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“APAC continues to be a global hub for clinical trials”

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The Asia Pacific (APAC) represents more than a third of all cell and gene therapy in global trials. In line with the trend, Sydney-based contract research organisation (CRO), Novotech has conducted a statistical analysis which indicates that, between 2017 and 2021, over 70,000 new clinical trials were registered in the APAC region, the US, and the EU5 (France, Germany, Italy, Spain, UK). During the forecast period, the APAC region reportedly accounted for 50 per cent of the trials, followed by the US (29 per cent) and the EU5 (17 per cent). China recorded the largest number of new trials, followed by the US and India. Dr John Moller, CEO, Novotech, provides his views on the APAC CRO market.

What is your outlook for the Asia Pacific CRO market in 2023?

The latest Novotech research with GlobalData shows that APAC continues to be a global hub for clinical trials. Our current data shows it had the highest growth rate globally with 9 per cent CAGR in 2022. In addition, the APAC is well positioned with 7,600 clinical sites, more than any other region, combined with higher urban density which translates to expedited patient access. We expect the APAC to continue this exceptional growth through 2023 and beyond, fueled by access to patient populations, quality medical and site facilities, site capacity and the ability to deliver accelerated timelines with globally accepted data.

What does Novotech's Cell & Gene Therapy clinical trial statistical analyses for APAC indicate? Which country is the leading hub for trial activities?

The APAC is certainly the global hub for cell and gene therapy research. The region's cell and gene sector is currently growing almost 50 per cent faster than the rest of the world (ROW) and we expect to see this sector continuing to grow at record speed, especially in oncology, vaccine, and cardiovascular research. In addition, China has an exceptional growth profile which is currently 15 per cent faster growth rate than ROW.

The latest research from GlobalData data shows APAC is involved in more than a third of all cell and gene studies. From 2017 to August 2022, there were close to 1,800 trials initiated in cell and gene therapy, with APAC involved in ~40 per cent of trials. In addition, the APAC is the leading location globally for CAR-T trials, with China attracting ~60 per cent of all CAR-T trials between 2015 and 2022.

We know the region is a proven destination for quality clinical data, exceptional medical facilities, and access to vast patient populations. Indeed, due to its large population and lower volume of studies, the APAC region has a trial density about 6 times lower than the US and 5 times lower than Europe. China has the lowest trial density.

The majority of cell and gene clinical trials are in oncology, specifically for blood cancers, viral infections, and solid tumors. After oncology, the majority are in infectious diseases, CNS, and cardiovascular diseases. The region also has a favorable research and development landscape for early and mid-phase cell and gene therapy studies with Phase I and Phase II trials accounting for the majority (>90 per cent) of trials conducted in the APAC region.

Which are the leading therapeutic areas for clinical trials in APAC?

APAC countries undertake trials across the therapeutic spectrum and the main underlying driver is sheer population, with lower trial density than the rest of the world. They have also experienced an increase in some cancers, infectious diseases and lifestyle and metabolic conditions. For example, one in three of the approximately 400 million hepatitis B-infected global population resides in China.

In comparison to the United States and Europe, Asia also has a significantly higher prevalence of non-Hodgkin's lymphoma, non-small cell lung cancer, and certain genetic disorders. These disease rates translate to a larger patient population, enabling rapid enrollment.

Additionally, China and Japan are the second and third biggest pharmaceutical markets in the world, respectively.

Further, the region has a lower trial density due to its vast patient population and lower study volumes, which means there is less competition for eligible patients. In addition, the multiethnic populations in the APAC region enables sponsors to gather a wide range of data on patients who have historically been underrepresented in clinical research. This has recently been emphasized by regulatory authorities to ensure the broadest access to novel medications.

For a CRO, which are the strategically significant locations in Asia? What is Novotech's approach to aligning its strategies with the market?

While the region as a whole is experiencing significant growth, the strategically significant regions in APAC are Greater China, South Korea, Taiwan, Australia and New Zealand.

Novotech serves specific and unique requirements including study phase, protocol, timelines and of course, therapeutic areas. The market dynamics that shape our clinical programmes include disease prevalence, access to standard of care, regulatory environments, access to patients, and our long-term relationships with sites and investigators across the region.

While our company has deep expertise in the APAC and the data shows a significant number of studies globally are conducted in the region, Novotech's European and US operations offer expanded services for global clinical development for biotech clients.

How do you perceive the complexity and regulatory process involved in cell and gene therapy research?

Cell and gene therapy research typically presents another level of complexity and regulatory processes which means an experienced CRO partner is vital. There are often additional regulatory agencies and complex definitions around the nature and risk of a cell and gene therapies that need to be complied with.

We are pleased to have been recently recognised with the Gene & Cell Therapy Excellence Award 2022 which is a real credit to our Novotech team and their expertise in this rapidly growing sector.

How would you describe Novotech's perspectives on global expansion, and stakeholder & investor relationships?

Novotech has been executing a global expansion strategy over the last 12 months. This has been driven by the demand of our larger biotech clients, many of which are undertaking global Phase 3 projects. We acquired a US CRO last year, and the recent acquisition of EastHORN completes the European part of this strategy giving us access to around 30 European countries.

We've been close partners with EastHORN for well over a decade and we take a similar approach to client service and we know each other well. While EastHORN operates throughout Europe it has a long history in Central and Eastern Europe, which has some of the attractive patient recruitment characteristics that Novotech enjoys in Asia, as well as some similarities in disease prevalence.

We have also recently acquired CBR International, a global product development, clinical oversight and strategic regulatory operations group.

Our US regulatory acquisition gives us additional FDA-focused regulatory expertise and services including regulatory strategy development and writing, FDA representation, e-submissions, and GMP support amongst those services.

The acquisition will strengthen Novotech's capabilities in regulatory strategy and US FDA interactions and submissions including IND, IDE, NDA, BLA, Fast-Track, Break-through and Orphan Drug Applications. This will be particularly important for many of our Asia-based clients who are moving into the clinic at an incredibly fast pace and often need external regulatory support.

The CBR acquisition, together with Novotech's existing regulatory affairs capability, creates a large global group of experts in toxicology, drug development, and global regulatory submissions support.

Novotech has decades of drug development and clinical trial experience with biotech clients, exceptional site and investigator relationships, access to vast patient populations, and a project management approach focused on problem-solving, ownership, and flexibility. We continue to invest heavily in our training and development as well as state-of-the-art systems which will be of enormous benefit to our newly acquired companies and our clients.

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