Interview with Professor Sir John Bell, Chair, Office for the Strategic Coordination of Health Research (OSCHR)

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Office for the Strategic Coordination of Health Research (OSCHR)

It are exciting times for the UK, with the public healthcare system undergoing so many changes. The Office of Life Sciences (OLS) and the Therapeutic Capability Clusters are just some examples of the new way forward. According to you, what are the factors that drove Government to pursue such drastic changes in the UK?

The actual history of these changes goes back about 6 years, when it was recognized that the strengths in clinical research activity had withered to the extent that the field had come in considerable jeopardy. This situation was the result of a number of factors.

First of all, the National Health Service (NHS) had become a very hostile place to do clinical research, and in fact did not want to do clinical research at all. Moreover, there was no money to support research & development.

Secondly, the three major pharmaceutical companies, of which both AstraZeneca and GlaxoSmithKline are based here, were experiencing challenging times with diminishing pipelines and low potential for products to undergo clinical evaluation.

Thirdly, there had been the fantastic flourishing of non-clinical medical science which already started in the mid 70s. Molecular and cell biology had been on the rise and had given a much better understanding of how many diseases work. As a result, it had become very attractive for young people to spend time in a laboratory centre, which caused a shift from clinically qualified scientists into laboratory-based scientists.

The Academy of Medical Sciences (AMS) therefore wrote a report to regain activity in translational clinical research, since this had become such an important and challenging piece of the drug discovery and development paradigm. The AMS report was sent together with a similar report on the biotechnology sector, presented by David Cooksey, to Gordon Brown. I believe it was then that Gordon Brown recognized the importance of this sector and the need to rethink how the NHS could be converted. On the back of that, the Treasure asked the Department of Health (DH) to carve out around GBP 100m to create a better arena for clinical trials in the UK.

By that stage, Dame Sally Davies started heading the sectorâ??s R&D and managed to create to some of the networks necessary to do large-scale clinical trials.

By 2006, David Cooksey produced another report that highlighted the need to devote more resources and support to the translation of medicine. It also had to be confirmed that the two streams of funding for medical research coming through the DH and the Medical Research Council (MRC) were efficient and well coordinated.

In the Spending Review of 2007, after increasing the budgets for the National Institute of Health Research (NIHR) and the MRC, the government devoted another GBP 200m annually to support enhanced translational activities through these two bodies. It also created the Office for Strategic Coordination of Health Research (OSCHR), a body that would help to align the activities of these two funding bodies.

These initiatives turned out to be quite successful. The clinical trials networks are now excellent, and slowly but surely the metrics and the number of companies doing large-scale clinical trials in the UK has gone up again. We do have to accept that the UK will never be the setting for large-scale late-stage clinical trials, because the cost base is not as competitive as other places such as China. Nevertheless, the situation is now in a much more robust health and is looking steadily better than before.

A second milestone was the creation of substantial infrastructure in a set of hospitals around the country to support clinical research, in the form of beds, imaging facilities, genetics capabilities etc. There are now 5 comprehensive biomedical research centres in the UK, being Oxford University, Cambridge Univeristy, University College of London (UCL), Imperial College London and Kingâ??s College London. These centres receive between GBP 15m and GBP 25m a year to support clinical research infrastructure. Such support is quite unique compared to other places in the world and has transformed the activity in these centres in quite dramatic ways. In Oxford for example, the total number of research beds has gone up from zero to roughly 40 or 50.

In total, the NIHR spends around GBP 160m on comprehensive biomedical research centres as well as specialist centres that focus on specialist areas such as bone disease or cardiovascular disease.

Thirdly, the MRC has now also recognized that it needs to become more involved in translational activities and therefore created a couple of schemes. One such initiative aims to prolong funding of innovative developments for new therapeutics and diagnostics to retain them in universities, before they are spun out as small companies. This program is only three or four years old but seems to gain quite a bit of traction. These are all examples of different schemes that have come forth of the UK and are clearly paying off. To put this in perspective, total government spending on biomedical research in 2003 was around GBP 400m a year, an amount that has now skyrocketed to GBP 1,7bn. There is no other place in the world that has seen such evolution lately.

In addition to that, the UK has the Wellcome Trust, spending GBP 700m a year, the worldâ??s largest cancer charity the Cancer Research UK (CR UK), spending over GBP300 to 400m a year, as well as a number of other big charities in different areas such as arthritis or diabetes. The money that is now being made available for biomedical research is in excess of GBP 3bn a year. On a per capita basis, this is a very competitive figure.

The next thing that needed to be done was to identify where further improvements could be made. Firstly, science needed to become much more responsive to the needs of the industry and work in partnership with the latter. The area of exploratory development, which is of course a sweet spot for commercial R&D activities, is the tipping point for most pharma companies on where they take their compounds. Given the recent investments and considerable strengths of clinical research in the UK, it has been clear that the UK is in a very competitive position. Hence, the efforts of the Office of Life Sciences (OLS) resulted in the creation of Therapeutic Capability Clusters which allow roughly 9

different institutions to work together and develop new exploratory development paradigms for new compounds and implement those in a very cost-effective and â??efficient way. Once again, this is quite unique in the world and even though such initiatives have now also been spotted in the US, the UK is certainly ahead in terms of organization. There is also a network of cancer centres, called the Experimental Cancer Medicines Centre, which are similar to these clusters. Such initiatives have drastically increased the UKâ??s overall attractiveness.

