Greg Reh – Global Life Sciences & Health Care Leader, Deloitte

The reality of how cell and gene therapies and some of the other novel therapies will enter the market with an outcomes-based reimbursement model is going to drive how the data to quantify outcomes is gathered and determined in the first place

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Greg Reh leads Deloitte's global life sciences sector which includes clients in biopharma, medtech, generics and distribution businesses, as well as non-profit patient advocacy organizations and regulatory agencies. He discusses talent acquisition and retention in global life sciences today, the challenges around data and AI uptake, and the future of next-generation therapies.

What is the scope of your position as Deloitte's Global Life Sciences Sector Leader?

I consider myself very fortunate to be serving in the global sector leader role. In that capacity, I am responsible for the services Deloitte provides to clients in the life sciences industry across our consulting, advisory, tax and audit businesses, as well as the research and solution development in which we invest. In many ways, our team reflects how the industry itself is organised in terms of the domains found within companies. This allows us to align our resources and capabilities in a way that is understandable to the market. We also have the advantage of being able to convene all those disciplines as we contemplate a particular issue or develop a solution. The sector leadership team includes regional leaders as well as our business and capability leaders.

Deloitte's life sciences offerings are very mature, and the sector includes a large number of life science-dedicated resources focused on the biopharma, medtech, and generics segments, which gives us a great perspective on the industry.

Deloitte seems to be dedicating more resources to life sciences than some of your competitors in the other Big Four consultancy firms. Is that correct?

We are very involved in the industry. Part of our advantage is that Deloitte never spun out its consulting arm, as others did in the early 2000s. That allowed our multidisciplinary model to evolve in a different way than of some of the other firms. It has resulted in a much more integrated industry model and allows us to go to market in a much more differentiated way. That comes through in terms of the points of view we author, the solutions we develop and invests we make. For example, our ConvergeHealth business is now being launched beyond the US. All of those are reflective of our heritage.

Deloitte has made a very significant commitment to life sciences, and I have the privilege of championing that commitment through the various investments we make to continuously grow the sector offerings. The other aspect of how we've grown over the past several years is the depth of skills we now possess; not just the breadth of what we bring, but our ability to hire and retain talent in specific therapeutic areas and creating centres of excellence around specific offerings.

How do you manage to attract talent from the pharma industry to work for Deloitte, especially given the long working hours?

We do manage to hire people from the industry. I recently had a conversation with a candidate in an interview trying to set expectations around lifestyle and travel – he told me that as a pharma executive on the manufacturing side, he travelled three to four weeks out of the month and kept a very intense schedule. So, not very different from what our lifestyle is.

Our life sciences practice is made up of over 7,000 practitioners across domains and capabilities, and our model enables us to attract and retain team members from industry as well as academia.

I used to be concerned about other consultancies recruiting our talent – now we have hospital systems and academic centres trying to recruit our team, which I guess is a sign of the level of people we have been able to recruit and their relevance to the market.

What are the most relevant regions to you today? Where needs Deloitte's services the most, excluding the USA?

Outside of the US, the greatest need is in China. The number of trials being conducted there, the manufacturing capabilities and joint ventures, not to mention the market potential itself, creates a significant demand for talent there. The industry itself is facing that same issue. In terms of experience levels, expat teams certainly are part of the answer, and certainly local resources are continuously gaining the requisite experience. The talent supply challenges will eventually be corrected, but that is also a reason why there is a greater need in the Asia Pacific region in general.

Will pharma companies come to display the same eagerness as Deloitte does towards China, or are they going to have a more complex relationship with that market?

The short answer is yes. The Chinese regulatory authorities have put in place the regulatory frameworks to ensure consistency and pathways for accelerated approvals. There are other dynamics that are driving the shift. New regulations in European medical devices space, for example, are going to drive more activity in China.

There are hundreds of cell and gene trials ongoing in China, and a significant increase in overall drug approvals last year thanks to the shift in the regulatory framework. The market is obviously attractive, and that will continue to be a significant factor in any commercial strategy.

Artificial Intelligence (AI) and data are hot topics in the healthcare and life sciences industry today, despite the fact that they are yet to deliver consistent results for companies' bottom lines. Are CEOs becoming unfocused in terms of their core business thanks to these new technologies?

They are focused on the right things. The speed of change is perhaps not as fast as they may have wanted, but the focus on data is spot-on. The industry has known that for some time that data was going to be the new currency of healthcare, whether it was the advent of real-world data (RWD) and real world evidence (RWE) or the need to have a more integrated information flow in the development process or patient journey.

