extensive collaboration. Professor Hughes identified a range of principles, from single points of contact to streamlined internal communications, which promote effective collaboration.

Research skills: Scotland

Turning to capacity-building and research skills, Professor David Webb (University of Edinburgh) provided a brief introduction to the Scottish Translational Medicine and Therapeutics Initiative, funded by the Wellcome Trust, and the Scottish Clinical Pharmacology and Pathology Programme, supported by the MRC.

Professor Webb highlighted the influential view of Garret FitzGerald, who has argued that the growth of 'omics' and other technologies is broadening the discipline of clinical pharmacology beyond classical pharmacokinetics/pharmacodynamics, with major implications for skills and training.

With colleagues, Professor Webb made the case for clinical pharmacology in a commentary in *The Lancet*, backed up by landmark reports from the ABPI.[7,8] In response, the Wellcome Trust launched a Translational Medicine and Therapeutics Initiative in 2007. Scotland had a number of features that made it an ideal location for such work, including academic strengths, excellent clinical research facilities, a single health provider with a good track record of working with academia, a stable population and a strong medical informatics framework.

Edinburgh and the three other clinical medical schools in Scotland (Aberdeen, Dundee and Glasgow) bid successfully for funding of £3 million from the Wellcome Trust with matched funding from industry (Wyeth, later absorbed into Pfizer). This funding was sufficient to provide 15 clinical PhD fellowships and 20 one-year MSc places in translational medicine. The MSc was mainly targeted at individuals early in their medical training. The PhD fellowship was aimed at more senior individuals in training, with Scottish Government funding providing a stepping stone to lectureships at the end of PhD training.

Much attention was put into the selection of fellows, Professor Webb suggested. As well as aiming for academically excellent and highly-motivated individuals, the initiative worked with candidates to develop 'customised' projects, which they defended at second interview.

Once admitted, fellows receive exceptional levels of support. This includes a supervisory team of at least two individuals, discipline-based mentorship, and extensive inter-institutional support. Fellows have access to multiple training opportunities and short courses, and organise an annual scientific meeting. They also have opportunities for industrial attachments. The aim has been to create a cadre of fellows able to play key leadership roles in the field.

Fellows have come from multiple medical disciplines, and have been exposed to a broad range of experimental medicine technologies and techniques, from translational cell biology to epidemiology, and encompassing biologics as well as conventional pharmaceuticals.

[7] *In vivo sciences in the UK: sustaining the supply of skills in the 21st century*, 2007 (http://www.abpi.org.uk/our-work/library/industry/Pages/in-vivo-report.aspx)
[8] *Skills needs for biomedical research: creating the pools of talent to win the innovation race*, 2008 (http://www.abpi.org.uk/our-work/library/industry/Pages/skills-biomedical-research.aspx)

