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## **The Irish Times**

### **Steve Cutler: ‘People understand what a clinical trial is now’ Interview: Icon CEO on Covid-19 clinical trials and business acquisitions**

By Dominic Coyle

In the middle of a pandemic, everyone just assumed companies running clinical trials on vaccines had more than enough to occupy them. The pharma companies might be grabbing the headlines as they raced to deliver a vaccine against a killer virus, but it was the clinical trials companies that did much of the heavy lifting.

They were the ones getting the vaccines through millions of dollars worth of testing in tens of thousands of volunteers to prove that the vaccines – some using never before seen approaches to vaccine development – actually worked. And, more importantly, did so safely.

So when Dublin-based Icon, already one of the world’s big players in the clinical research sector, announced it was taking over US-based PRA Health Services in a \$12 billion cash and stock deal, it was a moment to sit up and take notice.

But as Icon chief executive Steve Cutler sees it, Covid merely confirmed a decision the company had already reached.

“We went very close to making a significant acquisition about four years ago when I first came into the job. And over that period of time, we’ve been you know, looking at the market, looking at our competitors,” he says. That research identified PRA as a possible target, a strong competitor but, in Cutler’s words, a good cultural fit.

“We could have actually executed this deal a year ago, but we decided obviously with the pandemic it wasn’t the right time,” he says. Covid, if anything, proved the case, with both groups gaining momentum through the pandemic and an appreciation of how their technology could help them capitalise on a changing approach to how trials are conducted.

Trials are a costly business that can account for up to half of a drug’s development costs. Getting them wrong is costly both in time and reputation – even for successful drugs. As AstraZeneca discovered, even minor inconsistencies in data or methodology can have repercussions. And given the cost of drug development, that’s a significant issue.

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## **Pfizer vaccine**

But Dublin-based Icon had delivered. As the clinical trials operator behind the first vaccine to get across the line – Pfizer/BioNTech's BNT 162b2 – it was riding high. Cutler says the company, and its staff, are very proud of having been “instrumental really in getting the first vaccine to market”.

The research business was founded 30 years ago by two scientists, Ronan Lambe and John Climax, after they had been made redundant with the collapse of another business. At a time when many pharma groups conducted their own research in-house, the two men saw that the future for drug development would involve outsourcing clinical research and trials.

Resolutely low-key, Icon has expanded steadily since, taking a Nasdaq listing in 1998. But the PRA acquisition is a quantum leap for the business. It lifts Icon from big league players to industry leaders.

Ireland has had bigger deals before, but not many. And most of those have involved companies that had located here for tax advantage – companies like Allergan, Shire and Willis Towers Watson – not homegrown operations like Icon.

Cutler told analysts announcing the deal, the merged group will be either #1 or #2 in key clinical market segments and will have formal strategic partnerships with a majority of the top 20 biopharma companies.

## **Consolidation**

There has been talk for some time about the need for consolidation in the clinical research sector but everyone had assumed that would wait until the Covid-19 dust had settled and companies had digested the experience of the past 12 months and how that might affect the way the sector operates going forward. Not least as a host of trials are still ongoing both for new Covid vaccine candidates and tweaked versions of already approved ones to address new variants that were emerging.

So what does PRA bring to the partnership? What does it have that Icon needed?

“The first and obvious thing is scale,” says Cutler. “In our industry, having a breadth and depth of resource across the globe is important to be able to develop drugs and manage patients in clinical trials.”

The merged company boasts over \$6 billion in annual revenues and 35,000 staff worldwide, including 1,000 at Icon's base in Dublin, which becomes the headquarters for the enlarged business – even if it is not yet clear whether it will retain the name.

America will continue to be the focus. While Icon's business is currently split evenly between the US and Europe (with the rest of the world accounting for 20 per cent), around two-thirds of all mandates come from US pharma companies. That reality is reflected in the fact that Cutler, like his predecessor Ciaran Murray is largely based over there.

However, the acquisition will double Icon's resources in the important Japanese market and in China.

Where Icon previously had strategic partnerships – arrangements that deliver substantial work and revenues – with 40 per cent of the top pharma players, the enlarged group will have such relationships with 60 per cent.

“We are a very substantial player in the clinical development landscape, in the clinical trials game, you know. We're [now] really number one or two in all the key clinical market segments, so, we're in the conversation” when pharma companies are looking at who to manage the critical trials side of drug development.

