GLOBAL CHALLENGES IN DRUG DISCOVERY AND DEVELOPMENT

Report of a workshop organised by the ESRC Innogen Centre and the Association of the British Pharmaceutical Industry (ABPI)

Date: Thursday, January 25th 2007

Venue: The Raeburn Room, Old College, University of Edinburgh

Attendees:

1. Dr Frank Walsh, Head of Drug Discovery for Wyeth Pharmaceuticals
2. Professor Joyce Tait, ESRC Innogen Centre, Edinburgh University
3. Dr James Mittra (Research Fellow) Innogen Centre, Edinburgh University
4. Sir Alan Langlands, Principal of Dundee University
5. Catriona Graham (Scottish Executive)
6. Dr Geoff Burns, Director Pharmaceutical & Clinical Sciences, Charles River Laboratories
7. Nicky Lilliott Director of Regulatory Affairs, ABPI
8. Jim Jackson, Chief Executive of Alzheimer Scotland
9. Gino Toffano, Consultant for Wyeth Research in Europe & Asia
10. Ken Snowden, Co-Director of the Life Sciences Cluster at Scottish Enterprise (part of day)
11. Dr Robert H. Sands, Head of Medical Affairs, Sanofi-Aventis on behalf of Nigel Brooksby, Chief Executive of Sanofi-Aventis (President of ABPI)
12. Dr Diane Thomson, Government and Health Policy Manager Scotland, Wyeth Pharmaceuticals
13. Dot Anderson, Pharmacy Adviser to ABPI Scotland

Multinational pharmaceutical companies continue to face a number of global challenges. On top of the usual uncertainty about which research areas will lead to the next big breakthrough, many new issues will affect the future of the industry. These include how to bring radically new types of product to the market and sustain strong drug pipelines; a changing regulatory and post-regulatory environment, the impact of health service purchasing policies and other market-related factors; and stakeholder acceptance of new drugs and their associated benefits and risks. Until recently, the industry has been robust enough to cope with this turbulence in both internal and external operating environments. However, a systemic combination of circumstances has led industry to explore new models and strategies for translating new therapeutic discoveries into clinically beneficial products that can be delivered quickly to patients.

The aim of the Innogen/ABPI workshop was to bring together, for the first time, high-level managers from the pharmaceutical industry, representatives from key regulatory authorities and patient-support groups; clinicians and health care policymakers; as well as research scientists, to discuss the current global challenges of drug R&D and explore the benefits and problems associated with new translational models for delivering health innovation. A key focus was the Translational Medicine Research Collaboration (TMRC) recently established in Scotland, which involves the multinational pharmaceutical company Wyeth, Scottish Enterprise, four leading

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1 The views presented in this report are those of the workshop participants and do not necessarily reflect the views of Innogen or the Economic and Social Research Council

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Scottish universities and the Scottish NHS working together to improve the health innovation system. Innogen’s primary role was to set the agenda for the meeting, in consultation with ABPI Scotland, and chair the discussion sessions. ABPI Scotland took primary responsibility for recruiting delegates.

The workshop began with a keynote address by Dr Walsh (Head of Discovery Research at Wyeth) followed by roundtable question and discussion sessions involving invited participants. This report provides a detailed account of the discussions that took place in Edinburgh.

**Presentation by Dr Walsh – Global Challenges in Drug Discovery and Development**

Dr Walsh’s presentation focused on the innovative Translational Medicine Research Collaboration (TMRC) involving Wyeth, Scottish Enterprise, the Scottish NHS and the universities of Edinburgh, Dundee, Glasgow and Aberdeen, in the context of the R&D challenge currently facing the pharmaceutical industry. A number of key issues were raised in the talk.

Dr Walsh described TMRC as a genuinely innovative, world class and timely response to the R&D challenge facing the industry as a whole. These challenges include the rising costs of R&D with declining product output, Wall Street demands for growth, patient demands for better medicines, regulator’s demands for safer therapies and government demands for cheaper medicines. Recent announcements of job losses at Pfizer and GSK raise the question of whether size is still important for modern pharmaceutical R&D.

