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Real World Data Adoption About 10% Amid Challenges: Parexel Executive

Innovation Hub Set Up In India

by Vibha Ravi

While real world data is reliable, synchronization challenges limit its use, Sanjay Vyas, executive vice president and managing director Parexel India tells *Scrip* in a wide-ranging interview that touches on aspects from synthetic analytics to the interest among Indian companies in developing cell and gene therapies

Real world data has been gaining credence among regulators for decisions on drug approval and label expansion given that randomized clinical trials take place in controlled environments in a well-defined population that might also not be truly representative of ethnic or gender diversity.

After the US Food and Drug Administration (FDA) made its first label expansion based on real world evidence in 2019 for *Pfizer Inc.*'s Ibrance (palbociclib), it turned into a credible alternative to the gold standard of randomized clinical trials. Similarly, clinical-stage company *Medicenna Therapeutics Corp.* got the agency's nod to use a hybrid external control arm designed by *Medidata Solutions Inc.*, a Dassault Systemes company, in a Phase III trial for a candidate against recurrent glioblastoma.

The benefit of such flexible approaches to drug development was also seen with decentralized or hybrid trials that kept clinical studies going through the turmoil of the COVID-19 pandemic.

With drug developers and clinical research companies considering such alternate modalities, *Scrip* sat down with Sanjay Vyas, *Parexel International Corp.*'s global SBU head clinical trial

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Source: Parexel

supplies and logistics and executive vice president and managing director Parexel India to see where the boundaries are being pushed to make trials more effective, cost-efficient and convenient.

In the interview, he talks about driving diversity in trials via participation of groups like the LGBTQ community and via sites in countries like India, which is being included in an increasing number of global studies by companies ranging from *Novartis AG* to *Eli Lilly and Company*.

About 10% Real-World Data Adoption

Vyas says real-world evidence is gaining prominence given that it helps to position and get a therapy to the market faster "because there is no longer this whole battle of placebo, especially in rare diseases and other areas where it's an ethical obligation."

Adoption, particularly in the US and European markets, has been growing slowly and steadily. In the last 12-18 months, Parexel used a combination of clinical trial data and real-world data for two therapies and managed to get one to market seven months earlier than scheduled.

However, availability of data in a synchronized format is still a challenge, especially in India. "We still don't have consistency in terms of how data is captured. Today, there is a huge amount of data, either in physical form or in digital form, but the question is how much of that data has been aggregated in a very systematic fashion for us to use extensively. And that's the challenge we face in majority of the tier II/III countries."

Even in tier one countries, even if EHRs [electronic health records] are available, multiple systems exist and "different hospitals don't talk to each other. So, I personally believe that the adoption rate is about 10% at this point of time and it's

Parexel Exec Says Non-COVID-19 Drug Discovery Back With A Bang

By Vibha Ravi

13 Dec 2021
Clinical trial initiations in cell and gene therapies and immuno-oncology are seeing a spike as the COVID-19 experience has shown the benefits of beginning research early, Parexel's executive vice president says. In an interview with *Scrip*, Sanjay Vyas discusses a range of topics from diversity to the advantages of block chain and growth in China

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still a long way to go. Parexel is running 6000-odd studies and I don't have the overall adoption rate right now, but I'm just telling you from a product sales perspective."

Nevertheless, it's catching up much faster than other alternatives, especially since the pandemic proved that it's possible way to collect, process and compare such data remotely and successfully launch a product.

"We had launched remote monitoring and risk-based quality monitoring, but they [regulators] were always skeptical about the data coming in. But then they saw that there are examples that can be taken from a similar or almost a similar kind of an existing therapy which is already benefiting patients," he added.

Predictive Analysis, Synthetic Analytics

While companies have begun adopting predictive analysis to determine the probability of an investigative drug candidate's success, taking this route poses some challenges as well.

"It's still a one-off case at this point of time because there are other challenges. The regulators are very particular about the usage of data, whether there's confidential information related to that data. But I have seen examples where instead of using predictive analytics, what people are doing is synthetic analytics of the same," he says.