All these concepts have been evolving, and it is now a matter of how to act on them. If you want output from those concepts, you must have the appropriate data framework. This has driven an appropriate focus on trying to harmonise that data, which is still not where it needs to be either internal or external to an organization.

How do you foresee this process of harmonisation of large amounts of data taking place? Will companies improve their internal capacities or move more towards outsourcing?

A number of players will be involved. Major tech players are already involved in that space. Of course, service providers like Deloitte are also involved. When we made our initial investment in Recombinant Data seven years ago it was the beginning of our ConvergeHealth platform journey, which is now live in over 20 countries supporting heart-of-the-business issues.

We are starting to see, from a therapeutic standpoint, the focus on the data and the realisation of benefits of utilising RWE in R&D through innovation in trials. Screening patients to identify potentially better responders and linking payments to individual outcomes are among measures that payers are negotiating with sponsors to ensure value. The race to collect impactful data to expand biopharma's knowledge of the epidemiology of disease and to satisfy health authorities is also accelerating.

How is this going to change the taxonomy of the pharma industry? What opportunities and risks do you see in these new models of collaboration with tech companies coming from industries with less regulation and a different mindset regarding user data?

The growth in number and complexity of clinical trials, particularly in oncology, means there is also increasing competition for suitable trial participants and sites. These factors are shaping the highly competitive landscape. This was a big topic at the 2018 Financial Times Global Pharma & Biotech Conference that Deloitte helped sponsor – looking at a traditional Big Pharma model and the threats of disaggregation by virtue of new tech entrants. What does that potentially do to a pharma company looked at through that lens? Could one envision them being forced into de facto contract manufacturer with the patients and customers being "owned" by other B2C companies? There were many conversations and speculation about what the threat was posed to the model by some of these new entrants.

It may be a generalisation, but most understood what those threats were. I do think those threats accelerated the operational changes needed to shift to a more patient-centric model. Given the vast amounts of data that are now being created, whether from devices or by virtue of other data platforms available, the industry can start to track the effectiveness of the changes made. The

pharma model is very durable, and in terms of the shifts that they have made, I don't see any significant disruption in the near term, but there will be more collaboration.

How can the pharma industry improve its attraction, training and retention of talent?

I have seen a very decided adoption of new approaches, focused on the retention of talent. Many companies in life sciences have a common purpose, what we are seeing now is the re-articulation of that purpose. That was a big topic at the 2019 Financial Times Global Pharma & Biotech Conference. I moderated a panel focused on talent models, where we discussed the future of work and what it actually means in this industry. The sentiments that we have seen coming from surveys we have conducted, particularly our recent 2019 millennial survey are not particularly positive. Trust in business, government, and institutions was significantly low.

Given that environment, how does a pharma company attract and retain the right talent to be able to take advantage and ensure that there is enough capacity in terms of talent and resources? That, I think, is why companies are adopting new approaches to their management styles, such as the "unbossed" concept. This is an attempt to break down both the real and perceived hierarchical nature of many of the companies that have grown up in a regulated environment with these structures in place. How do you tap the innovation by removing some of those barriers, and encourage more cross-domain collaboration? It is also critical to ensure the workforce understands the degree of commitment to that shift.

The world of life sciences is divided between markets with and without universal healthcare. Will the question of data and who owns it become a second component to that dichotomy in the next five years?

There is no doubt. The reality of how cell and gene therapies and some of the other novel therapies will enter the market with an outcomes-based reimbursement model is going to drive how the data to quantify outcomes is gathered and determined in the first place. It becomes that much more of an imperative to ensure that those therapies can be launched with the appropriate outcomes tracking.

CAR-T therapies – while therapeutically speaking are inarguably a massive step forward – have several barriers to wider implementation in terms of reimbursement, manufacturing, scaling up, and talent. What issues are your clients presenting regarding CAR-T therapies?

We worked with industry stakeholders to create a next-generation therapy working group in the US and are working to create something similar in Europe. In the US, there are approximately 15 companies in the working group. It is an ongoing discussion that brings key stakeholders together to talk about non-competitive issues that the industry is needing to address. The industry is recognising that this dialogue is necessary in order to continue to have the ability to bring new therapies to market. Given the specialisation involved, these working groups are a great way to look at how the industry can collaborate.

From an operating model standpoint, the more integration the better across all the different domains. With cell and gene therapy you have no choice but to have a smooth orchestration of the lifecycle stages of therapy order management, product manufacturing, and order delivery. Some would say that the product is the process, and that is also were the focus is from regulators. It is driving a different way of thinking, which does not necessarily fit into the current biopharma model.