Wyeth is around number ten in the pharmaceutical company league tables and spends approximately £3 billion per year on R&D. Dr Walsh explained that his department’s discovery budget is £300 million and during his time at the company, Wyeth has seen around 75 compounds go through to clinical development, which is probably one of the highest levels of productivity in the industry. He referred to a Boston Consulting Group report, sponsored by Pfizer, which showed that the cost of putting a compound into clinical development at Wyeth was half that of its major competitors.

A major challenge for industry is to understand better the complexity of biological systems and associated hurdles, such as intellectual property, commercial and regulatory issues. The problems are not predominantly in discovery research, but in successfully bringing new compounds into the clinic. Attrition rates due to problems of safety and efficacy are a major problem, and often therapies fail because they are not economically viable. The challenge, according to Dr Walsh, is how to identify the most promising candidates earlier in development. Here, translational medicine becomes increasingly valuable as a tool to bridge the gap between pre-clinical and clinical studies. It is expected that TMRC will give Wyeth a better understanding of the behaviour of experimental medicines in humans and enable cost effective determinations of safety and efficacy through the use of biomarkers. As an example, Dr Walsh talked about current methods of assessing the efficacy of medicines for Alzheimer’s disease, which focus on cognitive changes. This can be complex, costly and, because the patient is continuously deteriorating, make accurate measurement difficult. Wyeth is exploring new mechanisms, such as imaging and MRI scanning to look at pathways of cognitive enhancement. They are trying to incorporate these types of measurement into clinical trials to identify surrogate markers for the drugs. Another example described by Dr Walsh was oncology, where there is an increasing need for patient stratification and sub-grouping. For instance, not all patients respond to AstraZeneca’s Iressa (clinical trials showed that Japanese patients with a specific mutation in a growth receptor tended to respond positively). The idea of personalised medicine is becoming increasingly popular, and Wyeth is developing this proactively in cancer trials according to Dr Walsh.

Dr Walsh also talked about the need for greater collaboration between academia and industry. Wyeth looked at many opportunities around the world before choosing to establish TMRC in Scotland. It wanted to avoid the conventional model of “no strings attached funding” and develop a new public-private joint funding partnership model focused on disease mechanisms. The basic idea is to share both risks and rewards. Wyeth has many productive and skilled bench scientists but does not have ready access to patients and clinical data. TMRC enables Wyeth to work with specialists that have access to a well characterised patient population. The long-

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2 Iressa is a tyrosine kinase inhibitor for the treatment of cancer
term goal is to validate newly discovered biomarkers, put them into a clinical assay, and thus create intellectual property and the ability to commercialise the biomarkers. This, according to Dr Walsh, is a “Hub and Spoke” model with each partner bringing a broad range of skills and expertise. TMRC managed to put in place so-called shared IP and an umbrella agreement. The first TMRC laboratory was opened in Dundee.

Dr Walsh argued that here are a number of key benefits to this model:

- For Wyeth, better translational research will hopefully lead to better compounds for therapeutic treatment and improvement in decision-making about phase 2 clinical trials.
- For academia, TMRC promises to deliver a much better understanding of disease and its associated biological pathways.
- For the NHS partners, the ability to maximise the value of the clinical infrastructure is seen as a key benefit of the model.

Scotland was an attractive location for Wyeth to base the collaboration because of its relatively stable and static population, existence of a single healthcare provider and very good health informatics, such as patient identifiers/disease registries; established and accruing tissue banks, and world class pre-clinical and safety research base.

Since 2006, TMRC has funded 28 projects selected from 81 submissions (at a cost of £8 million). Wyeth is working in five therapeutic areas – cardiovascular medicine, inflammatory disease, neuroscience, oncology and women’s health. According to Dr Walsh, Scotland’s clinical expertise in cardiovascular disease, and the high level of heart disease in its population, means the country is a good place to conduct translational medicine for this disease. Translational medicine will address the phase 2 attrition problem and, through the collaboration, biomarkers will be identified that can help Wyeth understand better the behaviour of its candidate drugs in clinical patients.

Questions/Discussion from workshop participants

Governance/Management

Jim Jackson (Alzheimer’s Scotland) – Could you say a little bit about how translational medicine is managed/governed and who actually chose the initial 28 projects?