Vyas says a trial he knows of was conducted in a synthetic environment where there was no real question computed, but the researchers tried to work with the analytics via machine learning to determine efficacy if the molecule was deployed in a patient's body and the drug received approval from the US FDA.

"How many such examples exist? To be very honest, just one or two examples where you can do this at this point of time. So, I would say everybody in the industry is thinking about it, but there's still not much progress on that," he noted.

Cell And Gene Therapy Studies

Cell and gene therapy studies are "popping up quite extensively" globally and they are at initial stages in India, Vyas told *Scrip*.

Could Synthetic Data Predict Rare Adverse Events?

By Alaric DeArment

22 Aug 2022 Accenture released its Life Sciences Technology Vision 2022 report, including a survey of biopharma execs on trends like synthetic data and quantum computing. *Read the full article here*

"The whole process of conducting a clinical trial has become a little complicated but it's to be the

new future. We have invested in a subject matter expert, we have a new head of cell and gene therapy who just joined us around eight months ago and we are trying to increase our focus to see how we can pivot to many cell gene studies as we go forward."

Indian companies have also started looking at cell and gene therapies, either themselves or in partnership, he added. While *Dr. Reddy's Laboratories Ltd.* is making plans to walk the path, others like *Gennova Biopharmaceuticals Ltd* and *Zydus Lifesciences Limited* have made strides in developing mRNA and DNA-based products.

Meanwhile, newcomer ImmunoACT has a portfolio of CAR-T therapy assets in various development stages. (Also see "*CEO Of India's mRNA Pioneer Gennova On Cancer Vaccines, VC Interest*" - Scrip, 27 Jul, 2022.) (Also see "*It's Coming Home: ImmunoACT Advances Plans For Cut-Price CAR-T In India*" - Scrip, 30 Jun, 2022.) (Also see "*STING Agonist to SOS1 Inhibitor, Lupin Lines Up Oncology Pipeline*" - Scrip, 17 Jan, 2022.)

"So I probably won't be able to tell you the names of the companies that we are speaking to at this point of time. It's not like they have a molecule ready, but they have set up an environment where they have started doing internal research on cell and gene molecules. It will be interesting to see if that/these molecule get(s) developed, but it's at a very nascent stage," he said of Indian companies.

The Indian government has set the stage to offer financial assistance to homegrown companies, which have so far focused on developing biosimilars and non-biologic generics, in their quest to develop cell and gene therapies.

Driving Clinical Trial Diversity

Vyas also sees companies make a conscious effort to increase diversity via inclusion of participants of different ethnicities and genders - expanding to LGBTQ communities as well - as they realize that the way a drug works in a subset might differ from others.

On its part, Parexel, along with The Association of Clinical Research Organizations (ACRO), released a white paper on the subject. It has also recruited a chief patient officer to drive patient engagement and inclusivity.

"We have recently conducted six patient advocacy groups across the globe, one in India, one in China, a couple of them in Europe, a couple of them in US as well," said Vyas. The effort to hear firsthand from the patient on more measures to drive inclusivity revealed certain insights that could be useful in designing future trials.

For example "I'm more comfortable with a doctor who is more ethnically close to my culture....this was very interesting to hear from the ground for us," he added. "So, we are making

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a very conscious effort to listen and try to improve protocols and inform our sponsors" about the sensitivities of the broader patient population, he said.

Besides, companies like Pfizer, *Boehringer Ingelheim GmbH*, Eli Lilly, *GSK plc* and Novartis are making a conscious effort now to improve patient population from India, particularly as decentralized trials opened up the market during COVID-19 and several drugs were given accelerated or emergency approvals, Vyas noted.

India was the second largest site for a COVID-19 oral therapy that came to India, "so definitely there is a lot more interest right now to add India as one of the strategic sites in addition to many other countries." (Also see "*COVID-19 Relapses, Lack Of Omicron Data Complicate Paxlovid Case In India*" - Scrip, 13 May, 2022.)

