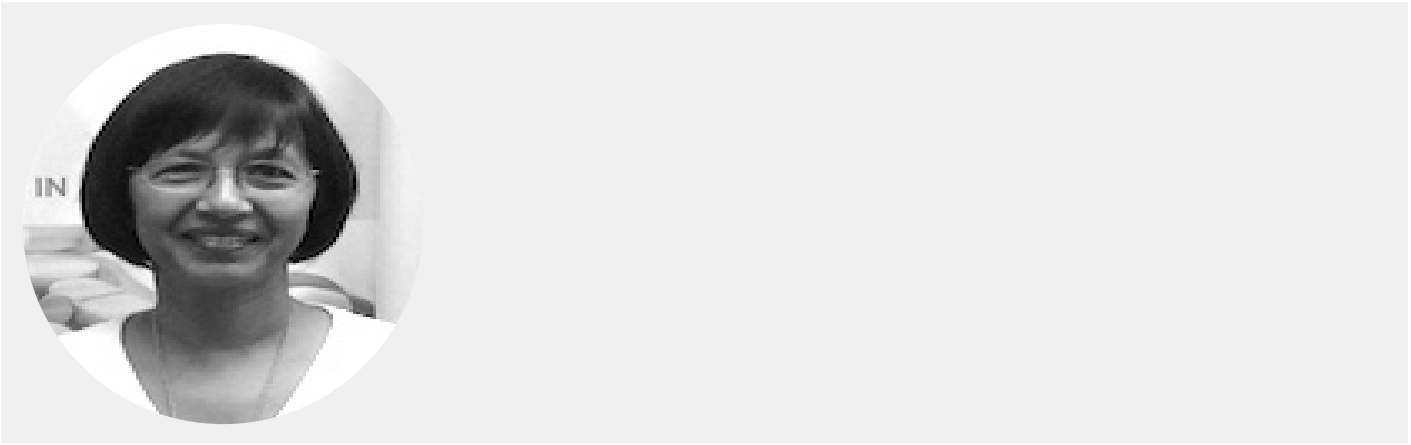
Klinsel – Sarojini Sivanandam, Chief Executive Officer



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Klinsel's CEO discusses the company's ambitions of growth in a very competitive CRO market and stresses that local experience is truly a distinguishing factor and this is why they are already partnering and performing trials for one of the country's largest local manufacturers.

Klinsel was appointed last year with a local pathological and medical testing laboratory to manage CCM's study (Epoetin-Alfa). Could you tell us more about the strategic importance of this collaboration and what it represents for Malaysia?

We can be proud to partner with CCM, a truly local flagship company. This is the second major local trial Klinsel is undertaking since inception, with the first being Nova, and demonstrates our ability to perform to expectations especially for strategic projects.

CCM's trial also entails cross border collaboration with a South Korean organization, PanGen. With each sponsor having their individual SOPs as well as differing needs and expectations, Klinsel's dynamic environment demands flexibility and understanding. Consequently, providing a unique learning experience and a necessary path to becoming a recognized Southeast Asian clinical trial partner.

With increasing demand for Klinsel's services, we are gaining a solid reputation as a dependable partner for regional CROs.

Dr Mohamed Ali at CRM was telling us about the need for Malaysia to pursue high quality pivotal trials to help Malaysia become a truly developed nation. Where do you stand on this idea?

Our regulatory authorities in Malaysia have instituted various standards and undertake ongoing monitoring for clinical trials. These efforts and the increasing demand by companies for clients to be GCP certified continue to drive improvement on the overall quality of trials undertaken locally. The Malaysian GCP also requires that investigators be GCP certified before they are allowed to conduct clinical trials.

At the core, Klinsel's duty is to ensure that the trials are performed according to the approved protocol, SOP's requested by our clients, GCP and applicable regulatory requirements. This means that our investigators must fulfill these requirements in terms of number of patients and second and undertake every single step of the process as per the requirements mentioned. Our team at Klinsel live and breathe this philosophy in driving quality trials.

Do you see a difference in the type of services that multinational and local companies demand?

Multinationals normally involve multiple countries and hence have bigger CROs to manage their trials at regional levels. We, the local CROs are then subcontracted to perform some of the services locally, be it, regulatory submissions or management and monitoring of local sites. The local companies however wants a one stop center that will do the A-Z of clinical trials. This then makes local CROs the ideal partners, with local companies wanting to conduct clinical trials.

In a country where MNCs and local companies are willing to collaborate openly with CROs, what is the company's main competitive edge?

At the crux of it, local experience is our main competitive edge. We know our clients, stakeholders, procedures and guidelines, therefore get regulatory approval faster hence reducing startup time and managing the operations of our trials effectively and efficiently. Being a fast track company having the ability to achieve results in limited time helps our clients save money and this is fundamental. Often we concurrently conduct trials at 10-20 different sites and our priority continues to ensure similar performance and training to the investigators performing at each site.

What are the advantages of conducting trials in Malaysia and do you believe Malaysia can become a clinical trial hub?

Malaysia's main asset is its regulatory framework. Although it is very strict, it is a critical success factor for Malaysia to become a clinical trial hub. Our clinical trial guidelines and audits and inspections by regulatory authorities is instrumental in ensuring that the standard of conducting GCP studies is on par with international standards. It is impossible to be recognized as a clinical trial hub with a loose and poorly defined regulatory framework. We also have the National Committee for Clinical Research and they play an important role in establishing policies and overseeing the clinical trial activities in Malaysia.

Our Malaysian investigators are experienced, well trained and speak English. These three factors along with our large patient pool make conducting trials in Malaysia very attractive.

What are the next development steps for Klinsel in Malaysia?

Our objective is to continue being the preferred partner of choice for local companies. Continued talent development to increase the depth of our resource pool is critical to Klinsel taking on more large scale projects with multinationals. On that front, we are focused on continued development of our resource pool so that we are well positioned to service the growing needs of multinationals.

What attracted you to join Klinsel and how did you adapt moving from the government to the industry?

After working 26 years at the Ministry of Health, I retired and was offered the opportunity to join Klinsel as the CEO. This represented a natural transition for me as I was very familiar with the clinical landscape, as I was operating clinical trials through the government clinical research center (CRC). This was my first experience in the private industry, at the head of a local CRO, at a time when very few local CROs were blossoming.

Biotechcorp has been an important partner since our foundation. Without its support, we would not have obtained the Bionexus status and we would not be where we are today.

So far we are 10 employees but my plan is to increase this number to be able to take on new projects. Klinsel has the expertise, frameworks, capabilities and know how to perform high quality trials, so recruitment and retaining talent is our priority to develop in Malaysia.

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