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19.07.2021

Tags: Singapore, IQVIA, Biotech, CRO, Clinical Trials, Research, APAC

IQVIA Biotech JAPAC's Dr Senthil Sockalingam outlines the evolving needs of the flood of early-stage drug discovery ventures in Asia, how biotechs in the region differ from their counterparts in the US and Europe, and the most important digitalisation trends to emerge from the COVID-19 pandemic.

Could you begin by explaining what IQVIA Biotech is and how the services you offer differ from those of the larger IQVIA group?

Globally, IQVIA Biotech has been around for a couple of years. IQVIA Biotech launched in 2019 to deliver superior, dedicated service to biotech and emerging biopharma customers. Backed by the success of Novella Clinical and IQVIA, we evolved both the offering and brand to become IQVIA Biotech. From the beginning, the way that we work with biotechs has been different from how we work with Big Pharma companies, simply due to the way that biotechs are structured and work with smaller teams. IQVIA Biotech provides the hands-on, individualised attention and flexible streamlined process of a smaller organisation but with the significant benefits of IQVIA's unparalleled data, advanced analytics and technology solutions to accelerate innovation.

In Asia, and especially in China, there has been an explosion of biotech companies and investments over the last five years. Almost 50 percent of clinical trials in the region last year were led by

biotechs and by 2025, biotech-led clinical trials will far exceed those led by Big Pharma. Start-ups in this region are not only developing drugs for their domestic markets but are also looking at global markets; therefore, they need to be able to navigate the global regulatory landscape and accelerate their drug development, either to exit at some point or commercialise their products themselves. Biotech teams tend to be very lean and therefore require a simpler interface with their CROs, who need to highlight problems before they appear and provide clear information so that biotechs can make it to their next inflection point.

For Big Pharma, when the first patient is in for a certain drug, they are already starting to think about the final report and commercialisation. However, for biotechs at the same point, the vision is more short-term and focused on getting to the next patient and milestone. Therefore, a different operational model is needed.

The Nespresso business model is a good analogy for what we do at IQVIA Biotech. Making an espresso using a standard machine is a complex procedure with a lot of steps. However, Nespresso simplifies this process for the user, allowing them to simply press a button to get their coffee, and masks the complexity behind its interface. In our work, we also bring forward a simplified technology stack to better meet the needs of our biotech clients. In addition to this differentiated technological interface, we have also innovated our processes in terms of how our people interact with biotech organisations to ensure that they match the client needs. Thirdly, as an organisation with expertise in clinical science, data science, and commercial know-how, we are well poised to marry these elements together and bring a client from development to commercialisation.

Unlike MNCs that can absorb a certain amount of failure in drug development, for biotechs the progression to their next inflection point can be a matter of life and death. How does that influence how IQVIA Biotech operates and interacts with these companies?

Our relationship with our biotech clients is that of a trusted partner rather than a mere service provider, offering opportunities to work in a closer, integrated fashion that capitalizes on the strengths of each organization.

In partnership, we look at risk management and take a proactive view on what we think the client should do; we want to be seen as part of their organisation. At the very early proposal stage, we are already looking through their protocol and our physicians and scientists are giving their input on what they need to do to be successful.

Our focus is on reducing amendments to protocols or elements of the clinical trial process, which come with a high cost, as much as possible. We also leverage our data science team to make decisions based on data. This could be in terms of site selection, where heat maps and algorithms based on real-time prescription data help us identify where best to situate a clinical trial, or other areas; all of this helps our clients to make better decisions, save on costs, and progress through the development process more quickly.

Compared to their peers in the US and Western Europe, where do biotechs in Asia excel and where do they struggle?

Biotechs in our region are doing well in terms of innovation. The number of new intellectual property (IP) filings in China for innovative products for example, is currently exceeding that in other parts of the world. Biotechs here are good at identifying unmet medical needs and creating new products and technologies to meet them; very few are developing ‘me-too’ products. Risk-taking is also a strength, which is hugely beneficial for patients.

The challenge is navigating the evolving global regulatory landscape, as most of these companies are single country-based organizations. Perhaps related to that point is the evolving medical landscape globally; an unmet need in Singapore may not necessarily be unmet in Europe, meaning that development plans need to be able to address a broad unmet need across geographies and populations which meet the criteria set by different regulatory bodies.

Ten years ago, drug developers were not overly concerned with the fact that getting a product approved means nothing if no-one is paying for the drug. However, today, the question of whether payers are willing to pay for a particular innovation needs to be taken into consideration at a much earlier stage. Partnering with a global organisation helps Asian biotechs to navigate these challenges.

To what extent is the lack of in-house expertise on global regulatory issues a problem for Asian biotechs, given that they can piggyback on the capabilities of a big CRO partner? Which internal areas do they need to build up?

It is a case of scale. For early-stage start-ups it can be a struggle, but we have seen many biotechs, especially in China, reach a level where they have US offices and no longer need to outsource so many competencies. They have enough internal expertise to navigate the complexities that exist.

Singaporean start-up ASLAN, for example, now has a chief medical officer and US office, but started off essentially as an Asia-based organisation.

IQVIA Biotech recently held a symposium with seven biotech CEOs, where there was a broad acknowledgment of the existence of a talent issue that cuts across all organisations, both small and large. When the audience raised the question of whether it was better to hire or to outsource, one of the CEOs said that it depends; on which stage a company is at, what expertise they already have, and what exists in the market. His advice was that, at an early stage, partnering with several organisations; from CRO to CMO and beyond, is crucial.

What do you see as the most promising therapeutic areas in which biotechs are working within Asia? Are you seeing a herd mentality towards the most potentially lucrative fields such as PD-1/PDL-1 inhibitors or is there a broader spread?

