

Interview: Renate Schirrow – Senior Vice-President, Operations, ACLIRES – Thailand



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ACLIRES's senior vice president explains the organization's ambitions to promote Thailand as a unique place for early phase studies, the company's partnership with Mahidol University and Siriraj Hospital and its dedication to the development of medicine for Thailand, the region and the world.

What brought you to work at ACLIRES?

My personal background is in early clinical trials and I am honored that I was asked to come here by Mahidol University in cooperation with Siriraj Hospital in Bangkok to help push forward early stage clinical trials in Thailand. ACLIRES is involved in more early stage clinical trials, from late Phase I to early Phase III studies specifically, as early case are not well known in Thailand and in recent years I have seen drug development research becoming more complex due to changing regulations. Hence it is necessary to have experts on the team in order to conduct proper trials and I was brought on to help facilitate this. Working in conjunction with the hospital and bringing my medical expertise and background we make an outstanding team of 13 full-time staff members in Thailand, in addition to some part time employees, who provide services to many Western organizations looking to Thailand for the prospect of conducting trials. Many Western medical organizations have a base in Asia because of the growing market, but do not necessarily conduct their clinical trials here. ACLIRES is here to assist those organizations looking to Southeast Asia as a place to conduct trials for development research.

Where does Thailand stand today with regards to drug development?

It is my personal opinion, the Kingdom of Thailand is looking straightforward and wants to assist in drug development. The nation believes in their potential and ACLIRES is here to provide the specialist expertise needed to demonstrate to large multinational players that Thailand possess the capability to do so. What we have identified, along with government officials, is that early stage clinical trials are needed because it gives Thai patients access to healthcare and places the nation at an advantage over other nations. Early stage clinical trials, not research projects, are not as well

known here, but there are endless opportunities for the pharmaceutical companies because they can be directly involved in Asia, which is predicted to be the largest market in the future. Moreover, common diseases, such as cardiovascular diseases, are increasing here, which will play a vital role in the future for the growing consumer demands of the Asian market. Thailand has the medical expertise and the infrastructure to become an epicenter of medical research and ACLIRES is moving the nation along in the right direction!

What main area of focus is ACLIRES dedicating its studies to?

ACLIRES covers an array of services, focusing on Phase I/II studies, which are continuously growing here in Thailand. ACLIRES also chooses locations and manages Phase III studies. We also provide scientific services and medical writing and regulatory support for all our studies conducted. Moreover, we also recruit patients, which makes us unique because not all Contract Research Organizations (CRO) do this. In addition, we monitor patients, draw up and provide data management and statistics, and provide an expert network due to our large data base and affiliates in Thailand. We are at a unique advantage versus our competitors because of our direct association to Mahidol University and Siriraj Hospital, which are two of the most highly regarded institutions in the Kingdom and regionally.

ACLIRES has a strong focus on Thailand but you also have a presence in other regions, including Latin America. What was the rational behind this choice?

When we started ACLIRES ten years ago, our clients were interested in having clinical trials conducted both in Latin American and in Asia. We conducted most of our studies in Thailand and previously conducted clinical trials in Argentina, and most recently in Peru. However over the years Asia has grown much faster so now we are concentrating in Asia and in particular in Thailand.

Our sponsors are different and come from various backgrounds, but we have a good amount of American and European investors and clients, so we had to adapt our services in order to facilitate a streamline legal method for them. As we understand our clients's needs, we have opened a consulting facility in Europe, in the country of Malta, while our legal office that promotes transparency of our organization is in Bermuda.

What differentiates Thailand from other locations where you have conducted clinical trials research?

Thailand is an especially unique environment to conduct clinical trials because it is part of a fast growing environment. Asia, as a whole, is a dynamic place in the global structure because it is quickly developing and is the next economic hub of the world. The potential here for companies is endless. A decade ago Mahidol University realized that there were not enough early phase trials being conducted here so they invited us to set up in Thailand and collaborate with them.

Specifically looking at Thailand, there are an abundance of well-educated physicians always willing to learn and further develop their skill set. Moreover, the nation has top-notch facilities to conduct trials. All these reasons make Thailand an ideal setting for pilot and Phase II studies. Additionally, patients in Thailand feel more connected to their physicians compared to Europe and the United States because once patients understand their role in the study and are convinced that they would like to participate, they trust in their doctors and build a unique bond with them. With that said, there are some obstacles because the processes are less established than the United States and Europe, but I believe this is a positive challenge because it allows for more flexibility in the way that things are done. Furthermore, ACLIRES believes we are in a unique position because we are able to assist in the development of regulations and processes because of our affiliation with public entities. This is an opportunity for the nation to grow quickly with regards to clinical development and we are proud

to play a central role for our clients, patients and the nation.

How do you compete with larger organizations and generate awareness amongst multinational corporations?

We are a small enough team to get things done quickly, but large enough to make an impact. We make quick decisions and have an established network at Siriraj Hospital, which is incomparable to other organizations due to our ability to bring over the best and most respected experts in Thailand. Establishing a CRO in Thailand requires time and dedication, but because we have been here for a decade we have been able to make the right connections and serve the needs of our clients. Consequently, we are able to conduct Phase I, II and III trials to the highest standards, which has been tremendously advantageous for our clients in the biotech industry. We also have a unique cooperation with Mahidol University, which places the organization at a unique advantage because we have access to train and recruit the best talent. Moreover, we have state-of-the-art facilities locally, which most of our competitors do not have. This translates into accessibility and better services for our sponsors, patients and medical staff.

What growth factors do you see for the Thailand and the organization in the coming years?

There are various growth factors in the coming years, which will result in success for Thailand and the organization. As the Thai population becomes more educated about diseases plaguing their society more people will want to participate in clinical trials to gain access to innovative treatments and drugs that they would normally not be exposed to with the universal healthcare coverage. Also, as the economy continues to grow and flourish more multinational players who want to play a larger role in Southeast Asia will view Thailand as a strategic location for business and clinical trials because it is well connected and possess an abundance of trained professionals and excellent facilities. Moreover, as early phase research becomes more known in Thailand we believe we will gain more patients and more clients who want to come and conduct their medical trials here. The nation of Thailand is quickly developing into a regional player and ACLIRES is proud to play a vital role in its development of medicine.

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