Dr Walsh responded by that although this is a collaborative venture, Wyeth has to ensure that the areas of interest map back to specific areas of interest to the company; particularly the five core therapeutic areas. Nevertheless, there are many diseases within these five areas. Regarding governance, Dr Walsh argued that a lot of time was spent devising an appropriate structure. For the most part, TMRC is managed through a number of committees. It is the scientific committee that approves funding for projects, and this is a joint committee with 11 members (three from Wyeth, and eight from the NHS and universities). Once projects are funded, they are referred to the steering committee, which approves the research budget and evaluates success. Project proposals are, according to Dr Walsh, far more interactive than standard research council grant applications. “Wyeth scientists meet with, discuss and almost solicit applications from the scientific community”.

Industry Challenges/Commercial Environment

Prof Joyce Tait (Innogen) – You started off, I think at the beginning of your talk, citing Wyeth costs for R&D being half of many of its competitors. Do you know why this is?

Dr Walsh stated that this figure applies only to discovery research, not to the whole of R&D. He argued that every company has its own preferred way of doing business. Wyeth has historically been a “thrifty and cost
conscious company”, reflected in the fact that it has always been listed as ‘long term stock’ on the US market. Across the industry there is generally a lot of waste and duplication of activities. The cost of developing a drug at Wyeth (the way Boston Consulting measured it) is roughly $17 million per candidate into the clinic. One of the other companies is $34 million. Dr Walsh believed that this is a significant difference. “At Wyeth you seem to get two for one”. Dr Walsh argued that this was not because Wyeth puts more compounds into the clinic that do not work. The report included an assessment of the success rates for particular compounds, and again Wyeth came top. “Wyeth is therefore a very lean, but also very productive organisation”.

Prof Joyce Tait: Is this because of intelligent use of translational medicine?

Dr Walsh replied that translational medicine is very much part of it. He also emphasised the important issue of company size/industry consolidation. Many companies, especially those that have undergone large scale mergers, have excess capacity which results in a downsizing of the drug discovery business. This has happened at GSK according to Dr Walsh. Wyeth is very much “right sized” from target identification right the way through to candidate selection. It has the same resource at each stage of development. Dr Walsh stated: “I can assure you that this is not the case with companies that have undergone recent mergers, where they simply take everything, throw it together and call it drug discovery and development.”

**Intellectual Property/Benefit Sharing**

Dr Geoff Burns (Charles River Laboratories) - Please could you clarify the intellectual property situation? In identifying biomarkers, does this ensure limited use by Wyeth?

Dr Walsh responded by claiming that IP is a fundamental part of the collaboration, but Wyeth do not expect exclusivity. He argued that of biomarker tests are to be of value, it is important that the maximum number of people use them. The IP will be “licensed out”. Ken Snowden (Scottish Enterprise) explained that the license may be to the spin-out company or other Scottish companies and this increases the economic value. “There is catalytic learning through working with Wyeth”. Many people assume that there is secrecy around the development of biomarkers, but in Alzheimer’s disease, for example, it is important that all the Principal Investigators and companies interested in Alzheimer’s disease are using the same marker. Dr Walsh reiterated the point by citing a related project Wyeth is conducting with the National Institute of Aging in the US on Alzheimer’s disease (a multi-company funded initiative involving the Institute of Aging, the FDA and others). “The question being asked is whether we can come up with additional clinical end points other than the cognitive endpoints in Alzheimer’s disease. A lot of work, some of it from the Institute of Neurology in London, shows that the brain shrinks in Alzheimer’s disease. The question is can we use, in very crude terms, brain shrinkage as a surrogate marker.” Dr Walsh also claimed that it would be “preposterous” for Wyeth to be working in an exclusive way on this research, rather than multiple academics and commercial organisations. A non-exclusive approach will lead to better outcomes.

**National Context of Collaboration**

Sir Alan Langlands (Dundee University) raised a point about the complexities of the Scottish context of the collaboration; in that many of the issues in Scotland are influenced by broader UK policy. The research councils and charities, for example, are all UK based. There are also changes in the boundaries between the MRC and the Department of Health. He asked for an industry perspective on doing business in the UK, and what issues needed to be addressed. Sir Alan Langlands suggested that there is a high level of support and understanding of the dilemma of how to support innovation on the one hand, and having to restrain and restrict health care costs on the other.