Companies who are succeeding are operating on the two “moments of truth” when treating patients with cell and gene therapies. First question is whether the product is available and ready to be used, on time, and at the right location when the patient needed it, and second, did the therapy bring about the outcomes that were expected and desired by the patient and the physician?

When operating with these two moments of truth as their north star, we’ve seen companies break down organizational barriers and build clinically connected value chains around patients.

Might these next-generation therapies have to be abandoned altogether due to their high costs, despite representing a significant improvement on more traditional forms of treatment?

These therapies are very early in their lifecycle and their durability will be evaluated over time but based on the trial data and everything that has been published to date, the consensus is that they are viable. It becomes a matter of determining how the manufacturing costs can be brought down. It is still early days in terms of the process, but industry’s efforts to begin to manage those aspects

are already underway.

We are also seeing new and innovative business models to address these barriers. Hospitals are building manufacturing consortiums which will allow manufacturing to come to the patient, and breakthroughs in science such as with NK cells treating cancer hold the promise of bringing down costs even more.

Nowadays, most Big Pharma companies seem to be focusing on oncology; is this at the expense of chronic diseases and more everyday illnesses?

Many pipelines are focused on oncology, but not to the exclusion of cardiovascular, immunology, CNS or other therapeutic areas. It is simply a matter of degree of portfolio strategy, degree of investment, and determining the highest probability of success. While oncology is clearly growing, it only represents approximately 35 percent of the pipeline value of the largest biopharma companies.

We are in the tenth year of publishing our Return on Pharma Innovation report, and it has documented a decade of decline in the return on investment. However, this decline has to be seen against the backdrop of innovative new treatments that are changing the face of disease management. New treatment modalities and an increasing understanding of precision medicine have led to the need for new R&D models and a future where medicine is more participatory, preventative and personalised. It also drives the need for more comprehensive data and digital technologies.

In five years' time do you feel that the return on investment in R&D will have improved, thanks to new technologies and the way that things are being organised.

Yes, the industry is going to have to find ways through data science and technology to reduce the cost and time intensity of R&D. This will be enabled by tools and methods that help accelerate or augment trials such as synthetic control arms, and more cognitive automation in operational trial tasks. There are still issues around cohorts and cohort identification, particularly in rare and orphan diseases, along with increasingly more finite entrance criteria. So that becomes a bigger constraint and a barrier that needs to be addressed.

The flipside of that is expanding the overall target of patient cohorts. Right now, a major challenge for the biopharma segment is recruiting trial participants from important demographic groups, including racial and ethnic minorities, women, and the elderly. How do we use some of the new tools, technological and otherwise, to overcome some of those barriers and potentially have higher participation from these, and other under-represented groups?

In what areas do you feel you are helping your clients most today?

It may be an overused phrase, but it is the ability to take a holistic view of the business. Whether it is the asset pipeline, the process to commercialise and launch, manufacture, engage with patients or operations in general, we bring the biggest value by looking across these domains to find opportunities to improve outcomes.

Are there any projects that you would particularly like to take on, after so many years in Deloitte?

We recently sponsored a clinical trial to study the effects of gamification on health behavioural change. This is something that had not previously been done at scale in a clinical setting. We started this work three years ago with the University of Pennsylvania to design the protocol and ultimately conduct the trial that tracked participants for a year – the longest and largest trial of this type. Results were published in JAMA Internal Medicine and picked up by major news outlets including CNN.

This is the first time that Deloitte has ever sponsored a trial, and we can now say with clinical data that “nudges” can be personalized and scaled with technology. This also supports our concept of Precision Engagement which is bringing behavioural science and data science together to make the healthy choice the easy choice. I’ve seen reports that 40 to 60 percent of death is preventable with lifestyle factors, and so the potential to make a meaningful impact nudging people to make the healthy choice is huge. I am fascinated by what is possible when you focus the data and behavioural sciences on making healthy decisions easier.

And we are starting to apply Precision Engagement to our patient support and patient engagement applications, as well as working with the largest private diabetes clinic system in Mexico. They have a very progressive and effective model in terms of an integrated clinic, but there stills needs to be an answer to the question of maintaining healthy decisions outside the clinic setting, and how

to create the right incentives to ensure that patients come back for more care. This is what our clinical trial was all about, and the data we've collected is continuing to generate new insights on how to improve engagement, so stay tuned for more publications to come.

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