Tom Oâ??Leary â?? CIO, ICON

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In an exclusive and wide-ranging interview, Tom Oâ??Leary, chief information officer (CIO) of leading contract research organisation (CRO), ICON, highlights how data is already revolutionising the CRO industry and the steps that still need to be taken to better match patients with targeted therapies and improve health outcomes. Oâ??Leary also touches on the incursion of tech companies into the medical research space, access issues, and the evolving requirements of sponsors.

Tom, as a veteran of the CRO industry, you have probably seen a lot of changes!

I started in London at Smithkline Beecham, which merged with Glaxo Wellcome in 2000, becoming GSK. Then, after being headhunted, I moved back to Ireland with ICON in 2001, very early in the companyâ??s lifecycle. We had around 3,000 employees then and today we have over 15,000.

I worked in both the clinical/laboratory side of the organisation, but over the past six years or so, I have worked on the IT side, transforming the organisation and bringing a focus to the data that we gather; internal patient and operational data as well as, increasingly, the abundance of data that is available through electronic health and medical records and claims. We are asking how we can leverage that data to solve the key challenge in drug development today: finding the correct patients to go into clinical trials.

There is a general assumption that clinical development has become extremely expensive. To what extent can the promise of data help reduce the costs and provide better patient outcomes in clinical development?

The reason we are looking at data is that the therapies that are being developed are much more targeted and specific than ever before. For example, cancer is a collection of rare diseases, so finding patients that are going to see benefits from the therapies being developed is key. To do this patient identification, you need to look at genomic data. Gone are the days of broad-spectrum antibiotic drugs and cardiovascular therapies. Today it is very niche, looking at cohorts of patients that are going to get benefits from very specific conditions. That requires us to find the patients that have the gene mutations and so forth that are going to get the greatest benefit from the therapy.

Secondly, we do not have enough data to help identify from where to recruit those patients. The way patients have been recruited traditionally is going out to a network of physicians, explaining to them that you have a clinical development program in a specific therapeutic area and asking whether they have patients in their practice that would benefit from this particular drug. While the physician may highlight 5-10 patients initially, when they are shown the inclusion/exclusion criteria, they may only be able to present 1-2 patients.

Now, we are looking to heatmap the world and find where there are concentrations of patients suffering from specific conditions or diseases with the help of electronic health and medical record data. There is no point in trying to recruit patients in cities where a disease is not prevalent.

Moreover, with the development of technology and the vast amounts of information out there, we are moving to a situation where we go direct to the patient. The percentage of total patients that actually participate in clinical trials is still very low and those that do participate only do so because their physician knows about the trial and its benefits. Now, we are going direct to patients with specific diseases and conditions, explaining that we have therapies and drugs that are under study, and outlining that if they enrol in a clinical trial, they will get their care for free for the duration of that trial. We are explaining that the therapies are targeted to cure or improve quality of life for a patientâ??s specific condition. The patient would then go to their physician and ask for help enrolling in the trial and for the physician to deal with the management of care for the duration of the trial. Demand for trial participation will increasingly come from the patient.

We are looking at how to engage patients more specifically in their care. All of the evidence shows that patients who engage in clinical trials achieve better outcomes. They better understand their condition, how to manage it, and when the therapies work, they get the direct benefits.

How well-received are CROs such as ICON in this new approach of targeting patients directly? Do physicians feel like you are stepping on their toes by getting involved at the recruitment stage of the clinical trial process?

Patients today are educated to the point where they no longer believe that their physicianâ??s opinion is their *only* choice. They are looking at what alternative options are available to them. If they have a very rare disease or indication that their doctor may not be experienced in, increasingly, they will seek alternative opportunities such as clinical trials. If a patientâ??s condition is life-threatening if not treated appropriately, increasingly they will look to take the situation into their own hands â?? they want the doctor there, but they want to manage their own care as far as possible.

They are prepared to travel, as evinced by the fact that we have patients all over the world who are willing to go to the US for stem cell treatment. CAR-T drugs currently in development â?? where the patientâ??s own immune system is enhanced by taking out their blood and working with that to enhance it against their condition and then putting that back into the patient â?? are not available in every country in the world.

Given that data often originates from a highly fragmented patchwork of sources, at ICON, how do you organize data and make it valuable?

The buzzword of â??big dataâ?? and its potential is being discussed a lot and fills headlines. However, the quality, consistency, and currency of that data is still very weak. I have seen situations where you may need to look at 50 million patient records to identify only 20 patients for a clinical trial. Beyond that, the data is not always complete, the patient may not still be alive, or the patientâ??s medical health record may have the wrong address listed.

