

## **IPPOSI National Strategic Forum for Clinical Research**

**Farmleigh, Dublin, 27 November 2009**

### **Flash report**

It is not too late for Ireland to take its place among the ranks of countries with a thriving clinical research base, but time is running out. That was the disturbing message to emerge from a unique meeting of patients, scientists, industry and policymakers at the Irish state residence in Phoenix Park, Dublin, on Friday 27 November.

Already Pfizer, the world's largest research-based pharmaceutical company, has deemed that Ireland is a "non-core" location for its clinical trials, the meeting was told. That was probably the last message that Damian O'Connell, Pfizer's Vice President for Clinical Research and an Irishman himself, would have wanted to deliver to the meeting, and the last thing the meeting wanted to hear...but his analysis was not disputed.

Irish clinical research, said O'Connell, is fragmented, costly, and time-consuming. Ireland, he said, has much of what is needed, but it is not joined up: "It is not a system." Everything depends on who you know, he said – and that's no longer good enough.

### **Get smart**

Ireland has a thriving industry in manufacturing pharmaceuticals – no country in the world has a larger positive balance of trade in pharmaceuticals – but the "smart economy" which all agree represents the root out of the economic crisis requires a larger stake further up the value chain, in clinical research.

The big gap is the human one, the meeting heard – there are simply not enough clinician scientists in the country funded for part or most of their time to do clinical research. How can this clinical research issue in Ireland be fixed? Prof John Crown, professor in translational cancer research at Dublin City University, was brutally frank: "Until the universities bite the bullet of developing full-time [clinical research] faculty, with the same core infrastructure that normal medical schools have internationally, we will have these challenges." There is also a serious shortage of research nurses.

The government is working to change improve the climate for clinical research in Ireland, and Jim Breslin, from the Department of Health and Children, and Enda Connolly from the Health Research Board described their two organisations' plans for the future of Irish health research.

"One thing coming out is that we can't afford not to support clinical research," said Breslin. "It is obviously going to be difficult, but it has to be done." He added: "This is a key priority for us. We can't deliver it alone. We want to tap into the enthusiasm and passion for research and innovation among diverse stakeholders." Connolly agreed: "It needs partnership with all those who use and exploit the system."

The plans, however, will have to be implemented against a background of fiscal retrenchment, and involve some redirecting of resources towards the applied end of

research. At the meeting, leading Irish clinical researchers from home and abroad warned that the economic crisis cannot be used to cut back on basic research and on the investment needed to sustain a research infrastructure.

The value of fundamental research was graphically illustrated by Anthony Moran from NUI Galway. He showed how seemingly obscure research on a narrow class of antibodies has resulted in dramatic improvements in the health of patients with the disabling condition known as Guillain Barré Syndrome by uncovering a link with a common bacterium that causes food poisoning.

But the knock-on effects of research go beyond improved health for patients. “If we are going to fix Ireland’s economy we will have to create a real economy,” said Prof John Crown. The public knows this, too, said Dr Seamas Donnelly from St Vincent’s University Hospital: “They get [understand] the smart economy,” he said.

### **Listen to the world**

Delegates to the meeting heard a clear message from top Irish researchers working abroad. Clinical translational research is essential to the health and wealth of a nation, said Prof Garrett FitzGerald, who heads the world-leading Institute for Translational Medicine and Therapeutics at the University of Pennsylvania. He cautioned against cutting basic research to fund clinical research. “The quality of clinical research depends on basic and translational research, particularly as we go to personalised medicine. Sustained funding is crucial for all interdependent partners,” he said.

“Irish patients and citizens feel that Ireland can make an important contribution in this area,” said Dr Brian Moulton from ICORG, the coordinating group for Irish cancer research whose success has sparked calls for equivalent groups in other fields. He singled out good organisation as a critical success factor. “For Ireland to be attractive internationally we need all clinicians in the island to work together,” he said, to build a reputation for Ireland as being at the leading edge of research internationally. Patients and patient organisations will play an increasing part in this process, said Prof Garrett FitzGerald.

Cooperative groups are a simple idea, yet critically important, said Prof John Crown. “You need large national groups coming together to do the kind of randomised trials you can’t do in single hospitals,” he said.

### **Ask the patients**

The tragedy is that there is great enthusiasm for clinical trials among patients with serious conditions that cannot be treated with currently approved medicines. The meeting heard two powerful pleas for clinical research from patients with multiple sclerosis. Jennifer Moran described how her life would be immeasurably worse without the chance to take part in clinical trials.