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## Technology

“The second thing they bring is technology that we didn’t have or we didn’t have as strongly as they do,” Cutler says. This includes mobile health technology to manage decentralised trials that have been essential during Covid and now appear to be the way forward for the industry more generally.

PRA also has a data network that will allow the enlarged Icon to source all-important patient volunteers for clinical trials.

Cutler has argued for a long time that one of the biggest restraints on clinical trials is the shortage of patient volunteers. He says that, in his 20-30 years in the industry, just 3-5 per cent of people say that they have been involved in a clinical trial.

“If there is one thing I could do to improve the efficiency of the trial process, it would be to get more patients into a clinical trial,” he said at an industry conference. Covid, he thinks, has fundamentally reset the bar.

“The fact is, people understand what a clinical trial is now. The whole understanding of the clinical trial processes has risen exponentially over the last year or so, as people are seeing the vaccines come to market,” he says.

The pandemic has also seen the sector tap technology that allows trials to be run in a decentralised fashion. “Patients who, in the past, didn’t have the time or weren’t willing to make the fairly substantial sacrifice in terms of personal time to travel to a site. They can be part of clinical trials.”

## Financials

From a shareholder perspective, Cutler says, the PRA deal is expected to add immediately to the company’s bottom line, with double digit growth in earnings in its first full year, growing to more than 20 per cent over time.

His team have pencilled in \$150 million of cost savings that can be made with the merger of the two groups . Another bonus will be a lower tax charge for earnings from the PRA side of the business as it will benefit from Ireland’s lower corporate tax rate.

Icon expects the effective tax rate on the merged business will be around 14 per cent. that compares to around 23 per cent currently for PRA and 17 per cent between the two businesses when the deal closes later this year. Like the cost savings, Cutler and his team expect the full benefit to materialise around four years from now.

On the revenue side, the target is for high single-digit growth on the back of continuing strong market demand, the expanded relationships with large pharma companies as well as a growing base of mid-sized customers.

In terms of leverage, net debt will be 4.5 times adjusted earnings before interest, tax, depreciation and amortisation (Ebitda) following the takeover. Icon expects that the “robust” cash flows it will generate will bring that down to around 2.5 times Ebitda by the end of 2023.

## Challenges

Before making his mark in the world of drug development, Cutler was a top international rugby player towards the end of the amateur era – part of the squad that won Australia’s first World Cup. Did the intensity on the playing field prepare him at all for his current role?

“Rugby is a contact sport, the kind of sport where you don’t have much protection in terms of pads and helmets as you do in the United States. But that’s a little bit like the CROs [clinical research organisations] in some ways, it’s a bit of a contact business. You have to be resolute; you have to be resilient. You win one, you lose one sometimes. You have to present your best face every day that has its challenges.”

He accepts integrating the two organisations will be a challenge, probably the biggest of his career so far.

“The integration process in the next maybe four years will be something that we have to focus on every. As I said to the board, this could be a challenging time but we love challenges, we’ve generally thrived on challenges.

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“I believe we’ll look back in three to five years’ time and say this was a really, really good deal to do. And we are in a much better position having done this deal than we would be if we just remained as a standalone entity.”

In the meantime, Covid hasn’t gone away.

“Icon still has around 1,000 people working on the ongoing Pfizer / BioNTech trial. That trial and derogations of that trial continue on and will continue on for a couple of years really. There’s still work to go in that area.

“We’re also working on a couple of other large vaccine trials that we can’t be specific about who the customers are. But we continue to work in that space.

“We’re also working in a number of treatment protocols – people who are actually being treated [for Covid] rather than [taking] the vaccine in the preventive manner. So, we have over 100 projects going in the Covid space.”

Between that and overseeing the merging of the businesses, the 60-year-old Cutler has plenty to keep him focused for the foreseeable future.

**Name:** Steve Cutler

**Age:** 60

**Position:** Chief executive, Icon plc

**Family:** Married to Carolyn for 31 years, they have two adult children, Ben and Emily

**Interests:** Away from the lab and the office, he enjoys golf, rugby, DIY and reading, mostly non-fiction.

**Something That Might Surprise:** Cutler was an Australian second-row forward in rugby, winning 40 caps for his country and part of the first Australian squad to win the Rugby World Cup.

Published at: <https://www.irishtimes.com/business/health-pharma/steve-cutler-people-understand-what-a-clinical-trial-is-now-1.4501410>

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