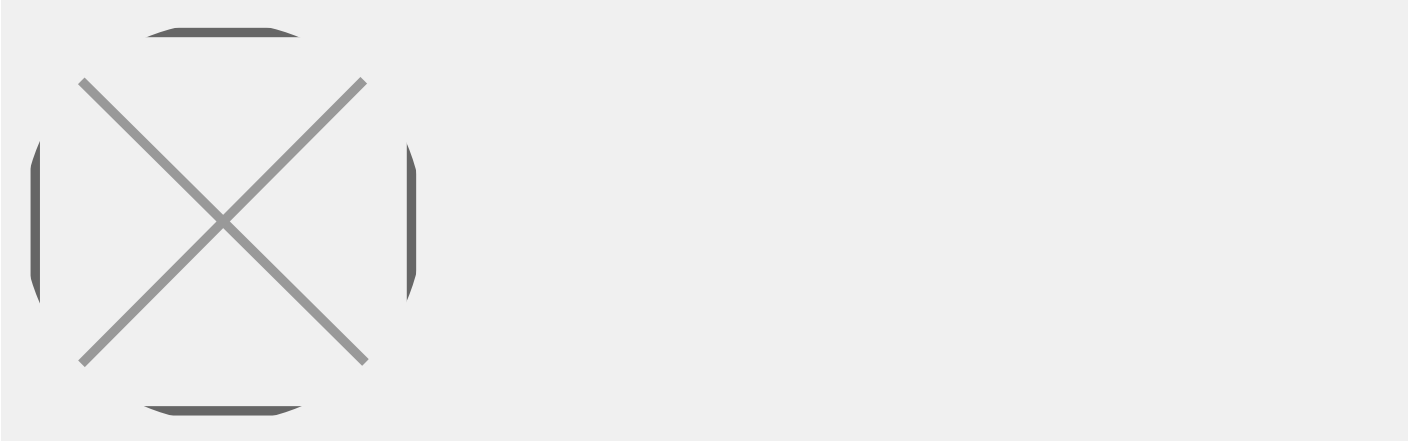
Interview: Endang Hoyaranda, President Director, Prodia Group, Indonesia



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Endang W. Hoyaranda, President Director of Prodia Group, speaks about the ongoing challenges of clinical trials in Indonesia, especially in remote medical communities, and why changing the mindset from 'guinea pig' testing to medical advancement opportunities is key to changing the landscape of clinical trials in the country.

Although Prodia started as a clinical laboratory, the group has diversified its activities over time. For several of these activities – such as clinical trials – you were the first company in Indonesia. Can you elaborate on this expansion and diversification path?

Our clinical trial activities started as from the mid 1990s onwards. During the late 1990s, we started cooperating with BARC, a Belgian company. We soon understood, however, that clinical trial activities are very different from our original laboratory services. There were no clinical research organizations (CROs) in Indonesia yet back then. We now had to prepare for sample handling, the sending of samples to central labs, prepare ourselves as a central lab, provide study coordinators, and so forth. All this was initially done under the clinical laboratory umbrella, until that activity was spun off in 2008. This resulted into the establishment of Prodia the CRO, of whom I am now the commissioner.

The next company that was launched after our CRO has been the Occupational Health Institute. This is another unique entity in the sense that we provide a whole range of occupational health

activities, which is quite different than most institutes around the world. We promote healthier lives in the work place, from mining to office environments, and are linked to the first and only educational program for occupational medicine at the University of Indonesia. We are also getting first-hand scientific developments of occupational health discipline. Today, this company has more than 700 companies on its customer list and handles perhaps more than 100,000 employees. We only have one occupational health clinic today –in Jakarta– and provide six in-house clinics at employer sites. Now, we are planning to build 10 to 20 in-house occupational health clinics around Indonesia. Also part of this is an occupational and environmental health laboratory, which is for instance equipped with markers for environmental, biochemical and other occupational hazards. The development of these activities is being pushed by the International Labor Organization (ILO). There are not too many companies active in this space yet, and we see Prodia as the first and real provider of occupational health facilities and services in Indonesia.

Our fourth company is active in stem cells, the technology of medicine of the future which will possibly replace many medical interventions. Now, it is already effective for several types of leukemia and diabetic ulcers. By growing and renewing cells, amputation would no longer be necessary. Such procedures are now also being made available for arthritis while further developments take place for Alzheimer's, stroke, Parkinson's, regenerative medicines, etc. In this area, we mainly focus on life saving activities. Much like anywhere else in the world, stem cells remain a controversial topic. For this reason, we focus on stem cell therapy rather than stem cell banking alone. Our fifth and latest company focuses on in vitro diagnostics (IVD). This is the first company in Indonesia working with such raw materials under license of the German company DiaSys. Despite its relatively small size, this is still one of the top 10 largest clinical chemistry companies in Europe. Due to licensing issues, we only started manufacturing and selling these products from 2012 onwards, but today we already have more than 50 laboratories as customers. Quite important is the fact that this company is once again a first of its kind in Indonesia.

You are part of the Clinical Trial Working Group in Indonesia, which means that you have seen the Indonesian CRO landscape evolving from close by. Where does the sector stand today?

Apart from our cooperation with BARC, we were gradually being updated on the huge potential that Indonesia had to offer for clinical trials through congresses overseas. But we had to put some effort into developing this industry here. Several friends and I were of the opinion that such efforts had to be institutionalized and went to Indonesia's BPOM – the National Agency for Food & Drug Control. At the exact same time – around 2001 – the BPOM was looking to have its Good Clinical Practice

(GCP) guidelines developed by an independent group. BPOM assigned our group of people to established the Indonesian GCP guidelines, which became an adapted and adopted version of the ICH GCP.