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Standardisation is vital. The challenge for the medical community is that the data has not been standardised, it is not captured consistently, and a lot of it exists in unstructured formats such as patient notes. The tech tools are advancing to be able to read that unstructured data, but we are not there yet.

Will the rise of cloud-based data and the Internet of Things (IoT) improve the quality of data?

It will in the future, but it will not be able to do so retrospectively. That is a key difference. The data that has been collected up to now has been done so for different purposes. For what we are trying to achieve, we can get some of the answers, but not the overall promise that is being talked about.

More data is now being collected than ever before, which is partly driving costs. We are calling for more and better imaging data, captured in a structured way, as well as all of the patientsâ?? laboratory data over time so that we can conduct longitudinal analyses. We need to know what is going on with the patient on an ongoing basis. The advance of technology is allowing the capture of data on the patient as they go about their daily lives. These devices can tell you how many steps you have taken, your heart rate, the amount of rest you need, and can get a lot more specific in terms of managing care for conditions such as diabetes. Moving forward, the idea is that we will be able to access this type of data and use that to better understand patientsâ?? conditions.

We are only beginning to understand what, for example, climate does to patients. In summer 2018, Europe was particularly hot, especially at night. There was, as a consequence, more air pollution in all the major cities and patients and individuals at large were achieving less sleep because they were more uncomfortable at night. Because of this, conditions such as COPD became more pronounced. Now, with the availability of meteorological data, we are beginning to contextualise all of that.

What sort of questions do the regulators ask you regarding trial data?

They actually begin from an assumption that when a submission for a new drug is made, the data is fictitious. They do their own analysis on the data again and if their analysis matches the analysis provided then you will move forward for drug approval. Even then, they really only give a conditional approval, noting that if anything is observed when the drug goes out into the wider population it has to be reported back on. For example, if there is a drug-drug interaction that was never seen during the trial before, those two drugs cannot be prescribed together and prescriptions need to be changed.

Continuous monitoring is needed. Patients are not seen every 2-6 weeks as they would be during the clinical trial, but 2-3 times per year. It depends on what the FDA and other authorities mandate. The number of touchpoints and data that is captured in a year is much less but would span over 5-20 years.

How difficult is it to access good quality data? How are new technological trends impacting this?

Provided that a CRO explains what it is using the data for and is fully transparent, getting the data is not that difficult. The intended use of the data is what needs to be explained, as well as ensuring that the consent of the patient to be able to use that data in that way is secured. Patients are actually prepared to share their data, to use it to achieve better outcomes for themselves but also for the community of people suffering with that same condition. Patients who have rare diseases are particularly keen to reach out to communities with that same condition to understand how they are progressing in their treatment and find out whether what they are experiencing is normal.

The â??Patients Like Meâ?? platform is a good example of the huge amounts of new information available today. Patients share their condition, experience and recommendations on the platform and it has given rise to a foundation of knowledge that the drug development community never understood before. All of this is creating an abundance of data â?? the question is how to use that data to show that the outcomes that are achieved are much better.

These are the outcomes that we should be measuring and looking to reimburse against â?? not where the world has been (paying for prescription) but paying for patient outcomes and how quickly a treatment can restore the quality of life for the patient. This is advancing, albeit slowly. Reimbursement based on patient-reported outcomes means that these patient-reported outcomes need to be able to be captured easily. Having a diary on a device that the patient uses or carries around reduces the burden on them by capturing information without them having to think about it.

Also, â??virtualâ?• or â??hybridâ?• clinical trials can reduce the burden on both the medical community and the patient in terms of conducting clinical drug development. Through these new types of trials, we are able to leverage devicesâ?? capabilities within patientsâ?? homes.

Clinical trial dropout rates are very high; to what do you attribute this?

Firstly, the trial itself may not be working for the patients. This relates to ensuring you identify the right patients at the very start that are going to achieve a benefit from the drug. The whole aspect of patient engagement is critical. Up to this point, when a patient was looking at the opportunity of a clinical trial or it was suggested to them, actually explaining what they were going to experience was often not done very well; it depended on the physician and their understanding of drug development. Were they interested in being part of a community of developing drugs in that area?

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Looking at a global clinical trial of 10,000 patients around the world, you could not rely on the consistency with which information was imparted to the patient about what they would experience during the trial. We have sought to address that by putting more of that information onto a platform that the patient can access and receive a short video explaining the drug, the mechanism of action and what their experience will be.