Dr Walsh claimed that compared to the US, the UK does not seem a particularly attractive place to invest in. Although the UK has a very successful pharmaceutical industry, “there is complacency at the level of government, which is both surprising and disappointing”. He stated: “I don’t believe that the policymakers understand how fickle or how transient the presence or absence of companies can be.” This can be contrasted

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3 It is important to note that the FDA is generally against the granting of IP on biomarkers.
with Ireland, where the government has a good investment policy. Wyeth invested £2 billion in the world’s largest biopharmaceutical plant, located at Grange Castle, Ireland. Many companies may choose to close down their R&D facilities in the UK if the situation does not improve. Dr Walsh proceeded to claim that since there has been a devolved government in Scotland, where there is money available, there has been a more entrepreneurial industry-friendly approach in the UK. Scotland is an attractive place to invest “because you have a set of individuals at Scottish Enterprise and the universities, who are able to mobilise resource, mobilise funding and actually make it attractive for companies to come here. I don’t think Scotland is getting that much help from UK Plc." The paradox, according to Sir Alan Langlands, is that the scientific community is almost entirely dependent on UK funding streams (Wellcome, Cancer Research UK etc) “so it is a tricky balance”.

Dr Walsh also discussed the issue of globalisation and its effect on national policy. He stated that “we are now in a world where the playing field isn’t just Europe”. Last year Wyeth wanted to increase the scope of its chemistry organisation (40% of Walsh’s scientists are chemists). The company conducted the largest ever pharmaceutical deal with an Indian company. By the end of this year, Dr Walsh expects to have an extra 200 chemists working full time for Wyeth at a very favourable cost and quality. Wyeth had talked to the DTI, but the deal was uncompetitive compared to the rest of the world. Many parts of the value chain in drug discovery and development are moving elsewhere.

### Challenges of Clinical Trials

Dr Walsh pointed out that the UK is not currently an ideal place to conduct clinical trials, and there are a number of reasons for this. One reason is that centres often fail to recruit sufficient patients to the studies. “In other parts of the world, you can recruit, get the data and there is no difference in quality.” Dr Robert Sands (Sanofi-Aventis) pointed out that the McKinsey report also endorsed this view that the UK was an unattractive place to conduct clinical trials. He stated that “basic science in the UK is probably rated as one of the best in the world, but the more clinical stuff is poor and, certainly at Sanofi-Aventis, they are finding it difficult to persuade colleagues to conduct studies here. Sanofi-Aventis are continuously losing personnel to Eastern Europe and elsewhere. Furthermore, despite government initiatives, and the efforts of UKCRC, costs are still going up while quality is going down. It is all very bleak for clinical researchers in both commercial and non-commercial sectors”. Dr Walsh stated that this view has also been expressed by his clinical colleagues at Wyeth. For oncology trials run by Wyeth, the cost per patient is $100,000. He stated: “If you set up a centre that’s going to recruit 50 patients and you don’t get any, which often happens, that is a huge loss. The industry is saying that it has had enough and that it will go elsewhere. Wyeth have a facility that is coming on-stream in Shanghai where the number of patients they get in a day is greater than you could find in months at some UK centres”.

Prof Joyce Tait asked Dr Walsh if he had any information on why the recruitment rate is so low. He responded that he had no definite answer, because this is not really his area. However, one issue is that “the process is very slow and putting contracts in place with Trusts/hospitals can be extremely complex and cumbersome”. Furthermore, the bureaucracy and time taken to get ethical approval for trials is increasing. Prof Joyce Tait then asked whether streamlining recruitment might help. Dr Walsh stated that the timeline (also known as “white space”) between coming up with the protocol and actually getting the patient’s first visit is “huge” in the UK, largely as a result of the approval process. All the pharmaceutical companies share this concern. Dr Walsh claimed: “We’ve seen in our own collaboration that by having an umbrella agreement, you can actually get things done a lot faster. We don’t have to reinvent the wheel”.