Research skills: North-West England

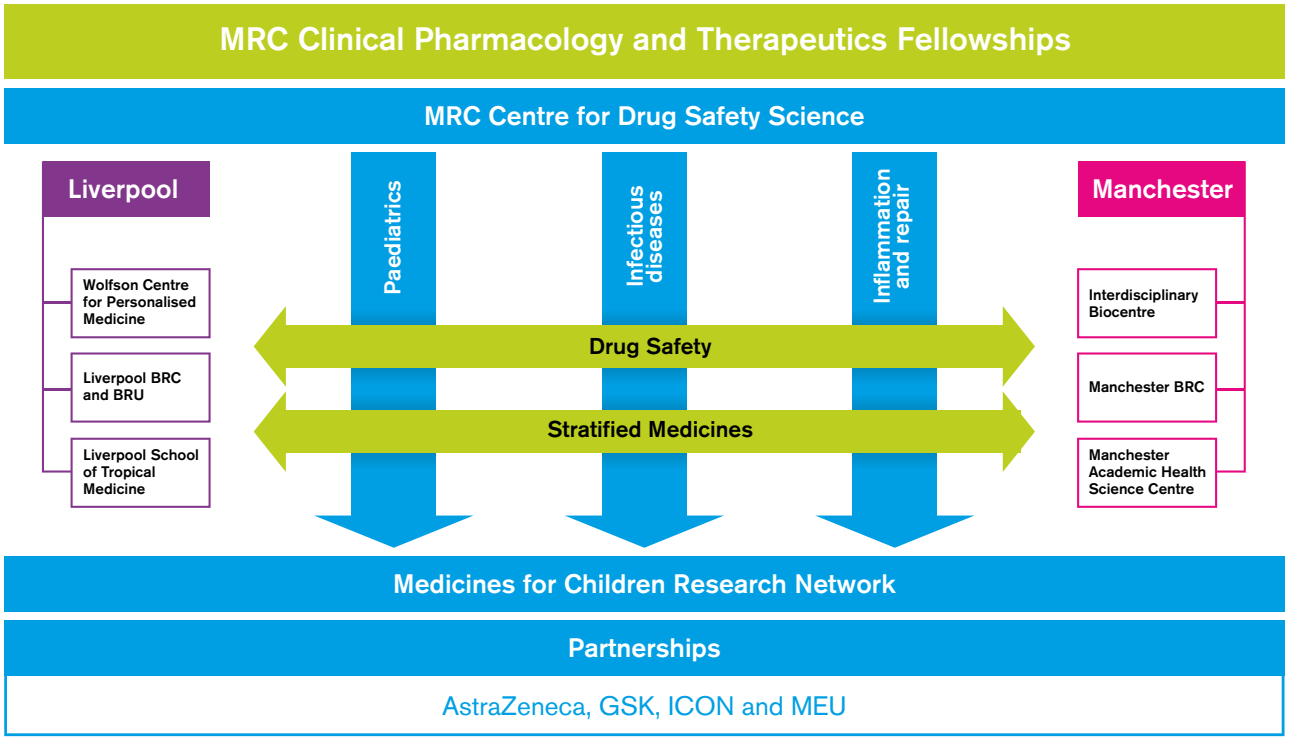
In the second presentation on skills development, Professor Munir Pirmohamed (University of Liverpool) described the North-West England MRC Fellowship Scheme in Clinical Pharmacology and Therapeutics.

Professor Pirmohamed drew attention to a third influential document, the 2009 Office for Life Sciences' Blueprint, which recognised the importance of clinical pharmacology and pathology and fed into the development of the MRC Clinical Pharmacology and Pathology Fellowship Programme. The North-West England initiative was one of two funded through this programme.

The initiative is a partnership between the universities of Liverpool and Manchester and industry partners including AstraZeneca, GSK, ICON and MEU. It is rooted in the MRC Centre for Drug Safety Science but integrates expertise from multiple academic centres in Liverpool and Manchester. It focuses on three main areas – paediatrics, infectious disease, and inflammation and repair – with drug safety and stratified medicine as cross-cutting themes. It aims to provide 'without walls' training, with fellows able to work seamlessly across the multiple centres involved.

Figure 3: Structure of the MRC Fellowships

This figure shows the collaboration between the universities of Liverpool and Manchester and the focus of the scheme (broad themes of drug safety and stratified medicine are addressed in three clinical areas).



As in Scotland, great attention has been paid to recruitment, with a similar two-step interview process and scope to develop project proposals between first and second interviews. Some 13 fellows have been recruited, the first three of which completed their PhDs in 2014.

The initiative has benefited from a dedicated programme manager and a management board with representatives from academic institutions, industry and deaneries, to ensure close integration with clinical training. Fellows have undergone a wide-ranging training programme, in academic centres, industry and at regulators – there are 91 session leaders including 35 from industry, 28 from academia, nine from the NHS and 15 from regulatory bodies. The programme has organised an annual showcase for fellows and facilitated extensive national and international networking.

Fellows have had opportunities to work with industry. Professor Pirmohamed drew attention to the work of one fellow, who has worked with a range of industrial contacts on a highly promising method for stratifying patients with drug-resistant epilepsy, which is leading to the testing of potential new therapeutic strategies in animal models.

In terms of future careers, around a third of the fellows plan to stay in clinical pharmacology while the others are pursuing particular medical specialties. Nevertheless, fellows will be able to apply clinical pharmacology and experimental medicine skills in their medical specialty.

