Sponsored by

PRAHEALTHSCIENCES

Clinical Research Opportunities In China

Vicky Chen, Vice President, Head of China, Product Registration at PRA Health Sciences, reflects on clinical research opportunities in China.

As the demand for clinical trials continues to grow around the world, geographic expansion into Asia is increasing and for good reason. There has been diversification among biopharmaceutical companies to file new drug applications in the Asian markets, requiring local trials and patients. In parallel, governments are becoming more aware of the economic benefit and positive health care impact a burgeoning clinical research industry can have. This expansion of trials has resulted in continued growth for the CRO market in the region.

WHAT IS FUELING CLINICAL TRIAL GROWTH IN CHINA?

Asia, with a regional population of over 4 billion, offers attractive resources such as numerous clinical trial centers, a vast patient pool, and comparable incidence and prevalence of Western diseases. The most significant growth in Asia can be seen in China. With a population of nearly 1.4 billion, and changes underway in its regulatory environment, the drug development industry is seeing a long-anticipated growth curve taking shape. In anticipation of an increase in clinical trial work, some biopharmaceutical companies have begun setting up hubs in Beijing and investing in the development of the Chinese clinical trial environment.


Vicky Chen

China's pharmaceutical market is the second largest in the world, just behind that of the US. The market is projected to see an annual growth rate of more than 9%, but historically the regulatory environment in China has been challenging, leaving Western pharmaceutical companies with limited access. That environment is now undergoing big changes thanks to reforms instituted by the China Food and Drug Administration (CFDA), which was reorganized to the China Drug Administration (CDA) in March 2018 and renamed as the National Medical Product Administration (NMPA) on August 30, 2018.

NMPA is also planning to adopt a patent linkage system under which drug applicants will be required to make a declaration on patent rights infringement in their applications. This will help address the lack of protection against infringing generic drugs, which has been a challenge for life sciences companies. While laws require that manufacturers disclose any potential conflicts, there are no enforcement or penalty mechanisms. Generics are often approved and sold before a patent holder can initiate legal action.

Beyond trial and patient access, many biopharmaceutical companies are expanding their trials into Asia to ensure they have sufficient native patient populations and data for local marketing applications. Historically, there have been significant challenges with clinical trial applications and regulatory timelines that have made the region less desirable as a destination. However, the 60-day silent approval procedure for clinical trials has been effective since July 27, 2018, and a clinical trial application will be considered approved automatically if no comments are received from CDE (Center for Drug Evaluation) within 60 working days. The clinical trial start-up timeline in China is expected to be shortened significantly, and a tremendous growth curve in trials being conducted in China is anticipated.

WHAT ARE SOME OF THE BARRIERS/CHALLENGES FOR DRUG DEVELOPMENT IN CHINA?

Although China is quickly becoming a preferred clinical research destination, navigating the complexity of treatment paradigms, local laws and regulatory requirements can be arduous. Because of China's massive cabinet restructuring within the State Health Committee, there is some uncertainty about what the new clinical trial application process will look like. As its regulatory environment im-

proves, China is poised to become an even bigger clinical research powerhouse, and PRA Health Sciences is one of the companies making the necessary investments in talent and infrastructure to help support this growth.

The Asian market has a reputation for having complex health care systems with a less uniform approach than the European Directive. Traditionally, one of the biggest challenges has been an inconsistent definition of health care and its infrastructure. However, this is changing. Technology-driven countries such as Japan and South Korea are pairing with efficiency-driven countries like China and factor-driven countries like India, and together they are making progress in developing strategies that can overcome drug development hurdles in the region, particularly now that the market is open to making changes. Collectively, there has been a focus on simplifying regulatory approval processes, increasing government support and improving clinical trial industry infrastructure.

In the last few years we have seen the introduction of adaptive monitoring across the globe, the biggest change to the industry since electronic case report forms (eCRFs) came into play. There have been large investments in technology around adaptive monitoring but implementation across Asia has been formidable. Enormous steps forward have been taken in improving the speed of clinical trials and the way each country embraces trials, but managing them has required new solutions to ensure smooth implementation and adherence to local ethics requirements. These challenges will continue through the next few years as the industry adapts.

WHAT DOES THE FUTURE OF DRUG DEVELOPMENT LOOK LIKE?

Drug development is complicated, time-consuming and expensive, particularly in the US and Western Europe. Virtual trials and mobile platforms are a viable option to make the patient experience more rewarding. Integrated health data and analytics delivered as cloud-based solutions demonstrate a more agile, flexible and adaptive future for clinical development.

A key opportunity for APAC is to embrace technology at the client, site, CRO and patient level. Everyone should be considering how technology can assist with faster drug development. Patients are consumers and we need to offer them ways to access these trials more easily – technology can help us do that. In every trial we see sites that fail to recruit patients. This is a waste of time and money. There has also been a lazy approach to patient recruitment where we wait for patients to approach us to enroll in a trial. There is an opportunity to use data to help with patient recruitment.

CROs need to use technology to provide deep, data-driven insights to optimize global clinical studies and drug commercialization from concept to compound to cure. Virtually connecting patients who are beyond the clinical setting through ***Bluetooth*** wearables and connected home devices reduces participation burden and fosters patient engagement throughout the continuum of care, while also supporting the collection of billions of data endpoints.

The CRO industry is well positioned to thrive in the Asian market, with some positive momentum already being seen in many countries to welcome clinical trials. It is this diversity and complexity that creates a great opportunity for CROs to provide subject matter expertise to sponsor companies, to help guide them in successfully conducting clinical research in Asia.

HOW IS PRA INVESTING IN THE REGION AND CULTIVATING DRUG DEVELOPMENT OPPORTUNITIES?

PRA is making a significant commitment to the region as it continues to strategically expand operations and local expertise. Sponsors want relevant clinical study experience and capabilities across all phases, language proficiency and technological expertise. PRA's innovative operational models, such as its dynamic partnership and joint venture with Takeda in Japan, allows the company to expand its full-service presence in the region and globally.

PRA has been delivering innovative drug development solutions in China for nearly a decade, offering specialized operational and therapeutic expertise through a broad spectrum of full-service clinical development and integrated outsourced operating models. With more than 200 clinical studies conducted in APAC in the past five years, and 130 currently underway, PRA has an experienced team on the ground.

PRA currently has over 400 employees in China and continues to expand rapidly, with new offices opened in Dalian and Shanghai in 2018. In building out infrastructure with key resources, the goal is to establish the most comprehensive and flexible offering in the region to support clients with global and China-specific trials, embedded teams and in-house biometrics.