### Public Perception/Engagement and Assessing Clinical Evidence and Risk

One key issue associated with the clinical trial problem that was discussed by the workshop participants was public perception and engagement with industry. Dr Walsh considered this a major challenge. He asked, “How

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4 The DTI is now known as the Department for Business, Enterprise and Regulatory Reform
6 See the impact of the “Clinical Trials” directive on the cost and conduct of non-commercial cancer trials in the UK, European Journal of Cancer, Jan 2007, pp. 8-13.
do you streamline clinical trial processes yet maintain public confidence about ethical practice, confidentiality, patient information, etc?” A great disappointment, according to Dr Walsh, was survey data showing the pharmaceutical industry to be near the bottom of the list of organisations/industries that the public trusts. He believed that the ABPI has a role to play in improving public opinion. In the US, this is not helped, according to Dr Walsh, by direct to consumer advertising. Nicky Lilliott (ABPI) noted that “one-off incidents such as the Northwick Park clinical trial make a major dent in public confidence, yet the number of patients volunteering for clinical trials increased after the event.” Catriona Graham (Scottish Enterprise) suggested that popular culture (TV soaps etc) might be better used to build confidence. Dr Walsh agreed that positive stories about people being helped by pharmaceutical therapies needed to be better publicised. Prof Joyce Tait also questioned the validity of some of the survey research conducted by social scientists. She stated: “To do the survey, social scientists must frame the context before asking the relevant questions. Paradoxically, however, by asking the public about certain topics you can make people more worried, by virtue of raising awareness about risk.” Nicky Lilliott mentioned that the MHRA and ABPI are working together with journalists and experts in risk communication to develop common language around risk and benefit.

Dr James Mittra raised the issue of the varied and unpredictable nature of public perception. “On the one hand, there have been cases such as Vioxx, where public perception was that industry and its regulators allowed an unsafe drug on the market without adequate safety data. Yet, on the other hand, there are cases such as Herceptin, where the reaction is completely reversed. Here, the public is calling for a by-passing of conventional regulatory processes in order to make a new drug, with largely unknown risks, available to patients as quickly as possible.”

Dr Robert Sands argued that the structure of the NHS provides an opportunity for secondary research of clinical effectiveness with real life data. Sir Alan Langlands pointed out that there are differences between Scotland and England in terms of health initiatives and databases that may be relevant for assessing clinical safety and efficacy. “The question is whether Scotland’s electronic and integrated system for health records could be better used in post-marketing surveillance for pharmaceuticals”.

**Regulation, Policy and the Role of Patient Organisations**

Jim Jackson (Alzheimer’s Scotland) raised the important issue of regulatory/policy agencies and assessment of clinical efficacy data in the context of Alzheimer’s disease. He claimed that “organisations such as the Alzheimer’s Society have lots of anecdotal evidence from patients about the efficacy of particular drugs, but organisations such as NHS Quality Improvement Scotland reject this evidence. They have also refused to analyse the NICE data (which led to the recommendation that three treatments should not be provided to patients in the early stages of the disease) – where the economic model is very complex and difficult to understand.” There is concern amongst patient organisations that regulatory agencies such as NICE and NHS QIS are too reliant on traditional clinical trials and have created a cost-benefit model from which it is difficult to identify the underlying assumptions being made. NHS QIS, according to Jim Jackson, have made no attempt to improve on and develop the NICE model. “If the assumptions of NICE are false, their conclusions are at the very least unsound or challengeable.” However, Jim Jackson said that he cannot get anyone to consider the patient perspective that a cost of £2.50 per day for these treatments is low compared to other medicines. Prof Joyce Tait suggested that academics might be well positioned to examine the economic model of NICE, perhaps funded by the Department of Health or MRC. Jim Jackson replied that he had talked to health economists, but his organisation could not afford to commission them. Dr Walsh wondered whether pharmaceutical companies would be interested in funding this kind of study. Jim Jackson responded that this actually raises a dilemma. Other charities have been severely criticised by the House of Commons Select Committee because they receive sponsorship from drug companies. Nicky Lilliott stated that the preferred approach is matched funding between patient organisation and a number of pharmaceutical companies, although Jim Jackson claimed it was often difficult to get more than one company to enter into a partnership arrangement.