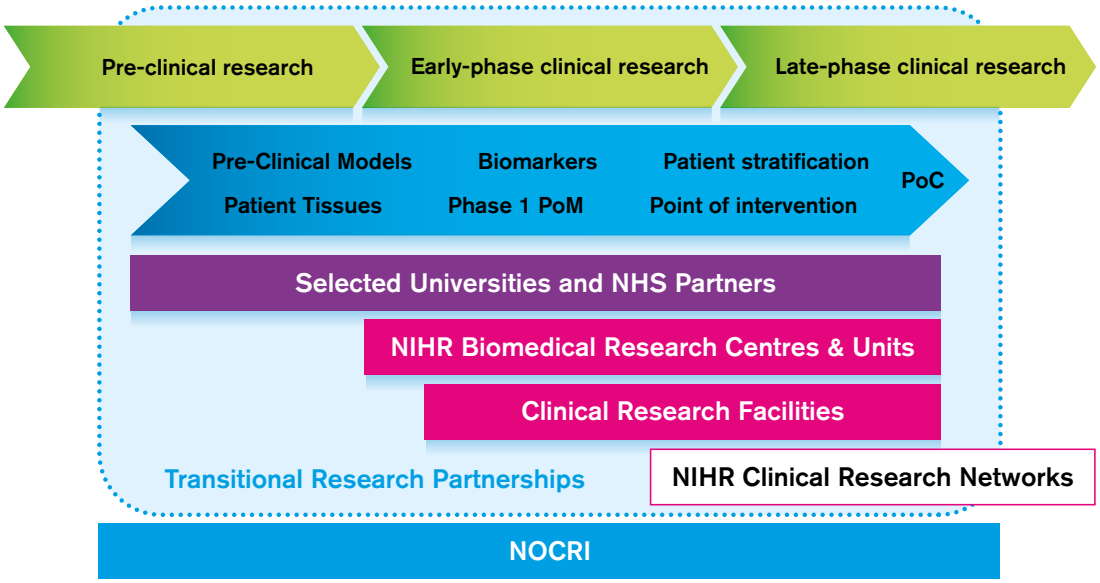
Professor Pirmohamed suggested that further engagement with industry would be advantageous, such as one-year post-PhD placements. This would, however, require further time out from clinical training.

Translational Research Partnerships: the academic view

The origins of TRPs, suggested Professor Ian Bruce, Academic Lead for the Joint and Related Inflammatory Diseases TRP, date back to 'therapeutic capability clusters' first proposed in 2010. These targeted areas of high unmet medical need, where the UK had underlying strengths, and there was potential to drive forward new and improved treatments. The clusters were to focus on inflammatory respiratory disease and joint and related inflammatory diseases, and phase Ib/IIa trials. They were anticipated to attract considerable industry collaboration, which would gain access to world-leading expertise and ideas and in return provide access to laboratories and resources and publish findings.

Following the 2010/11 Life Science Strategy and Plan for Growth, clusters ultimately morphed into TRPs, formally launched in autumn 2011. Each TRP would have both an academic and business lead in each institution. TRP network members would have formal collaborative agreements, and NOCRI would act as a single point of contact, with standardised non-disclosure and other legal agreements.

Figure 4: Structure and capabilities of NIHR Translational Research Partnerships



TRPs occupy a specific niche, based on genuine collaboration in early clinical development, distinct from contract research or phase III trials (for which other mechanisms exist to support interactions with academia).

The Joint and Related Inflammatory Diseases TRP brings together nine leading academic groups from around the UK, as well as associated NHS partners. It covers rheumatoid arthritis, systemic lupus erythematosus, psoriatic arthritis and a range of other disease areas with varying levels of unmet medical need, including skin conditions. The Inflammatory Respiratory Disease

TRP, similarly spanning nine academic and NHS partners, focuses on chronic obstructive pulmonary disease and other important respiratory conditions.

One important role of TRPs, suggested Professor Bruce, was to unite different elements of local health research infrastructure, such as NIHR Biomedical Research Centres and Units, Clinical Research Facilities and Clinical Research Networks, plus wider research in academic centres. TRPs provide a way to navigate what can be complex territory.

