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Diversity and complexity create a great opportunity for CROs in Asia

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Asia as a region is comprised of a diverse set of countries and cultures as well as a tremendous population of patients for possible clinical trial participation. Navigating the complexity and diversity of these countries, their treatment paradigms, their regulatory requirements, as well as local laws can be extremely challenging to ensure successful conduct of clinical trials in the region.

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With consistent and growing demand for clinical trials worldwide, geographic expansion into Asia continues at a steady pace. The need for Asia as a region for clinical trial conduct and clinical trial sites is a result of both the competitive landscape for patients as well as a diversification among sponsor companies to file new drug applications in the Asian markets, requiring local trials and patients. While the last decade has seen ebb and flows of trial participation by Asian countries, with stops and starts in major countries, the last few years has seen steady and consistent growth in the region.

This expansion of trials has resulted in continued growth for the CRO market in this region as a response to need. This is evidenced by robust growth seen in the CRO market in the region compared to the rest of the world. While globally clinical trials are expected to grow at a compound annual growth rate (CAGR) of 12.4% from 2015 to 2020, topping out at $57 billion in revenue, North American expected growth is only at 10.4% CAGR, while Asia is forecasted to grow at a CAGR of 19.9% over the same time period. (Frost & Sullivan, Asia: Preferred Destination for Clinical Trials, 2016).

Not surprisingly, as the number of global trials continues to expand, so does the demand for patients, driving sponsor companies to expand their reach to find potential patients to participate. With a regional population of over 4 billion, with approximately 2 billion in urban areas, Asia as a region for clinical trial recruitment is extremely attractive. In addition to sheer potential patient volumes, clinical trials as a treatment option can be very attractive to potential patients in many Asian countries. In the majority of Asian countries, the per capita spending on healthcare is lower than the US and Western Europe, as is access to many novel therapies. These two facts make participation in trials attractive to many Asian patients as an effective way to get access to potentially innovative therapies.

Beyond trial access, and patient access, many sponsor companies are expanding their trials into Asia in order to ensure they have sufficient local patient populations and data for local marketing applications. Historically, there have been significant challenges in many countries with regard to clinical trial applications and regulatory timelines that have made them less desirable as a destination. However, with current proposed changes in regulatory review timelines in countries such as China, it is anticipated that start up time will decrease from 12-18 months to 6 months.

Once implemented it is expected that there will be a tremendous growth curve in trials being conducted in China.

China represents one of the largest potential growth regions for clinical trials and CRO market in the next 5 years if the CFDA reforms are enacted and start up timelines decrease significantly. The access to large numbers of patients, both disease specific and treatment naïve, in urban settings will continue to make China attractive for trials. That said, GCP and quality challenges can be an issue at trial sites with limited trial experience. Therefore, the use of SMOs and the provision of GCP training and site support will be critical to ensuring high quality data is produced at these sites. It is anticipated that as a result, in addition to CRO growth in the country, SMO growth will also be required to meet these needs.

At the other end of the spectrum in Asia is the Japanese clinical trial market, which is facing considerable challenges due to a lack of available, experienced, clinical trial resources. The rapid expansion of trials in Japan has put significant pressure on the labor market that supports clinical trials. Limited availability of experienced, Japanese speaking clinical and medical staff for direct site interactions coupled with an outdated resourcing model by local CROs has made reliable and consistent staffing a bottleneck for some providers in the country. However, there continue to be collaborations between regulatory authorities in Japan and other countries in the region to accept early clinical supportive data as justification for PMDA applications. The ability to share safety data between countries such as China, Taiwan, Japan and Korea may help streamline clinical trial applications as well as marketing applications in Japan. Both the limitations in available staff and the increase in demand for trial sites in Japan present growth opportunities in the country for global CRO market expansion.

Of all the countries in the Asia region, South Korea seems to be enjoying the greatest growth in clinical trials and clinical trial sites. The extensive infrastructure, state of the art hospitals, high quality medical care and access to experienced staff have made Korea a primary choice for trial participation in Asia. Routine audits by regulatory authorities such as FDA and EMA, as well as sponsors, routinely support the high quality work that is achieved in Korea by clinical trial sites. Furthermore, from a disease state perspective, given the disease burden in Korea mirrors much of what is seen in Western countries it is ideal for continued CRO growth for new trials.

Taiwan remains a good midsize country for clinical research. The infrastructure and high quality performance, particularly when compared to China, are attractive to sponsors. There is hope that the Cross Strait agreement may support the sharing of data between China and Taiwan to speed clinical trials but political positioning has slowed the realization of this goal.

The mainstay of research and general hub for CROs in Asia continues to be Singapore. While there is significant investment and infrastructure to support R&D and Drug Development, the country and its participation in clinical trials remains limited due to size. While the work conducted in Singapore is some of the highest quality in the region, the limitation on access to sites and patients makes any significant expansion in the country unlikely.

The remaining Southeast Asian countries, (Malaysia, Philippines, Cambodia, Vietnam, Myanamar, Thailand, Laos, Indonesia) all represent a small number of active clinical trial sites today. However, with respect to populations and access to treatment naïve patients, as well as certain therapeutic indications (tropical disease, infectious disease, certain cancers) these countries present excellent growth opportunities for CROs. The challenge in many of these countries however remains infrastructure,

and access to well-trained clinical sites and staff. In many of these countries the clinical trial models are still relatively new, and thus access to talent for CROs for hiring experienced, GCP trained staff can be very difficult. Malaysia, Thailand, and Philippines represent the best option for most indications however Vietnam is attracting some interest.

Despite the potential barriers in some Asian countries, it is anticipated that the region as a whole will continue over the next 5 years to exhibit significant growth in clinical trials, and as a result so will the CRO industry in the region. Based on the projected CAGR through 2020, it is anticipated that the CRO market in Asia will grow at almost 2x that of North America.

With regard to costs in the region, while it is true that costs for procedures, diagnostic test, office visits and standard of care may be 30-40% lower than in Western countries, these costs are balanced out by the additional support needed to ensure training and quality deliverables at these clinical trial sites.

For CRO growth in Asia, while much of it will be as a result of the addition of clinical trials sites in the region, a large proportion will be support and infrastructure to train sites in GCP and to ensure quality via clinical monitoring and QA audits. For expansion to continue in this region it is imperative that the data being generated remain of consistent and high quality.

Asia as a region is comprised of a diverse set of countries and cultures as well as a tremendous population of patients for possible clinical trial participation. Navigating the complexity and diversity of these countries, their treatment paradigms, their regulatory requirements, as well as local laws can be extremely challenging to ensure successful conduct of clinical trials in the region. However, 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 conducting successful research in Asia.