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

Block Chain Use Could Aid Trials

by Vibha Ravi

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

COVID-19 saw companies target vaccines and therapies to tackle the disease, but the focus is back on non-COVID-19 drugs, particularly on cell and gene therapies and immuno-oncology, says Sanjay Vyas, Parexel's executive vice president, managing director India & global SBU head-clinical trial supplies & logistics.

"I believe it is back and better than before, because there is a keen desire to bring more innovation into the market. The pandemic has created a new avenue or thought process for the industry to start innovating much, much more in advance. The mRNA technology is a great example of that," he told *Scrip* in an interview.

Parexel, which now has new owners in EQT IX fund (EQT) and the private equity business within Goldman Sachs Asset Management, did see a slight drop in trial initiations during the pandemic but was conducting 400-odd trials for COVID-19 vaccines and therapies and another 4,000 studies in parallel across different therapeutic areas.

Now that areas like hematology, oncology and orphan diseases and cell and gene therapy have "seen a solid spike.....we have never been so busy in our lives," Vyas said.

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Sanjay Vyas, Parexel

Diversity In Enrolments

The pandemic has also opened the eyes of several multinational sponsors to the importance of diversity in trial enrolments. (Also see "*Breast Cancer Trial Enrollment Illustrates Diversity Challenge*" - Scrip, 19 Aug, 2021.)

Given that the leading pharmaceutical companies are based in US or Europe, the trials for COVID-19 vaccines took place in those regions. However, the nature of the pandemic meant they had to be administered in several other countries in Asia and Africa as well.

Some companies included more such countries in Phase III of their trials. Several COVID-19 vaccines got approval for emergency use in India via bridging studies. Among companies conducting bridging Phase II/III trials in India were *Serum Institute of India Pvt. Ltd.* for *AstraZeneca PLC* and C#702:Novavax, Inc.], *Dr. Reddy's Laboratories Ltd.* for Russian Direct Investment Fund and *Biological E Limited.* for *Johnson & Johnson*'s *Janssen Pharmaceutical Cos.* .

The need for studies in different ethnic groups and nationalities “is one of the reasons why many of the pharmaceutical companies have now broadened their research.”

Pandemic Perspectives: Shifting Research Realities After COVID-19 Place Decentralized Trials Center Stage

By Vibha Ravi

31 Mar 2021

Agreeing that decentralized trials are here to stay, experts discussed in a recent meeting ways in which the pharma research landscape is set to change. With nearly 85% of the industry at different stages of adoption, such trials have seen greater traction in the US, while stricter data privacy laws have hampered progress in Europe, ISCR’s annual conference heard.

Read the full article here

Chinese Policies Not To Hinder Growth

Meanwhile, China has been one of the fastest growing countries within the Asia Pacific region for Parexel and continues to hold great potential. The CRO has had operations in Greater China for 22 years and is one of the largest CROs in the region.

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In line with its growth ambitions, Parexel has entered multiple partnerships. A collaboration with Beijing Illness Challenge Foundation in China aims to gain direct insights from rare disease patients to improve their access and experience in clinical trials.

Another one with Cancer Hospital Chinese Academy of Medical Sciences (CHCAMS) is focused on developing patient-centric protocol designs and methodologies for decentralized clinical trials in China. CHCAMS is linked to other institutions including the China National Cancer Center.

Several Chinese biotech companies are looking to enter global markets and "the whole reason why we continue to look at these partnerships is because these are the same Chinese biotech customers who are required to do the study locally, but also want to take the molecule globally."

The partnerships with CHCAMS and cancer hospitals are meant to ensure "we are getting the right kind of patient population. The more partnerships we bring to the table, the more accessibility we are going to get across not just tier I or tier II cities, but tier III and IV cities as well."

Impact Of Policy Changes In China

Responding to *Scrip*'s question on whether China's recent "inward" looking policy and new regulations for the use of human genetic resources that come from Chinese participants could pose obstacles to Parexel's growth in the region, Vyas said he doesn't see them stopping the show. (Also see "*APAC Podcast: Policies Play Out Against Pandemic, Corporate Activity Remains Strong*" - Scrip, 30 Nov, 2021.))

"I don't know what the near future will hold....I wish I had a crystal ball to talk about it. But ultimately, we will take it as it comes. But right now, nothing is stopping us from doing those continued alliances and partnerships and investments in China."

Vyas said the CRO's planned $3m investment in setting up its own clinical supplies depot in Suzhou New District will not only help Chinese biotech customers conduct studies locally, but also aid international sponsors looking to run trials in China and Asia. (Also see "*China Clinical Trial Crunch Continues But Innovative New Drug Studies Rebound*" - Scrip, 13 Dec, 2021.)

Work has already begun and "hopefully by July of next year" Parexel will have its own infrastructure to support timely access to critical clinical trial supplies, ancillary supplies and laboratory logistics services to clinical sites and patients across the Asia Pacific region.

Putting India On The Map

Parexel is also making efforts to put India on the map for clinical trials. Notably, under 2% of global trials are estimated to be conducted in the country.

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“We have a 1.2 billion patient population today here in India and by not having trials being conducted in India, our patients are going to suffer at the end of the day.” The infrastructure in tier I and II cities and the pool of talent available to conduct clinical trials is a draw for clinical research organizations (CROs), he added. (Also see "*ISCR's Davis On Pandemic Adaptations, Value Of Multi-Regional Trials*" - Scrip, 26 Apr, 2021.)

Besides “there is fantastic regulatory support at this point of time. I have never seen so much of optimism within the Indian regulatory landscape since 2019 when the DCGI [Drugs Controller General of India] changed regulations.”