He also suggested that TRPs provide a unique opportunity to address the challenges of early clinical development. They provide a seamless transition from pre-clinical to clinical phases, incorporating first-in-human studies as well as associated biomarker and mechanism of action studies, and potential for proof-of-concept studies in well-characterised patient cohorts. Notably, through a single point of contact, NOCRI, industrial partners can gain access to some 30 world-leading UK institutions.

Nearly 20 projects are in various stages of development and maturity across both TRPs. Most, but not all, have been industry-sponsored, and there is scope for academic investigator-led ideas to be taken forward in collaborative projects. Projects include early studies of new therapeutics, as well as pre-clinical studies and research on target identification/validation.

Discussions ensure that projects are the right 'fit' for the TRP model. Sometimes, therapeutics are at too early a stage for experimental medicine studies, or clinical development too advanced for TRPs to add value. In these cases, the TRPs and NOCRI can still signpost companies to a more appropriate part of the higher education institutions or NIHR research infrastructure. Notably, TRPs can also highlight new opportunities in relatively neglected disease areas. Several projects in Sjogren's syndrome and interstitial lung disease have been launched after academic input.

Professor Bruce also highlighted challenges that have emerged during the early years of TRP operation. Late withdrawal from projects by industry has on occasion been an issue. TRPs also face a difficult balancing act, with local resources also in demand from, for example, phase III trials. The size of networks is also an issue – smaller collaborations are easier to coordinate but reduce the number of patients that can be accessed. On the other hand, coordination of TRPs with other clinical and translational research infrastructure can enable local centres to establish integrated systems that are more than the sum of their parts, and deliver enhanced care to patients.

Translational Research Partnerships: the industry view

Continuing the TRP theme, Dr David Close (MedImmune) provided an industry view on their approach and operation.

Dr Close pointed out that pharmaceuticals is a global business, and companies think globally when deciding where and with whom to work. There needs to be a compelling answer to the question 'Why choose the UK?'

The TRPs have created an excellent foundation for interactions with industry, Dr Close suggested, at an important stage in clinical development. They open up networks of world-class experts when previously companies would have approached researchers individually.

Work within TRPs can provide important information to guide commercial decision making, with increased scientific evidence of compounds' disease-modifying potential. Information can be generated at an early stage of clinical development to guide the choice of disease area to be targeted.

Indeed, suggested Dr Close, TRPs have several strengths valuable in early clinical development. These include the potential to carry out biomarker and mechanism-of-action studies before or in parallel with first-in-human studies, as well as access to well-characterised patient cohorts to support proof-of-concept work. Access to retrospective cohorts, data or samples can also be a critical test of whether the most appropriate condition has been targeted. And as well as interventional studies, associated non-interventional investigations can provide further useful data. Work with TRPs can also provide important input into target product characteristics.

These strengths translate into a number of possible opportunities for industry. These include a greater awareness of disease mechanisms to shape intervention strategies, as well as an important clinical perspective that ensures such strategies are aligned with current clinical practice. The potential is for both faster and more cost-effective early clinical development, with more informed go/no-go decision making based on data from patients.

However, industry has well-established development models and has expectations of process and timelines. TRPs need to be aware of and sensitive to these competing demands, while industry may have to show more flexibility to gain full benefits from engagement with TRPs.

Finally, Dr Close asked whether industry fully understands TRPs, and whether TRPs fully understand industry. Industry may be inclined to adhere to established methodologies, and may not appreciate the value that working with TRPs could add. In particular, company staff outside the UK may not be familiar with TRPs or appreciate the benefits of working with them rather than academic groups in, for example, the USA. Industry may also not fully understand the niche that TRPs occupy in the translational landscape, distinct from contract research organisations or other bodies to which it may outsource work.

Similarly, there may be scope for TRPs to engage further with industry to understand their needs and expectations, and to ensure that their work can integrate efficiently with industry. At individual TRPs, it is essential to have individuals familiar with the sector liaising closely with industry partners, and more generally there may be benefits in approaches such as TRP–industry fellows.

