Jia Liu â?? CEO, DreamCIS, South Korea

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Jia Liu, CEO of DreamCIS, a Korean CRO, part of the Chinese company Tigermed, talks about her vision for DreamCIS to be â??the CRO everybody wants to work withâ?•. Liu assesses the changing environment for clinical research in Korea and offers her view on the successes and scope for improvement regarding government action to foster a clinical research ecosystem.

You became the CEO of DreamCIS in 2017. What have been your key priorities during this time?

This is my first role for a company based in the Asia-Pacific region. In my previous 20 yearsâ?? experience, I always worked for multinationals headquartered in the West, such as Bristol Myers Squibb, Roche, and Syneos Health (formerly INC research). I became the CEO of DreamCIS four months after joining Tigermed as the head of international business. Tigermed is an international company based in China, with offices in the USA, Australia, Taiwan, Malaysia, Singapore, Switzerland, and Romania.

Upon arriving, my first priority has been to ensure that we have the correct business and operation strategy to enhance the financial situation in the operation. The company was not in good shape initially, not only in terms of high staff turnover, but also in terms of how the clinical trials service was conducted, and how the financial reports were being completed. We invested significant efforts to introduce the appropriate financial management system, and to emphasise the sufficient project management strategy, based on quality, resource management, finances, and timelines.

My second priority has been to promote a cultural change to alter the philosophy of the organisation, better aligned with our mission and core values. We donâ??t aim to follow the traditional Asian working culture where the CEO has absolute power over all decisions and other employees must follow in line.

How has DreamCIS been performing in recent years?

We have observed a turbulent period within the Korean team as a result of the acquisition in 2015. Hence, instead of managing the operations remotely from China, it was decided that I should manage directly in Korea. Having made the changes to the business strategy, we reversed the trend in increasing losses; since December last year we have generated positive profits. We are aiming to launch an IPO in the year 2019 or 2020, based on the trend of our financial recovery.

What are the advantages of being incorporated as a Tigermed company?

One advantage is the very strong ownership spirit of everyone involved at Tigermed. This was not the case with DreamCIS when I arrived, which had a much more traditional CEO-dominated environment. Tigermed is now listed and has a reputation in the Chinese market of very strong employee engagement; we want this to diffuse across into the Korean operations.

Moreover, DreamCIS now has a much more stringent system of financial and operational regulations, which will raise the quality of the services provided. In Tigermed, we hold the view that pharma companies and CROs are partners, rather than clients and customers. We believe we have a duty to deliver the services for their project and we have the expertise in clinical trials and the

resources and the capital to manage the projects.

Can you tell us more about your offering to clients?

At the moment we have a diverse offering, quite simply because we need to remain flexible to survive in the current market. While we can facilitate trials in any therapeutic area required, we have recently accumulated great experience in oncology and infectious disease. In the past we had more experience in cardiology but following the market trend our projects are becoming more concentrated on oncology.

Instead of specialising in specific therapeutic areas, we have moved our attention to the phase of the drug trial. We hold a leading position on post marketing studies â?? a post approval trial required by Korean regulators.

How would you evaluate the current environment for clinical trials in South Korea?

It is interesting to see three clusters of companies forming. Firstly, there are the affiliates of the multinational companies who are organising parts of their global trials in Korea. Korean regulations have been favourable to this group, encouraging them to conduct their trials, introduce their product, and then make it available locally. This is a shrewd strategy to match the current needs of the market. Clients launching their products in the Korea market then have to conduct regulatory-required Post Marketing Surveillance (rPMS) with a much larger Korean patient population. A CRO with a full-service chain in Korea, like DreamCIS, is naturally their partner to work with.

The second cluster are the traditional Korean big pharma companies. Their traditional expertise derives from generic production and manufacturing. However, around ten years ago they began to realise the importance of innovation. Consequently, they have invested significant funds, and have developed, or are in the process of developing some robust products.

The third cluster, the area where we see most promise, consists of the bio ventures â?? small start-up companies who have both a great idea for a new drug development, with a regional or even global development vision, and have also amassed significant investment. However, they lack the infrastructure to complete the clinical trials required for commercialisation.

This is where our operations become especially critical. We can act as a partner and bring value to them. We understand the regulations, the requirements, and we also have a network of physicians who know the patients, as well as the medicines and treatments. Thus, we can collaborate and implement a clinical development plan on their behalf, walk them through the approval process. We are also observing this phenomenon in China, where Tigermed has a very close working relationship with bio-ventures.