Sir Alan Langlands suggested that “there appears to be a disconnect between high level policy and action on the ground”. Dr Walsh wondered whether the government, when they put NICE in place, “anticipated the monster they were creating”. From his perspective, what is happening is that whatever NICE says in the UK,
governments worldwide are taking note of it. Sir Alan Langlands stated that NICE “was set up as a vehicle to control costs and eliminate postcode prescribing. They have got to deal with efficacy and equity issues and they’ve got to deal with affordability issues. I think they have an impossible remit”. Dr Walsh responded by stating that “the view from outside the UK is that the UK is now practicing third world medicine”. There was a general consensus that if not abolished, NICE needs to be significantly improved and become more than simply a rationing tool. Prof Joyce Tait recommended that the basic model be more effectively challenged.

The Blockbuster Model and the Future of the Industry

In light of the public challenges to pharmaceutical innovation, and the complexity of the regulatory situation, Prof Joyce Tait wondered whether the conventional big pharma model of blockbuster drug discovery was sustainable. “Perhaps the future will be in novel therapeutics for niche populations”. Dr Walsh suggested that “the industry has not done itself any favours by slavishly popularising the blockbuster model”. He could not understand why they continue to do this, because “companies like Wyeth want to give drugs to patients who will respond to them and if that means restricting it to those people who respond and not giving it to those who do not respond, that is a good thing. Drugs like Herceptin operate in this restricted market model.”

Prof Joyce Tait raised the question of what type of companies would benefit from a non-blockbuster, niche model. She suggested that medium and small companies might use new technologies and market approaches to take drugs all the way from discovery to market without going through a multinational pharmaceutical company. Dr Walsh was more circumspect in his judgement. He said “it is of course a dream for venture capitalists to have small companies developing drugs cheaply. However, there is no magic solution to the problems. Failure is the big problem, which requires putting more drugs into the system. The reality is that clinical studies are extremely expensive and middle sized companies cannot deal with the costs on their own”. The relative positioning of small and medium sized companies is not, according to Dr Walsh, going to change in the short term. The trend is for companies like Serono, German Merck, and Ferring to merge with larger companies.

Technologies/Biomarkers

Jim Jackson asked Dr Walsh how quickly biomarkers for Alzheimer’s disease will become available. Dr Walsh responded that this is a long-term plan, for both Alzheimer’s and oncology medicines. “The current problem with regulatory approval and the FDA is that it uses previous markers of cognitive improvements. Pharmaceutical companies want to examine markers of prevention.” Wyeth are involved in a National Institute of Aging study, with other companies, to investigate whether brain atrophy or a whole variety of other measurements are better indicators of drug action than very inflexible cognitive measures. “Biomarkers are not a magic bullet, but they can identify what will work and what will not work at an early stage”. Prof Joyce Tait claimed that if it does work, it could lead to cheaper drugs. Dr Walsh countenanced this argument by stating “if you can reduce the length of time of development by even just a year that would represent a huge saving”.

Afternoon Discussion – Moving the Agenda Forward

In the afternoon session of the workshop, remaining participants considered how we might take forward the issues discussed. Nicky Lilliott suggested we should look at how the Wyeth model has worked and consider whether it could be used to attract more inward investment into Scotland. We should also consider how replicable it is for different countries. Nicky Lilliott also outlined the Ministerial Industry Strategy Group (MISG), co-hosted by ABPI and the government, with representatives from the Department of Health, the DTI and the Treasury. There are three work streams. Nicky Lilliott is involved in the regulatory work stream and her team are “asking the extent to which the regulatory framework is a hurdle, and whether it can be developed such that it becomes a help to innovation”. In this work stream, there are representatives from industry, the MHRA as well as academics, patient groups and clinicians. Nicky Lilliott stated that the recommendations of this work will be published shortly. A new panel has also been set up, chaired by Prof. Alistair Breckenridge and comprising the MHRA, three pharmaceutical companies, two academics and a lay representative, to look at new technologies and how the regulatory system might have to subsequently adapt.
The range of issues to be discussed include: personalised medicine, imaging for cardiovascular disease, and the use of different statistical models for clinical trials.

Dr Diane Thompson asked how the ABPI overcame the hurdles (access and misconceptions about how to take initiatives forward) when setting this up with the DOH and DTI. Nicky Lilliott said “there is a political will at certain levels of government to keep industry invested in the UK, and this is what the strategy group is all about. Lots of multifaceted discussions really help. This is very much a UK initiative.” Catriona Graham (Scottish Executive Enterprise and Lifelong Learning Team) stated that in Scotland there is the Life Science Industry Advisory Group, which meets four times a year, and includes civil servants, industry and academics. The focus is mainly on the Enterprise rather than the health side. However, Catriona Graham did state that they are hoping to get health colleagues involved as well. Catriona Graham also mentioned the Life Science Alliance, which is a separate group started by Scottish Enterprise. Members from the Education department have attended some of their meetings, because of the important science education issues.