Breakout discussions: Training schemes

The two schemes discussed earlier have been designed to build capacity in translational medicine and are thus addressing an important issue. However, with only around 100 individuals being trained over the past four years, they are obviously limited in their potential impact. The focus should therefore be on *continuing support* to generate a critical mass of individuals with appropriate skills in experimental medicine to drive continued success in the UK. It is also important not to concentrate on short-term measures of impact, and it will therefore be crucial to follow up the cohorts to assess what career paths trainees had subsequently followed and what impact their work had had on translational medicine.

There was a discussion of various training schemes from an industry point of view. Here concern was highlighted that from past experience the potential benefits to industry of schemes designed to increase mobility between academia and industry had not been consistently realised. Questions were raised about whether current fellows have established close enough ties with industry. It was noted this depended on the definition of success – whether measured by collaboration, or movement into industry. A number of examples were given of fellows working alongside industry partners in the course of their PhD. It was also emphasised that the schemes were not solely designed to increase capacity in first-in-human studies, and the fellows who had successfully completed their training had expertise in many different aspects of translational medicine, including early phase studies. Industry representatives particularly stressed the importance of a workforce sufficiently skilled to design early clinical studies, as well as an infrastructure and personnel to deliver such studies, at a standard and speed to ensure the UK is globally competitive.

A comparison was drawn with a PhD programme in chemistry run by GSK, where students spend most of their time in industry with a short period at Strathclyde University. However, clinical fellows tend to be older and may be geographically less mobile, which could present issues. Research on human participants is also expensive, raising questions about resourcing. However, it was noted that it was important to encourage such fellows to keep a human focus to their work. This could feasibly have an impact on the amount of data generated and opportunities for publication. Alongside this, in the past, work on commercially sensitive projects has presented problems for publication, but this may now be less of an issue. In general it was agreed that account should be taken of such difficulties in securing publications when setting recruitment requirements at the next level (usually clinical lectureships).

The desirability of having strong industry links in clinical research training schemes was repeatedly stressed. A previous ABPI scheme supported a year in industry, which was felt to be beneficial. A concern about three-month placements was that they provided little time to integrate fellows fully into projects. However, it is not straightforward for medical trainees to take time out from clinical training, particularly in England where Local Education and Training Boards (LETBs) may have little flexibility – demand for a consultant-led health service providing a more powerful driving force. More could be done to raise awareness of these conflicting priorities and the importance of allowing clinicians to move out of programme, perhaps through discussions with the Chief Medical Officer. Flexibility with industry interactions was also important – while it may not be possible for fellows to spend prolonged periods while undertaking their PhDs, there may be opportunities later – for example with postdoctoral placements, fellowships after completion of clinical training, and joint positions between academia and industry.

It was also suggested that medical students and junior doctors frequently have negative views of the pharmaceutical industry. Often, their main contact with industry is through sales representatives, and it would be helpful if they had greater exposure to scientists and medics working in industry to gain more insight into their roles, for example, through career case studies.

It is important to ensure that trialists of the future are coming through training and into the NHS. This cannot depend solely on those coming through schemes such as the MRC and Wellcome Trust fellowships. It was noted that phase I studies are part of the clinical pharmacology and therapeutics specialty training curriculum. Consultants in this area could make an important contribution to phase I studies (and therefore deliver training to a wide range of specialists who could act as future trialists), but as a recent BPS report[9] has highlighted, there is a relative dearth of suitable training posts and consultant positions, a serious disincentive to doctors considering the area as a career.

[9] *A Prescription for the NHS: Recognising the value of clinical pharmacology and therapeutics* (http://www.bps.ac.uk/details/news/6901701/BPS-Warns-More-Clinical-Pharmacologists-Needed-to-Improve-Health-of-Patients-and.html)

Breakout discussions: TRPs

In breakout sessions, participants discussed how well TRPs had achieved their aims and what might lie in store for them in the future.

The consensus was that they had made an encouraging start, and that it was too soon to draw firm conclusions about their lasting impact. NOCRI has established a range of key performance indicators for TRPs, but these are largely short-term and operational measures – such as industry engagement, contracts negotiated, and numbers of patients enrolled – that would not be suitable for judging long-term impact.