Their testimonies gave the lie to common misconceptions about clinical trials. “I felt when I was doing the trial I was wrapped up in cotton wool,” said Jennifer, whose family had initially opposed her participation in a trial. “For two years I was well catered for, well looked after. There was never a problem ... I would definitely do another trial, definitely.” The previous year her multiple sclerosis had taken over her life. “Now I am back to being me again,” she said.

Carol Galvin related how the disease had hit her as a young mother, and how a new drug had helped her. “Thank God for clinical trials, that’s all I can say. Down the line I may have to come off the medication I am on, and I would jump into a clinical trial with both feet if that happened,” she said.

One lesson here, as explained by neurologist Michael Hutchinson from St Vincent’s University Hospital, is that clinical trials are a source of hope for patients with unmet clinical needs. “Keeping your research profile high leads to improvements in your patients,” he said simply.

Earlier, the tone for the conference was set by the launch of the report of the IPPOSI National Survey on the Irish Public’s Attitude to Clinical Research – the first such survey in Europe. Yes, said Barry Egan from Drury Research, there is confusion and fear about what clinical trials mean, particularly among healthy people. But once trials are explained, even briefly, attitudes transform. “In the main the public were of the view that Ireland should be at the forefront of clinical research,” he said. “If we can move people in an hour from serious concerns to advocacy, what could we achieve with a public campaign?”

Eibhlin Mulroe, CEO of IPPOSI, backed the idea of a national public information campaign about what it means to take part in Clinical Research, and what a biobank is, for example. “The public are very important in Ireland,” she said. “If the public support Clinical Research, then things will happen.” She also saw “huge opportunities” in working with other organisations over this campaign, such as EPPOSI, the European analogue of IPPOSI. “How to bring the public along is a discussion that’s happening at the European and also at global level,” she said.

### **Yes, Ireland can**

Can Ireland do it? An inspiring example was described by Prof Ed Holmes, Executive Chairman of the National Medical Research Council of Singapore. There are similarities between Singapore and Ireland, he said. They have roughly the same population, they both speak English, and they are both dependent on the manufacture of pharmaceuticals and IT devices. Yet Singapore – perhaps because it started from a clean slate – has rapidly built up the capacity to become a world centre for clinical and translational research.

Scotland, too, has established itself as a leader in clinical research through the Scottish Academic Health Science Consortium, said Prof John Savill, Chief Scientist at the Scottish Government Health Directorate. He stressed the role of coordination, international peer review, and IT systems in creating the foundations for success.

“Everything Damian O’Connell from Pfizer said about Ireland could have been said about England and Scotland eleven years ago,” he said. And Ireland, he said, has an extra thing going for it: “You have IPPOSI,” he said, with the ability to mobilise all the stakeholders.

“We can’t compete on everything,” acknowledged Dermot Kelleher from Trinity College Dublin. The answer is to look at where Ireland can be competitive, and then – as has been done in the NHS in England through its director of research, Sally Davies – “force the universities with their hospitals and medical schools to focus”.

“We are in an economic downturn, but we have to have funding to slingshot us into the clinical research world,” concluded IPPOSI Chairman Godfrey Fletcher. Despite the problems of the past months, he declared, Ireland has the passion for research to rise “like the Phoenix”.

“This meeting has reinforced to me that Ireland can become a leading centre for clinical research, he said. “The will is there. It is obvious that work has to be done, and we are a small country with limited resources. But so too are Scotland, Singapore and Denmark. We need to make changes to make this happen: we need to make Ireland core.”

#### **Key conclusions from the meeting:**

- Without a thriving clinical research culture in Ireland, Irish patients with severe unmet medical needs will be deprived of life-saving treatments.
- The Irish public will support clinical research, and Irish patients are keen to be involved in them.
- Basic, translational and clinical research support each other – and all three must be supported by funding programmes.
- Ireland must transform its clinical research into a system that is clearly seen by pharmaceutical companies as organised, speedy and effective.
- Focus on the human resource – trained clinical researchers with protected time for their research, backed up by research nurses.
- Focus on excellence: Ireland cannot do everything, so pick the right fields to aim for international competitiveness.
- Ireland has become a major manufacturer of pharmaceuticals. Now it needs to move up the value chain to become a centre for research and development – but time is running out.
- This will require investment, but the costs of not doing this are immense, both for patients who will suffer and die unnecessarily, for health systems coping with the results of their illness, and for the economy as a whole.

*Peter Wrobel, Rapporteur*