Dr Robert Sands drew participant’s attention to a recent editorial in the Lancet about drug development in the UK moving towards partnership and shared development.7 The idea of shared objectives is important, and must involve patients, researchers, the medical community and industry coming together. Jim Jackson mentioned Generation Scotland, which is very much a Scottish version of UK BioBank, but with no direct industry involvement. Alongside TMRC, Jim Jackson wondered “whether this is part of the way things are working and whether people should be simply smoothing the wheels for more of these kinds of initiatives. Or, alternatively, are these unusual examples of collaboration?” Catriona Graham suggested that some collaborations are “alleged” to be unique (such as TMRC), but she was sceptical about the foundations of these assertions by Scottish Enterprise and asked “whether they had actually researched it or if they believed it to be unique simply because they hadn’t heard of any similar collaborations”. Dr Diane Thompson claimed, from a pharmaceutical industry point of view, that TMRC is unique, particularly in getting the universities to work together rather than compete with each other. Furthermore, “involving a national health service with a pharmaceutical company is quite unique. It is not happening anywhere else in the world”.

Prof Joyce Tait stated that one can believe it is unique and works well and then attempt to replicate it. She asked: “can we find another company, group of universities and researchers and part of the Scottish economy that wants to collaborate within that kind of framework?” However, she recognised that there is probably a degree of serendipity in how these things come together. “We therefore need to look at how we build on the current TMRC model”. One particularly important area to look at is clinical trials, particularly the problem of recruitment and cost. This is perhaps an issue that is fixable and extendable from the current initiative, even though TMRC is mainly about the early stage research. Dot Anderson (ABPI) suggested that there may also be more fundamental issues. She stated, “I think it goes back to the perception in, not just the Scottish Executive but in Westminster as well, that there is somehow no connection between life sciences, science in schools and developing children into the high-end, high-value jobs that is the strategy for economic investment in this country. On the flip side, we have this negative public perception of big pharma. What is needed is for people from enterprise and health to sit down together and start making that connection and find out how best to move forward.” Catriona Graham responded by stating that the problem is that within the Scottish Executive, as it is currently structured, the education department (which runs secondary education) is separate from the Lifelong Learning department (which controls higher education). Important continuities can often be missed. Dr Robert Sands mentioned the additional problem of the European Time Directive, which means that the training of doctors is now systematic with no encouragement to do two or three years in clinical research. “Therefore, fewer doctors are doing clinical research. This will eventually lead to a significant skills gap.”

**Key Conclusions from the Workshop**

- Need for consistent messages, for example on clinical trials. Why is there a poor uptake into clinical trials in Scotland, and are there good comparative data on other countries that may help us resolve this problem? One of the main problems is the length of time between signing agreements and recruiting patients. Need also to assess well meaning initiatives such as the European Clinical Trials Directive.

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7 (See ‘drug development and clinical research in the UK’ - editorial Lancet vol 369 Jan 20th, 2007).
• Need to engage the minds of people in Scotland. There are useful examples from Generation Scotland, which has produced a lot of publicity material to gain the commitment of families and communities to being involved in the research. How do we actively engage people for involvement in clinical trials?

• Need to push for blanket agreements on the costs of clinical trials and revisit previous work and discussions. There is a need to garner information on a number of issues, and understand what the costs for clinical trials are made up of. For example, what are the indicative costs and how do they compare with the competition; and what are the causes of delay in recruiting patients? The question might also be asked as to whether the NHS is sometimes using clinical trials to pay for things they would pay for anyway.

• There is perhaps a need for the University Principals to work together on a joint message to ministers about the value of partnerships between the pharmaceutical industry and academia.

• The way forward is not to replicate the TMRC approach but to optimise the outputs of clinical trials. The initiative should be contained within Scotland for the time being as it is a big enough issue to ensure success here.

Glossary of Terms/Abbreviations

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