Colin Edwards – CEO, Merlin Consulting, Ireland

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Colin Edwards, CEO of Merlin Consulting, a consulting firm providing services to the pharma, life sciences and digital health sectors in Ireland, discusses his reasons for leaving Boehringer Ingelheim to set up the company, his thoughts on the digital health landscape in Ireland, and the challenges that he foresees.

We met you four years ago as the Country Manager for Boehringer Ingelheim. What made you decide to start your own pharma consulting company, Merlin Consulting?

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I had been with Boehringer Ingelheim for around 25 years at that point, and I left for two reasons. Boehringer Ingelheim was about to undergo a restructuring and I took advantage of this opportunity to restructure my own career. I had begun to build a lot of interest in digital health and was keen to pursue this. For example, while at Boehringer Ingelheim, we were entering the stroke prevention market and had come across a device that you could put on your phone to take an ECG to diagnose arrhythmia, which was fascinating.

Digital health is a very exciting area and I have learned so much in the past year alone. I am now Scientific Director for two digital health start-ups, PatientPharma and patientMpower. What I bring to these digital start-ups is the medical research expertise that allows them to demonstrate the value of their digital interventions.

Beyond that, Merlin Consulting can provide strategic advice to pharma companies for product launches – to map out a medical affairs and communications program, and do pre-marketing strategizing, for delivery by our client's own staff. There has been quite a bit of consolidation in recent years, with pharma companies moving their medical affairs and marketing strategy teams into regional hubs. Ireland is a small market so pharma companies may not wish to bring in a dedicated medical affairs person for just one product for the pre- and post-launch period, so this is where we could step in.

Can you elaborate more on the regionalization occurring within the pharma industry?

Even four years ago, the industry was seeing increasing regionalization in terms of how local pharma business was managed. Companies used to have programs in local markets led by local marketing, medical affairs and medical communications staff – people who knew their market well. The downside there was that maybe they were too close to the ground to see the broader picture. There has been an increased centralization of marketing, medical communications and medical affairs to regional hubs – for Ireland, that is usually the UK. Quite a lot of companies have become very customer-facing with mainly sales staff; some of the medical affairs team roles would have become more customer-facing as well.

While this may increase local profit margins, I think it fails to achieve the full sales potential, because companies are

applying a global, standardized campaign to local markets. There could sometimes be new opportunities within local markets that may not be immediately visible to the regional hubs; a company with a sales-only function may not be able to take full advantage of them. Furthermore, as the industry becomes increasingly focused on sales-only functions, it reduces the diversity of roles available and the attractiveness of the industry as an employer within the local market.

How are you going to position Merlin Consulting to compete with the giant consulting firms like PWC and now Quintiles-IMS, for instance?

We have a strong competitive advantage in the Irish market because of our strong relationships with healthcare specialists, especially clinical experts at secondary-care in certain specialty areas, and because of our strong knowledge of the market. Big consultancies do not have this intimate knowledge of markets, particularly smaller markets like Ireland. They typically look at markets from a macroscopic level or therapy area level, leaving the local teams to actually implement a strategy (which is often geared towards the needs of large markets). Their expertise is really in analyzing and fine-tuning business processes, and they do that part of the job very well, but we are able to provide the local expertise, business contacts and support in implementation.

Another key service we provide that is essential to companies is the review and approval of advertising material and activities for compliance with local regulatory guidelines. Increasingly, these have tended to be produced in the UK for use in Ireland, which has resulted in a few cases where the material ran into significant regulatory difficulties for not complying with local marketing and healthcare advertising regulations.

Can you tell us more about the two digital health companies you are currently working with?

Both companies, PatientPharma and patientMpower, are focused on working with patients to improve their health outcomes.

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PatientPharma has developed a unique, secure video messaging platform which is a powerful tool to enhance patient engagement. This can be applied across a wide range of therapy areas. People often forget the instructions from their healthcare professionals due to information overload. The idea is that the treatment center uses the PatientPharma platform to increase patient engagement and improve how COPD patients use their inhalers and do their rehabilitation exercises. We have just started a multicenter clinical trial in chronic obstructive pulmonary disease (COPD).

patientMpower has developed mobile phone-based health diaries for a variety of conditions including renal transplantation and prostate cancer. The underlying principle is that patients monitor information (e.g. vital signs, quality of life, medication compliance) relevant to their health condition and are consequently more empowered and involved in managing their health. The information recorded by patients can be shared with their clinical teams in

real time (and vice versa). Patient-reported outcomes and clinic-observed data can be compared.

patientMpower is developing this application for people with idiopathic pulmonary fibrosis (IPF), a rare and very challenging condition, to help them better manage their lung health. When we asked people with IPF what bothered them, we learned about previously unknown nuances to their conditions. For example, they find it difficult to breathe outdoors in windy weather. In response, we are now incorporating geolocation to better understand how patient outcomes might be affected by environmental factors such as weather and ultraviolet index. We are currently working with the patient group and clinical experts to design two structured clinical trials of this application in IPF.