Oncology accounts for over 40 percent of our work, and within that, we are seeing a lot of developments in cell and gene therapy and regenerative medicine. Even within cell and gene therapy itself, there is a lot of diversity. PD-1 nowadays is the domain of more mature biotechs, with products in Phase III trials, although there is still huge potential and a lot of room for innovation in the field.

Other promising areas include neurology, where we are seeing significant levels of interest and innovative products, including for mental health, although most are still in early stage or Phase I trials. It was only when PD-1 products went into Phase II/III trials that they began to garner more attention, so we expect to see neurology/mental health gain in coverage in the coming years.

The cell and gene therapies that have so far reached the market, such as CAR-T, have come at an extremely high price. What work needs to be done to ensure that the therapies currently being developed are ultimately accessible to patients?

CAR-T therapies are currently only being used in indications where life expectancy is extremely short and where they have the potential to extend that life expectancy and provide a good quality of life. All current pricing models for CAR-T are innovative, performance-based models, which are crucial for such high-priced therapies. If the developers of CAR-T manage to build these pricing models into their business cases, then I have no doubt that they will achieve success. Additionally, this is still a new technology and – as we have seen with other new technologies – the costs will

reduce as the efficiency with which a personalised approach can be created improves. This was the case for next-generation sequencing (NGS), which was previously extremely expensive but is now available to individual consumers.

Given that you have taken on this role during the COVID-19 pandemic, which has led to widespread uptake of digital tools in the life sciences industry, what would you highlight as the most important trends to emerge from this pandemic period?

COVID-19 has accelerated the digitalisation and virtualisation of our services, as well as clients' willingness to accept them. Digitalisation within clinical trials has increased significantly; trial sponsors today have no choice but to digitalise while hospitals and patients have become accustomed to it, even in countries that have historically been resistant to using digital tools.

Ensuring the continuation of clinical trials during the past 18 months has been challenging, with hospitals inundated with COVID-19 patients. Against this backdrop, telemedicine became an important tool. For many countries in JAPAC, telemedicine was already approved or received expedited approval and became an important element of patient follow-up and other tasks.

Secondly, patients needed to stay at home during this period, which meant that bringing care to homes also took on increasing significance. The investigational product supply chain has transformed, with infusions being done in the home for example, which could have long-lasting consequence for patient care moving forward.

The other area that changed was the operationalisation of clinical trials. All site engagements, whether investigator meetings or site initiation visits, were done remotely, as was monitoring where possible. Identifying errors through data checks became the norm, which is helping to drive efficiency.

The administrative part of clinical trials has also changed and simple things like the digitalisation of the contracting process has really helped expedite timelines. Previously, a contract could spend almost two weeks bouncing around from office to office waiting for signatures, whereas now it can be done immediately. A delay of two weeks can make a huge difference down the line for a drug launch and peak sales period.

Post-COVID, as AI begins to be talked about even more, is there a danger of overselling its potential given that no global regulator has yet approved a drug based on AI data?

Yes and no. Machine learning is only as good as the data that is put into it and its potential depends on what an individual's aims are. For me personally, AI is not an over-promise in terms of machine learning as an accelerator. Within IQVIA, we have coined the term 'connected intelligence', an innovative approach which enables our customers to generate insights more quickly. This is already being utilised in site selection – as mentioned earlier – as well as patient recruitment and identifying the right patients, especially for rare diseases, with predictive analytics.

We are trying to break the silos and connect the data that already exists with our machine learning technology and bring that to bear in the R&D decision-making process. For example, a traditional feasibility study would involve a form being sent to a site, the site filling out the form, and then sending it back; a process that takes between four to six weeks and for which there is a lot of potential bias and recall bias. The technology already exists to speed up the patient recruitment process by over 15 percent, which then improves the timelines for providing data to the regulator and arriving at an approval decision.

In the US, we are also now conducting just-in-time site initiation visits, which also helps reduce costs and improve recruitment rates. From an operational and decision-making perspective, machine learning is already having an influence, connecting the intelligence that exists within hospitals and within our organization. However, different actors adopt technology at different rates, and we are still waiting for a regulator to approve a drug based on AI data.

There is a huge variance of economic development within the JAPAC region, which contains both highly developed and emerging markets. Presumably, these sorts of data-driven solutions would primarily be relevant in countries like Singapore and Japan…

The cost of structuring data and natural language processing is still very high but is dropping and governments are taking more interest in it. When I joined IQVIA's clinical development team ten years ago, Asia was predominantly a clinical trial site and patient source, with 60 percent of the world's population and a high burden of metabolic disease. However, today companies conduct clinical trials in Asia because they want to register their products here. Within the last ten years, we have seen the China market grow tremendously as well as countries like Malaysia and Thailand move towards reimbursement and we foresee more rapid shifts within the next ten, although the

talent gap will remain an issue.

What makes IQVIA Biotech the partner of choice for biotechs in Asia? Might they be better off partnering with more specialised local CROs?

We are the partner of choice for biotechs, given our global footprint and ability to deploy specialists across the world. Our clinical development team brings expertise from two decades of planning and executing clinical trials exclusively for biotech companies. For a biotech that wants to go global with their drug, we provide a holistic solution and a great deal of efficiency with one protocol, one project manager, and one team to navigate the entire spectrum. As the largest global CRO, we have the scale and the specialised teams, scientists, and physicians across all therapeutic areas and around the world.

On a personal level, what keeps you motivated?

Having been in this role for two months, I have been struck by the passion of our clients to bring their drugs forward and really make a difference for patients. My second motivator is innovation. It is clear to me how our clients' products can impact patients, as almost all address significant unmet needs, from vitiligo to late-stage liver cancer. Being a cog in the journey of improving patients' lives is incredibly fulfilling.

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