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Good patient retention for clinical trials gives an edge to Vietnam

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by **Nguyet Tran**

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The clinical research environment in Vietnam has grown in the right direction with some remarkable achievement, in the last decade. However, in order to be a better destination for clinical trials, all the key players including Vietnam Ministry of Health (MoH), Ethics Committee (EC), investigational sites that participate in clinical trials and investigators, and sponsors for clinical research organizations (CROs) and site management organizations (SMOs) that provide site management service to hospitals, have to cooperate more actively.

Vietnam needs to learn from the successful endeavors of developed countries, especially in improving relevant laws and regulations, and to build up a synchronized system to ensure the smooth process for clinical trials, effective intellectual property protection for pharma/biotech companies, the legal assurance for institution and investigators, and beyond all, the safety and human rights of study subjects while still participating in the research and development of modern medicine/technology through early phase clinical trials and through own local research and development center in the future.

The first multinational clinical trial involving Vietnam was registered in *ClinicalTrials.gov*, a registry and results database of publicly and privately supported clinical studies of human participants conducted around the world, in 2002.

Although, Vietnam has come a long way since it humble beginnings as clinical trial destination, it is still many steps away from becoming a sought after center for clinical trials and match up to its neighboring countries like Thailand, Singapore,

Philippines or Malaysia. In the past few years, many initiatives were taken towards clinical research in drug and healthcare development by Vietnam Ministry of Health (MoH). Also, the MoH endorsed several activities including a workshop on clinical research environment in Vietnam for CROs and SMOs in 2011, release of a circular on clinical trial guidelines in 2012, providing guidance on CRO and SMO activities in 2012, and two workshops, so far, this year to finalize detailed circular on this matter.

Though, the current laws and regulations for clinical trials still not fulfill some important requirements from clinical research industry such as SUSAR reporting, shorter approval timeline or mandatory professional insurance for investigators, there has been remarkable improvement in the upper management of clinical trials in Vietnam. For example, now a company can obtain MoH approval within three months of submission. Also, the members of Ethics Committees, both local and central, are better trained on Good Clinical Practice (GCP) and inspection from Vietnam MoH as well as from World Health Organization and US Food and Drug Administration (FDA). They utilize the knowledge while carrying out their daily activities in form of standard operating procedures (SOPs) to review, approve/reject a study, and monitor/inspect any trial ongoing at their sites or under their supervision. The Vietnam MoH also issued some specific guidance to local Institutional Review Boards (IRBs) who frequently take role of local EC as Vietnam does not have an independent Ethics Committee.

Increasing involvement of regulators in GCP clinical trials, both global and local, in Vietnam, is attracting more trials to the country. In 2012, the number of investigators who participated in the instructor-led training and received GCP certificates from MoH is more than 1000, according to Department of Science and Training, Vietnam MoH. The current regulatory policy, valid since 2005, cites that drugs marketed for less than five years in the country of origin will require local clinical trial. However, Vietnam data from global trial can be considered by Drug Administration of Vietnam (DAV), which has similar role as US FDA, for granting visa to a drug marketed less than five years without requirement to conduct another local clinical trial. Until now, most of the clinical trials conducted in Vietnam were carried out for other reasons like, Vietnam has faster patient recruitment and good retention.

The country can offer large patient pool, where US/EU treatment guidelines are followed in the treatment of disease in main therapeutic areas. Also, a large chunk of naÃ¯ve population suffers with diseases that are common to both developed as well as developing countries. This offers strong prospects for large and rapid patient recruitment. Typically, doctor-patient relationship is strong in Vietnam, thus, securing good patient retention by sites. Another factor is cost benefits. Including investigator sites in Vietnam can help reduce the overall drug development timelines. A higher number of patients in fewer sites enable faster patient recruitment. Cost for conducting clinical trials in Vietnam is still favorable compared to other countries in South East Asia. Besides, on an average, the literacy of Vietnamese population is 90 percent.

When CROs in the country started to follow different models of operations like representative office or home based, Vietnam MoH raised concern about the quality of clinical studies with the involvement of several CROs. Then, the CROs were invited to MoH conference on issuing new guidance on CRO/SMO activities in clinical trial in Vietnam. There are pros and cons of this deep involvement from upper management into clinical research activities. The main benefit is that in the near future, the sponsor can search for those CROs already registered and accepted by Vietnam MoH or CROs who are disqualified by MoH. And with some standard requirements on quality assurance for any CRO doing business in Vietnam, MoH can help to minimize the risk of non-GCP following CROs indulging in unhealthy competition with CROs following GCP.