“We did see a fall in the clinical trials conducted in India due to ethical code of conduct and compliance challenges in 2004....(the number of studies) fell from 300-plus to the range of 70-75 today.”

But, the new regulations are at par with international standards on matters ranging from patient protection rights to investigator protection rights, sponsor protections and ethics committees, Vyas added.

“It was a big surprise also for myself about when I came to the country after 17 years. I personally went down with my clinical monitors to visit a few investigator sites to see how they manage the protocol. I was thoroughly impressed with how they follow SOPs [standard operating procedures] to the point, documentation is so good and accurate, at least with good sponsors and good investigative sites. So, I believe that it's only opening up and bringing the trust back,” he said.

Changing Landscape In India

Clinical trials in India were earlier conducted in accordance with Schedule Y of the Drugs and Cosmetics Rules, 1945. However, concerns regarding patient safety and compensation to patients in cases of adverse effects suffered due to participation in clinical trials were not addressed.

Post a flurry of clinical research that led to allegations of malpractices and a public interest litigation in the country’s apex court, activity slowed down.

On March 19 of this year, the Ministry of Health and Family Welfare notified the New Drugs and Clinical Trials Rules, 2019, thus concluding a long-drawn-out process to codify such rules applicable to clinical trials.

As a result, when sponsors are drawing up protocol designs, they are trying to include India as part of the initial feasibility analysis. “We are saying, hey, while you're looking at 15 other countries, why don't you look at India also,” Vyas added.

Future of Block Chain, Data Mining In Trials

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While technology advancements like machine learning and data mining play a minor role in clinical trials today, their use could be expanded substantially if regulators and governments work together to drive technologies like block chain.

For instance, he noted how Estonia literally moved their entire healthcare system into a blockchain technology where people's health data was available through that blockchain. "And that blockchain enabled each patient to decide how much of their information could be made available on the clinical trial platform when new therapies come," Vyas said.

Having a readymade base of such health information could provide investigators or clinical research organizers a head start in enrolling patients for a study. A blockchain could ensure that the data is secure, fungible and cannot be attacked since "the data sits in different ledgers and and every time you make a change, it monitors that change and records the timestamp of the person who has changed that data." (Also see "*US Survey Shows Pharma More Open To Remote Patient Monitoring*" - Pink Sheet, 10 Jun, 2021.)

> ***"Today, when you go and look at all the social media websites, you know, your information is already available out there. Many companies are using social media information to even do patient recruitments" - Sanjay Vyas, Parexel executive vice president, India country head***

Already, decentralized trials are utilizing social platforms to reach out to prospective patients based on the data that's already available on the market.

On data privacy concerns, particularly in emerging countries like India, Vyas said "It's not only here in India. I believe it's a concern in all parts of the world. So that needs to be weighted very, very closely by the regulators and there have to be proper processes around that."

However, for data to be aggregated on a single platform, regulator or governments will have to take a lead. Apart from looking at such technologies, they will need to start convincing consumers to put that data onto the platform which gives them full autonomy and control.

Parexel is considering mining data from past trials for predictive analysis on the possibility of a molecule's success before it is trialed. "If a new therapy in the same therapeutic area with a similar molecule design is brought into the market, what are the chances of success of that

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molecule....so that you don't have to invest the next three to five years doing the full study to find out whether finally the therapies worked or not."

While it would not be wholly accurate, it could give a fair estimation of the investigative drug's chances, he added. (Also see "*IQVIA COVID-19 Vaccine Revenues To Soar But Pandemic Will Impact Overall Global Medicine Spending*" - Scrip, 10 Dec, 2021.)

In April, Parexel signed up Veeva Systems as a partner to develop a standard technology platform. With insights from sponsors, site and patients, the companies plan to improve Veeva's cloud technology and Parexel's processes for delivery of clinical trials.

"When you work with a single cloud platform provider, your ability to gather data in an integrated form becomes much easier," Vyas said. While a shift to a new technology is not easy to implement and benefits of the partnerships are "yet to be seen", Parexel has continued working on other platforms like Oracle as well.

Hybrid Trials, Use Of Synthetic Arms

Meanwhile, research programs across the world are continuing the shift to hybrid trials. Parexel has been a strong advocate of decentralized trials and reaped the benefits during COVID-19. (Also see "*Industry Is Moving Fast With Decentralized Trials, But Is It Too Fast?*" - Scrip, 3 Nov, 2021.)

On the future of trials, Vyas said purely decentralized trials could not only be very expensive to conduct but the need for regulator approval for a shift in trial protocol could pose a hindrance.

"Regulators have realized that this [decentralization] is possible, which is one of the reasons why there is a new hashtag trending in the clinical trials industry #nolookingback." The intent of putting up an alternative trial strategy was to ensure patient efficacy and safety and since Parexel was able to achieve that, sponsors are willing to conduct more hybrid trials.

Janssen's Sarich: Randomized Controlled Trials, Real-World Evidence Go Best Together

By Anju Ghangurde

04 Oct 2021

Janssen's Troy Sarich outlines why it's hard to emulate randomized controlled trials with real-world evidence studies, emphasizing that the two are "not in competition." He also highlights the huge strides made by AI-driven technology firms to provide "research-ready" structured data and new game-changing advances in the area of health sensors.

Read the full article here

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Overall, the hybrid model accounts for 50-60% of trials now and a McKinsey study predicts that share is set to jump to 70-80% over three to five years, with 100% decentralized or site-less trials accounting for 5-10% and the traditional model for 15-25%.

On the use of synthetic arms in clinical trials, Vyas said Parexel conducted a trial during the pandemic, which normally would have taken 18-20 months to complete, but on account of using a synthetic control arm, "we were able to use real-world evidence and real-world data combined with the clinical data, so that we were able to launch almost six months in advance of the actual timelines."

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