Then, if the patient agrees to participate in the clinical trial, it is critical that they are allowed the ability to contact you and you have got to contact them to let them know what has/is happening with that drug/drug class and what you are seeing in terms of the overall understanding of that disease and condition.

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With the incursion of big tech companies into the drug development space, are CROs potential acquisition targets? What role will CROs such as ICON have in the drug development landscape of the future?

There are many ongoing discussions around this issue. Google could decide to buy any number of CROs tomorrow, if it wanted to.

Better data depends on the quality of the data that goes in. The tech companiesâ?? AI platforms are very powerful, so their ability to analyse massive amounts of data very quickly is something that nobody can compete with. The challenge remains understanding what the data means, this is where a partnership with the Tech companies really add value with both sides working together to produce meaningful analyses of the data.

CROs, at least for the moment, and indeed pharma, are the ones that understand what the data means. They understand where regulators will or will not give approvals. The FDA, EMA, and the big regulators in Asia do not make any apologies about the fact that the quality, consistency, and reliability of data has to be regulated.

How much can better utilisation of data reduce the length of time it takes to conduct clinical trials?

If we speed up drug development and the data is made available for analysis sooner, we will be able to take some of the cost out of the time that it takes to get drugs developed. The collection, analysis and getting to a point of understanding whether the drug works or not will be achieved much quicker. It will allow us to select the right patients from the start. Currently, a lot of time and money is wasted on not getting the right patients at the start of a trial.

Of course, it will vary depending on the therapeutic area. But data has the opportunity to take years off clinical trial timelines. The time that it takes to recruit the patient is so long, because we are not scientific enough in our approach and we are only now leveraging technology to identify the patients

that are going to achieve benefit from a particular treatment. We know where they are and we can get them engaged and get their data available in real-time through platforms that are more powerful than ever before. That is where the opportunity is â??speed and efficiency.

What excites you most nowadays about the ICON journey? Where do you see the future of the organisation?

The most exciting thing is understanding the power of data and using technology to drive insights from that data that were not previously known. The power of the tech platforms has advanced so considerably because previously we collected data into a repository and only when further analysis was run on that data would additional insights be generated. Now the tech platforms are continuously running analyses on that data, creating a lot more insights.

From an organisational standpoint, how nimble is the CRO industry? What challenges are going to present themselves regarding talent acquisition, for example?

Process change in any industry is particularly slow. Getting human beings to move to a more efficient process brings with it a fear factor.

The graduates that are coming out of universities today want to spin off their own companies and are impatient with what they find in established organisations. They are looking at faster ways to get things done. These graduates will not be the issue â?? they will rise to the challenge. Transforming processes and making sure that the data being delivered will be admissible may be more of a challenge. As you change processes, you may be producing data that does not stack up, so the amount of drug failures will go way up. That is too costly. Patients will not like it and they will feel that the whole clinical trial process is complete nonsense if no new therapies are coming through.

That process change is already happening to an extent. Robotic process automation, for example, is a huge opportunity. The ability of bots to speed up processes is immense. For every drug that is developed, we put together an electronic trial Masterfile which contains about 500 document types, including ethical permissions, insurance papers, and physician CVs. Today, these files are sent by email and humans are manually opening the emails and moving those files into specific folders in the Masterfile. The bot can go in, open the emails, screen them, find the correct files, can do it 24/7 and will be much faster than a human. That is starting to happen already.

Moreover, these bots can clean data; even though we receive data in a very structured way in clinical trials, about ten percent of that data comes in erroneously.

How are sponsorsâ?? requirements evolving?

They basically want the same thing: faster and cheaper trials of a good quality. We, as CROs, compete for those sponsorship opportunities, they usually invite 3-5 organisations in, some might be strategic partners already, they hear our proposal for how we would conduct that clinical study, what we would cost to do it, and the timeframe in which we would have the data package back to be submitted to the authorities.

The sponsors have to be convinced of the knowledge and experience of the CRO team and that where you are going to get the patients from aligns with their own expectation. They are always asking whether they can conduct these tasks internally or whether they need to outsource it? Then comes the questions of cost and speed.

Our sponsors have very advanced contracting models. They are looking to put the risk in terms of delivery on us as a vendor and the clinical drug development industry. If we submit the drug data package at the price agreed in the timeframe agreed everyone is happy. But if it takes the CRO longer, the price remains the same and the CRO bears the burden.

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