There was a feeling that the TRPs were taking time to become established, but that this was not unexpected given that they offer a radically different model of industry engagement. Industry has well-established and effective ways of interacting with academia, which TRPs are aiming to complement in specific areas, but it will take time for an awareness of their niche to filter through into industry.

Nevertheless, it was also felt that awareness of TRPs was low, even within UK-based industry. The value of using TRPs, rather than contract research organisations or independent academic experts, was not widely appreciated. Hence, TRPs could usefully aim to raise their profile nationally and internationally, for example through roadshows. In particular, it was suggested that the TRPs website was not sufficiently user-friendly for potential industrial collaborators, especially those from outside the UK. The complex 'brand hierarchy' – NHS, NIHR, NOCRI – may also inhibit clear communication.

Hence, it was suggested that NOCRI could aim to develop its industry engagement, with the joint aims of fully understanding industry's needs, raising awareness of TRPs and their advantages, and gathering input into redevelopment of the TRPs website.

The underlying principle behind TRPs was still felt to be valid and to offer distinct advantages to industry. There was some concern about variation in costings across centres, although overall costs were felt to be reasonable. It was also pointed out that the quality of data generated was crucial, and value for money more important than cost per se. The speed at which studies can be established and delivered is also critical.

Third-party funding of 'add-on' studies, to gain more understanding of underlying mechanisms, was also felt to be desirable. Although examples exist, it is not yet common. Industry may not see the need for additional information, and the timelines associated with academic funding applications are generally not compatible with industry's 'need for speed'. The possibility of national resourcing was raised, to manage variable demands and to generate momentum as TRPs build up their portfolio.

As for future development, the potential to engage further with the biotech sector was raised. However, in general, larger pharmaceutical companies are better placed to establish the kind of strategic partnership characteristic of TRPs. Pharmaceutical companies may also be more able to take a broader perspective and consider alternative indications for a developmental drug.

Additional TRPs could be envisaged in other disease areas, such as orphan diseases, although this could lead to a complex environment. Alternatively, existing TRPs could expand their remit into related areas, although larger networks might be harder to coordinate.

One imaginative proposal was for TRPs to focus more on mechanistic approaches, reflecting the growing realisation that diseases affecting different organ systems often share underlying mechanistic similarities, such as immune system involvement. However, although some companies are beginning to adopt this approach, it is not the standard industry way of working, and could potentially create a disconnect between TRPs and industry when closer alignment is desirable. Furthermore, the need to align with clinical practice adds further constraints.

It was agreed that it would be beneficial to hold further meetings between industry representatives and NOCRI/TRPs to follow up points raised in discussions and to help raise the profile and effectiveness of TRPs.

Recommendations

Training

This meeting identified that skills in clinical pharmacology and pathology are crucial to experimental medicine and highlighted the need to move towards a critical mass of individuals with expertise in translation.

An enabling environment for physicians to move off-programme for research training is needed. This must be recognised as an investment, especially in terms of creating a cohort of individuals capable of bridging academia, NHS and industry. The best trainees are likely to be attracted into research positions by having a clear and secure career trajectory.

The long-term impact of current training schemes should be measured, recognising the aim to build capacity. Research training must be considered as one component of moving towards a critical mass of expertise and therefore growing aligned workforces (e.g. clinical pharmacology and therapeutics consultants, for whom training in research/clinical trials is a key component of the specialty curriculum).

TRPs

Interactions with industry need to be enhanced by raising awareness emphasising the 'unique selling points' that TRPs can provide. Further meetings between industry representatives and NOCRI/TRPs were highlighted as a next step.

Association of the British Pharmaceutical Industry
7th Floor, Southside, 105 Victoria Street, London SW1E 6QT
Tel: 0207 930 3477 Email: abpi@abpi.org.uk

British Pharmacological Society
16 Angel Gate, City Road, London EC1V 2PT
Tel: 020 7239 0171 Email: info@bps.ac.uk

abpi.org.uk

www.bps.ac.uk

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