There are three ways in which information collected from such applications can be used. Companies developing new interventions need to provide new patient-reported outcomes to regulatory agencies as a measure of efficacy. Companies having value and reimbursement discussions with healthcare payers also need patient-reported data from the real world (i.e. data collected from patients in regular clinical practice outside of an artificial clinical trial setting). Finally, these data can also be used anonymized on a population level to generate more information about the conditions from a patient perspective.

Ireland seems particularly well-placed for the digital health revolution with the concentration of pharma, medtech and tech companies here. How is the industry coming along here?

There is a very active digital health ecosystem here. The presence of major tech companies here means we have a lot of talented tech workers with experience within large organizations, breadth of imagination from a technical perspective about product potential, and also a global markets perspective. Ireland also has fantastic universities and academic institutions producing good technical graduates, and while the large tech industries may not be very actively locally yet in the health scene, they are definitely watching the space closely. We have a couple of accelerator programs going on for young health tech companies at the National Digital Research Center, for instance.

Some digital entrepreneurs lack understanding about the patient journey, because they usually have not worked in healthcare before. In addition, they may not have a strong understanding of the cost drivers in healthcare and how it is paid for. You can have a great idea about a technological product, but you need to show that it actually works for the patient. For instance, blood pressure can be measured quite objectively, but for something more subjective like chest infection recovery, even if there is no measured change in patients' lung capacity, they could still feel less breathless because their legs are stronger from physiotherapy. These are things that could be measured if better patient-reported outcome data were available. The development of digital health tools and the wide availability and usage of smart phones means that patient-reported data of real value will become increasingly available.

What challenges do you foresee as this convergence takes off?

My impression of Big Pharma companies is that they are cautious in adopting digital health as part of their offering. Understandably, they are not rushing to introduce digital health interventions for established treatments because these already have a market and any new initiative will cut into the profits. Digital health solutions that capture patient-reported outcomes are more feasible for newer companies just entering a new disease area, with only a couple of molecules in their portfolio. Rare diseases is another area where digital health interventions could be very useful, because they have smaller patient populations and the patients are much more engaged with their treatment.

One key barrier is with the regulations surrounding advertising of medicinal products. Outside of the US and New Zealand, you cannot advertise prescription drugs directly to consumers. In terms of this digital health revolution, pharma companies cannot engage with patients as readily because direct interaction could be perceived as advertising.

The other big concern is with reporting potential safety events. Pharma companies face stringent regulations

surrounding the reporting of adverse reactions to regulators, so they will need to consider how to incorporate app data into their drug safety reporting systems. Digital health developers are working on solutions to make sure that patient reports of symptoms entered into digital apps are linked automatically into the pharma safety reporting system. However, this creates the possibility that pharma companies may receive a large number of reported events that may not actually be related to the treatment.

The current regulations make it very hard for pharma to engage with digital health. The FDA have delivered some regulatory guidance, for instance, in clarifying that fitness wearables are not medical devices but the data can be used to support some medical findings. In Europe, the regulators have not really delivered regulation on this besides a Green Paper on mobile health.

Who will be leading this convergence?

I believe this convergence is definitely patient-led as patients behave more as active consumers of healthcare. What the digital health movement is illustrating is that the patient is no longer a passive recipient of healthcare. Patients now want more than just a pill, they want a whole treatment program, with recommended exercise and a method to help them remember to do those exercises and take their medication correctly. In any case, people who are more involved with their healthcare tend to have better health outcomes because they actually follow the recommended health prescriptions.

The privacy issue is very important but people are getting used to the idea that information is being collected about them every day. It does depend on the particular type of medical interventions and the patient groups, but even then, the applications are broader than we think. People used to think that you cannot have a digital health app for people over 60, but with IPF, where the age of diagnosis is often over 60 years, when we met a patient support group, they were very interested in the health diary and tracking app. In fact, several people bought a smartphone device in order to be able to try out the app.

The pharma industry tends to be cautious at adopting these new technologies. But if you look at digital health as patients capturing data about their conditions, not necessarily through a specific device, we see significant interest from patients, who are looking to take more control of their medical conditions and treatments. Patients will lead the way here and all of the contributors to delivery of healthcare will need to follow!