Clearly, the funding is now there, the infrastructure is thereâ?¦ yet it is still hard to do clinical trials quickly and efficiently in the UK. What are the next key steps to be taken?

There are two major outstanding barriers. One is that, culturally, the NHS is still not a great place to do clinical research. If you go to most hospitals, where hospital managers have not been exposed to centralisation, the culture is generally anti-research: they are slow, cumbersome, and do not encourage their staff to do become engaged. There is a continual effort at the centre of the system to try to push this culture in the right direction, but there is still a long way to go.

The second issue is regulation. The UK has got perhaps the most cumbersome regulatory environment to grant permissions for clinical trials in Europe, and is one of the slowest places in the world to obtain such permissions. It is essential that the regulatory structure gets fixed.

Before the last election, the AMS already went to speak to the leading figures of the main political parties, arguing that a new approach to medical research was needed. One suggestion was to have an independent review of the regulatory environment to make the system much more streamlined and efficient. Interestingly, all parties agreed to the suggestions. The Review was launched under the Labour Party first, and enjoyed continued support by the New Coalition afterwards. The final report will be announced on January 10th 2011. Such thorough review could turn the UK from the worst into the best place to do clinical trials in Europe.

Clearly things are going betterâ?¦ do you feel the pace of change is fast enough to cope with competitive pressures from the BRIC countries?

Competition from the BRIC countries could be seen as a challenge, but also be seen as an opportunity. A first point that benefits the entire industry is the fact that total market size increases as these countries grow in importance. If you look at most companies, a significant part of their growth is now coming from these countries, in particular from China and Brazil, and to a lesser extent from Eastern Europe and India. These countries have high numbers of patients, and therefore have a good profile to do large-scale clinical trials. It is worth noting however, that many of these large-scale trials will still be run from the UK, simply because UK scientists know more about clinical trials than any of these emerging markets. This is how the UK can continue to play a key role in a global clinical trial context. Oxford, for example, now has a clinical trial networks in China, India and Africa. Rather than isolating ourselves as an island that aims to do everything by itself, the UK is in fact well positioned to play a key role in the global arena.

In addition to that, it is not simply about numbers of patients. Therefore, in terms of exploratory development, the UK is uniquely positioned because of its quality of clinical infrastructure, its highly intelligent clinical scientists and a great patient base in the NHS. Exploratory development is also about carefully selected patient populations and very extensive levels of information, aspects where the UK can be competitive in.

How far do you feel the UK is on the path to stratified and personalized medicine, in particular compared to other key markets such as France and Germany?

I think the UK is probably more advanced in this view, for a number of reasons. Firstly, some of the underpinning technologies which will make personalised medicine work, have always been a key strength for the UK in the past. In terms of human genetics for example, it could be said that, per capita, the UK is the leading place on the planet.

Secondly, the UK in fact recognized the importance of stratified and personalized medicine quite a long time ago. There are indeed a number of national programs in stratified medicine, launched for example by Cancer Research UK, the Technology Strategy Board, the Medical Research Council etc. There is thus quite a number of people in the UK that are trying to build capabilities in that space.

Now, one of the problems of the UK is that the pharmaceutical industry did not really value the importance of personalised medicine until very recently, as it was riding the waves of the blockbuster model instead. Some companies are way ahead, but a lot remains to be done. In particular today, the private sector is increasingly focused on personalized medicine.

What will be necessary to further progress in this sense?

What probably needs to happen first, is to have a lot of failures because things were not done right from the start. Secondly, the entire organisation needs to become completely committed to supporting a paradigm shift. This is a cultural change and requires a different thinking all the way from discovery through late stage development. â??Which subpopulation of patients does this work in?â?•, is a question that needs to be raised in all stages of product development, a change that does not happen overnight. A lot of effort is being put now on re-stratifying and redefining disease, but the question remains â??How do you redefine disease based on underpinning paths of physiology rather than what is seen from clinical observations?â?•.

Why do you think it took so long to start thinking in a different way?

If you have success with the old model, why change? There needed to be some road crashes before the importance of change would become more prevalent. Moreover, big pharma companies are huge organisations employing 70,80, 90,000 people, which makes it very difficult to change a culture. Interestingly, the Department of Health approved an initiative in stratified medicine by the Technology Strategy Board only in the last couple of years. While the DH is enthusiastic about stratified medicines, the first response of healthcare providers was that a stratified approach would be much more costly. While the added value is obvious, it has taken time to convey this value and the added advantages of a stratified approach to these people. Certainly, the UK pharma sector is in the right place to advance in this context.

Chris Brinsmead has just been appointed life sciences adviser to Government, bridging industry and the government. If you were to sit between Minister Willetts, Lord Howe and the industry, what would be the first advice you would give them?

It is very much needed to get the small sector back on its feet. That involves creating a model that generates significant profit and returns for investors in venture capital. First, the gestation period needs to be reduced, which means that academia needs to be involved for a longer time.
The second thing is that the UK needs aggregated biotech companies. The UK does not have a midsized biotech company, such as former Celltech, anymore. There are plans to create at least one or two such entities. The essential bit of this is that investors need to receive a good return.

What is your final message to the international readers of Pharmaceutical Executive?

If the UK gets all this right, it will be back in play as one of the leading places to do discovery and development.

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