While the number of clinical trials has fallen worldwide, they have remained stable in Korea. What makes Korea a popular destination for clinical research?

Considering the KoNect data, the total number of applications for clinical trial approvals in Korea has remained more or less constant year on year. What is changing are the types of trials being introduced. In the past there were more phase III trials, usually carried out by the global

pharmaceutical companies. However, now we are observing more early phase studies, corresponding to the start-up bio venture companies.

Korea is an attractive destination for clinical trials because of its regulations: they still play a critical role in location decisions, and the Korean government is continuously improving their process and review methods, sending a very positive signal to the industry.

For bio-venture companies, there is a vibrant ecosystem. Many of those involved in these endeavours were historically part of the global development team. With industry gaining the knowledge and confidence, and after the hospitals and research centres also became more involved in clinical research and gained the know-how, it established the foundations for a clinical trial environment. The Korean government has promoted innovation and biology as key sectors within the economy, so are encouraging investment and developing policy to attract the capital to this area. That is the ecosystem which bring s technology and capital to Korea; with that, a very dynamic development environment has been generated here.

Finally, Korea, being one of the most developed Asian countries, open and connected to the world, encourages local bio-ventures to consider that their programme is not limited to Korea. They have global ambitions from the outset, ensuring their research meets global standards, and using international platforms to present this research to attract partners such as big pharma, or companies from the USA and Europe.

Korea is set to become the major hub in Asia-Pacific for early phase trials. However, no country in the region can compete with India and China for population-intensive trials. Given this context, how do you see KoreaÂ´s role evolving?

I still believe Korea can maintain its leading position in Asia by continuing to develop its infrastructure. It has a very high standard of medical care, with an efficient medical insurance programme. Moreover, it has a strong network of clinical research centres, who, regardless of size, value clinical research. Hence, those already participating in clinical trials are very motivated. The infrastructure for hospitals and clinical trials system is already well designed so that there are healthy revenues generated. These revenues can support the sustainment and even growth of the research centres. As the leader of a CRO which acts as a business, I can only echo that the model they are following is effective.

Clinical trials depend on the number of patients. Given Koreas 56 million population, there are an abundance of patients to meet the required sample size. The challenge is to find the appropriate, motivated investigator who can gain access to the right patient population.

How do CROs overcome the homogeneity of Koreaâ??s demographics in these trials?

The scope for multi-ethnic trials in Korea alone is limited and usually only possible in phase I trials, with a sample size of only 10-20 subjects. Accordingly, we believe that international partnerships are the best solution to Koreaâ??s lack of ethnic diversity. This will provide access to the populations to cover the multi-ethnic trials. Given that as part of Tigermed we have access to its international partners, we can source more ethnically diverse patients and overcome the limitations presented by the Korean patient pool.

Where do you see the potential improvements or extra support from the government, and groups like KoNect to catalyse the growth of clinical trials in Korea?

From my experience coming from China and trying to bring Chinese clients, the regulatory review process could be defined in a broader approach. Hence, there could be a better emphasis on the quality of the data, rather than the origin of the data. Nonetheless, this is a global situation, not unique to Korea.

In terms of clinical trial operation related policies, currently we are seeing some limitations in the resources for the base work such as study nurses and other on-sight professionals. To overcome this, intervention is needed to make this career as attractive, to the younger generations. Of course, this is not only the responsibility of the government, it requires an education system as well as job opportunities in the industry for those finishing their formal education.

What are you looking to achieve with DreamCIS in the next 3-5 years?

We have a five-year plan, which strives for DreamCIS to become the â??*CRO that everyone wants to work with*â?• â?? the preferred CROs for the pharma companies, and also viewed as the favourable CRO to work with for the hospitals and the investigators. We also want to develop our human capital and ensure that our employees are proud and want to continue to work for us. In terms of our clinical trials systems and expertise, we want to stay up to date with the new advanced technologies.

We hear often from KoNect about the new processes being introduced in clinical trials. We are eager to implement these. Tigermed as our parent company has a much larger scale to develop these new technologies, so it will be important to harness our connections with them to leverage these technologies when we conduct our operations in Korea. We donâ??t want to consider ourselves as simply 200 people working in Korea in isolation: we are part of an international company.

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