Susan Hsu â?? CEO, StatPlus, Taiwan

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Susan Hsu,

managing director of Taiwanese data-driven CRO StatPlus, speaks about the key trends impacting Taiwanâ??s clinical trial environment and goes on to share her views on the increasing attractiveness of the island. Hsu concludes by explaining the service providerâ??s strategic position within APAC and its unique strength as a globally active, local expert.

Please begin by introducing StatPlus, a Taiwanese CRO founded in 1998.

StatPlus has been operating for just over two decades, founded on the model of statistic-based services then later entering into the CRO space â?? similar to players like IQVIA and Covance. From data management and statistical analysis, we began to offer clinical research services as well because at the time there was a major market need for a comprehensive industry solution.

StatPlus works with both global pharmaceutical MNCs who have operations in Taiwan as well as the countryâ??s own local companies. Since begin founded, StatPlus has conducted over 600 trials and received multiple accreditations for our CRO services, including FDA inspection.

What main trend have you seen in the evolution of Taiwanâ??s clinical trial landscape?

Three years ago, we saw a major change in its clinical research environment due to the infamous failure of a phase II/III study for breast cancer. Since this moment, Taiwanâ??s biotech investment market came crashing down as investors here have a low failure tolerance. At this moment, we began to think about how we can face this challenge. Under the new regulation of the government, there has been a push to develop more advanced, value-added medical devices in Taiwan. Therefore, last year StatPlus expanded its services to cover the medtech sector.

How is StatPlus able to adapt to the needs to this changing client demographic?

Providing CRO services for new drug, medical device, and even cell therapy studies all have the same process, just the intervention is different. However, for cell therapies and new drugs, studies may be more conservative and concerned with quality and ethicality at each step. These clients

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understand the ultimate global standards that they will need to meet, so they are willing to allocate more budget to their trials. On the other hand, medical devices do not need such a high number of patients to prove their clinical results. For this reason, we need more clinical and regulatory experts to communicate with the authorities to explain this.

There still a higher volume of new drug studies than medical device studies in Taiwan, but we do expect to see the sector grow in the near future. For drug studies, our standards of operation are well defined, we do not need to spend a significant amount of money to run these trials, and our client pool has a steady inflow. When it comes to medtech, we have to take more time to develop our clients and educate sponsors about when is the right time to initiate clinical research. Additionally, they often do not know how much budget they need to prepare for trials or how to assess the value of their product. At this point, the vast majority of medical device companies do not realize that conducting trials can actually increase the value of their product.

How is StatPlus positioned within Taiwanâ??s clinical trial ecosystem?

Many Taiwanese companies are too small to enter the global market on their own. In order to be able to attract international partners, more data and evidence is needed to prove the efficacy of their products. Conducting clinical trials is the only solution for this. Furthermore, as a local CRO with a global reach, StatPlus can play a key role as the central coordinator of global trials at a much more competitive price point than players like PAREXEL for example. Although we may still be more expensive than other more localized CROs, StatPlus brings greater authority in international regulation, data monitoring, and overall cost reduction.

What competitive advantages can Taiwan offer to the biomedical industry as a clinical trial destination?

Taiwan has a clinical trial environment which is up to par with global standards yet still has a lower price tag than the US or Japan. In Taiwan, it is important to evaluate the population and consider the disease area of the trial. For example, head and neck and colorectal cancer along with liver disease are very prevalent in Taiwan and our investigators have a lot of clinical expertise in this area. In regard to other diseases, the National Health Insurance (NHI) allows us to easily access Taiwanâ??s patient pool and determine where are the best candidates for the study.

In 2011 StatPlus played a major role in forming Asia CRO Alliance which cover seven countries in the region. What was the rationale behind the creation of the alliance?

In recent years, there has been a notable consolidation of the sector as many CROs merge as an attempt to scale up. Big pharma typically selects the massive global providers as their standard of operation. Local CROs tend to have a much lower chance of attracting these clients, however, we work well with local biotechs and SME pharma companies. For this reason, we decided to form the Asia CRO Alliance (ACA) to be more competitive and establish a network throughout APAC that can bring together the regionâ??s resources.

When we first established ACA it included India, Malaysia, South Korea, China, and Japan. Today we have narrowed down to Japan and Korea, but we are still evaluating Chinese partners. In Japan, research and trial costs are high but because the PMDA does accept clinical data from outside of the

country, many companies look abroad to find their service partner. In medical culture, Taiwan is more similar to Japan than South Korea, so we encourage the industry to come here for their trials.

How is StatPlus able to stand out from local players and international heavyweights as the industryâ??s partner of choice for CRO services in Taiwan?

Unlike many of the international CROs in Taiwan, StatPlus takes full advantage of the NHI when planning studies. These players may just repeat the structure of a previous study they did before or find a KOL to lead the study which is very costly, whereas a smaller local company might lack the experience to properly navigate all the data the NHI can provide. At StatPlus, we fully utilized the NHI data network to determine which hospitals and doctors are best positioned for running a trial in any disease area.

Not only do we have a strong scientific and regulatory point of view, but StatPlus is also dedicated to integrity in working with our clients. We chose to be very transparent about what the needs of a project are when planning a research study. We view each project from different perspectives such as financial, regulatory, and success rate to determine what are the best options for the country, hospitals, and patient size.

In Asia, we have a strong culture of including investigators in the conversations of CROs and sponsors. We make more of an effort to work alongside doctors to ensure that trials ultimately reach global standards. If sponsors have very little experience in clinical research, especially in medical device, StatPlus is diligent in coordinating this triangle of stakeholders. We have medical doctors in our team who are able to communicate effectively with investigators to ensure the quality which may not be the case in global CROs.

To give an example of our abilities, one of our Japanese clients have received health authority inspections for three proposed projects over the past three years. Between the one project designed by StatPlus and the other two designed by a global CRO, our project was the only one to be approved.

What final message would you like to deliver on behalf of StatPlus and its team?

I love conducting clinical research and find it very interesting. As Managing Director, I encourage my team to first consider why they want to be in this field, then I work to train them and help them find their passion. This way the entire StatPlus team is dedicated to making sure our clients can achieve success.

What advice would you give to someone looking to follow your career footsteps?

As a student, I believe the most important first step is to understand why the global regulatory standards and industry requirements are in place. Next, one should understand the industry needs and to what extent CROs can play in fulfilling them. Once they understand these things, it is important to get real experience and learn what their skills are. I encourage the new generation to understand that their strengths and weaknesses are, how they can try to improve their weakness, and finally to work collaboratively so the strengths of others can support their weaknesses vice versa.

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