Will Pfizer's Paxlovid Go The Lagevrio Way In India?

By Vibha Ravi

23 Mar 2022

While the Medicines Patent Pool has sub-licensed Paxlovid to multiple Indian firms, it isn't approved in the country yet. It will get there, but molnupiravir's sales might give an indication of what is in store for Pfizer's oral antiviral COVID-19 treatment post a lost opportunity with vaccine Comirnaty.

Read the full article here

Environment In China, Taiwan

Meanwhile, countries like China and Taiwan are creating trial friendly environments, Vyas pointed out.

"In Asia, I would say Taiwan, China, I would even call out countries like Vietnam and Thailand. But Taiwan and China are mostly driven by local government investments and the funding is big. So, if you see most of the small biotechs coming up are in Taiwan and China and that is what is pushing the whole clinical environment to be in their favor."

While Mexico is stepping up, cross border regulations are still a challenge. Brazil is also making efforts, but visa regulations are still complicated regarding import and export of clinical trial materials and samples "so that becomes a hindrance plus the protocol, the compliance environment is still a challenge."

Innovation Hub Set Up In India

Meanwhile, Parexel has set up an innovation hub in India given the encouraging startup environment.

Starting off small for now, academics are welcome to come into a dedicated area in its head office

called the “innovation room” to experiment and try any innovation they wish to launch and “if it hits the wall, then we might even further invest to use it in the real world.”

Besides, Vyas has launched a postgraduate program in clinical studies and pharmacovigilance with the help of Parexel Academy. The program is expected to bridge the gaps between academic learning and skills required in a real-world corporate setting. (Also see "*Pfizer's India MD On Funding Healthcare Startups*" - Scrip, 11 Apr, 2022.)

“We are now in the second year and the third batch is going to come on board. We take them for six months as interns, and if they prove to be good, offer letters are given immediately. We're creating talent for the industry as well,” he added.

Vyas leads a team of 6,000 employees in India and is looking to increase this number to over 8,000 by 2025. “Between last year and this year alone, we have added 1600 plus people and I personally believe India is slated to be the face of clinical trials. Obviously, we still have a long way to go when I compare India to China, or Taiwan in terms of the number of biotechs or the number of new molecules, but the environment is conducive to support this.”

Onsite Trials Gain Prominence?

On whether there is a greater skew now towards onsite trials compared to when the deadlier waves of COVID-19 were drowning the world, Vyas responded with an emphatic “absolutely”.

In Pfizer, J&J's Innovation Centers, Incubators Lie Paths To Indian Innovation

By Vibha Ravi

30 Nov 2021

Executives from J&J, Pfizer and Johns Hopkins share ideas on driving Indian biopharma innovation via innovation centers and incubators set up in association with academic institutions. On the other side of the table, Indian academia highlights the need for industry participation in skill building and the perils of ‘targeted thinking’

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“The decentralized trials became a very strong mitigation strategy and remains an alternative strategy. I always say that these plus trials or hybrid trials are nothing new. It's just that the pandemic pushed the boundaries because there was no alternative strategy,” he pointed out.

“From my experience, or proposals experience at this point of time, about 15% of studies are now in hybrid model, which is a great number. If you had asked me this question three years ago, we were a three to five percent range.”

However, hybrid trials can’t be applied across all therapeutic areas. Apart from the GCP (Good

Clinical Practices) environment, the type of drug being studied makes a difference. For example, an injectable has to be administered versus a pill which a patient can pop, or products which need to be stored at a lower temperature compared to a standard temperature product.

Besides, costs also rise in a hybrid model with additional layers added like logistics and compliance to make sure data collected in non-laboratory conditions is reliable. Nevertheless, he doesn't foresee a situation where the hybrid model is completely rolled back.

Progress on medical devices and software development is only going to help. "For example, blood draws, there are new devices that are coming. So, you will no longer be required to come to a hospital just for a blood prompt, you can just put the whole device on your desk that goes on to draw the blood out and you just ship the device."