Despite the fact that the government really started looking at developing the clinical trial environment in Indonesia, our clinical infrastructure, public awareness and the talent pool of clinical investigators are still very poor. Now, we are increasing public awareness, the talent pool, the capabilities of all people involved and the number of trial sites. The Clinical Trial Working Group has also evolved from an assigned body into an association, with a supervisor and an executive board. These board members are all involved in clinical trials, with representatives from Pharmametric Labs – the CRO from Kalbe Farma – Abbott, Bayer, the University of Indonesia, the hospitals, Prodia etc. This association is now known as the Indonesian Assocation for the Study of Medicinals (IASMED).

We have been booking success in acquiring new members, but still need to progress further. We want to expand our current base of roughly 100 members and still have a long way to go to increase the awareness of the value of clinical trials. Prodia – together with IASMED – is now in the process of building trials site capacities at several hospitals. We have nearly finalized the first site at a government hospital in Central Java. There, we expect the first clinical trial to start in July 2013.

To develop this site, we had signed a memorandum of understanding (MOU) with the Ministry of Health and the hospital itself. We are working with several other hospitals on this initiative now. This week, we will approach a hospital in Bali for instance. This too is being done in cooperation with IASMED.

You said that there is work to be done on making the Indonesian society understand the value of clinical trials. Why was Indonesia behind in the first place?

From the governmental point of view, the workload is already very high. Even though they are working on clinical trials too, they are not independent enough. For this reason, they need such independent organization to make the public aware of the different possibilities. From an investigator perspective, the most prominent key opinion leaders are already very occupied with their existing patients. Moreover, once the universal healthcare coverage comes in from next year onwards, their number of patients will increase four to fivefold. Apart from that, due to the size of our country we also have significant geographical limitations.

How do you start the initiation to clinical trials in some of the more remote medical communities of Indonesia?

In general, they all saw clinical trials as a form of basic research. Certainly, it took quite a while to make it clear to them that clinical trials and research are two different things. We therefore offered them help in establishing the trial sites and – once the site was established – providing SMO services. The SMO model is a great way to sustain quality while reducing the time consumed by the medical practitioners.

'Love for quality' is the company's slogan. How is the quality concept integrated on a day to day basis at Prodia?

The mission of our Group 'For better diagnosis' has been in the company since its establishment. At that time, the Group's founders understood that the existing clinical laboratories were not providing quality results. From day one, their aim was to provide better diagnosis for better outcomes. Back in 1973, the poor or low quality laboratories would create certain hazards for the population. I joined Prodia ten years after it was founded, and have observed the evolution of the company in this regard. Each person entering the company would need to adopt the concept of 'quality as a way of life'.

Quality became a sort of indoctrination, an implanted concept within the company culture. As a result, we successfully became the first certified laboratory in Indonesia for ISO 9000, ISO 15189, CAP accreditation, NGSP accreditation. Subsequently, these values spread throughout the group beyond our laboratory activity alone.

Currently, Prodia Lab is involved in proficiency testing worldwide, organized by a third party. Within this frame, one of our labs has reached the position of ten best of over 3,000 labs in the world. This is quite an achievement. Today, we have 112 stand-alone branches with 250 outlets in total. This coverage provides us with a growing number of nationwide investigators.

Rather recently, Prodia engaged in an agreement with Quintiles, one of the world's largest CROs. Can you provide us with some background on this cooperation?

This cooperation has its roots in the regulation on material transfer agreements (MTAs), which became an approval rather than agreement. The MTA regulation is a common regulation where two parties agree on the confidentiality of material transfer. Indonesia was hit severely during the widespread SARS pandemic, resulting in governmental steps to become more cautious in transferring materials abroad. At that time, the Minister of Health published a regulation requiring

all samples sent out from Indonesia to have an approval from the Ministry. In addition to that, it was stipulated that all samples that could be tested in Indonesia should not be sent overseas. This hit the clinical trial business very hard, as central labs outside of Indonesia could no longer be used for routine testing on Indonesian samples. Companies like Quintiles – which already had large operations in Indonesia – took us on board as a partner for harmonization. Doing so, it is possible for them to engage Indonesia in global clinical trials without having to send any samples overseas.

It seems that the cooperation came forth out of a regulatory necessity. However, do you see the possibility of working with a global CRO also as a learning opportunity?

We developed from a laboratory and were still setting up our CRO business. We see our collaboration with a global CRO leader as a recognition of our CRO activity. Our collaboration with Quintiles is a win-win situation, where both organizations target cooperation for the long run.

How do you see your growth estimates for the trial business now?

In a short period of time, the number of trial sites will increase. The awareness of the public about clinical trial activity will also further develop, away from the image of clinical trials as ‘guinea pig testing’. Instead, the public will grasp the chance to see clinical trials as an opportunity to make new drugs available in the country.

At group level, there have also been a number of other initiatives beyond your day to day activities, including the Child Lab, projects on thalassemia, Family Health Care, etc. What can you tell us about some of these initiatives?

The CSR activities of Prodia Labs were already there from the very beginning – the 1980s – when we started supporting doctors in their basic research studies. We provided them with the necessary infrastructure, materials, reagents, and so forth. For some of their doctor studies, everything moved to Prodia. Already back then, we told ourselves that Prodia should act as a partner to the doctors by helping and supporting them. When I was first hired, I was mainly tasked with helping these doctors with their studies and research. When Prodia the CRO emerged, we already kept in mind the need to be socially engaged. Although we cannot yet go into too many specifics, this is definitely an important part of our future.

The Child Lab was not a CSR activity however, but rather part of our laboratory business. Handling children is very different from handling adults, which is why we prepared a special laboratory for children. This is also more specialized than the paediatric corners we used to have at normal laboratories. The Child Lab provides a very spacious area with a playground, aimed at changing the

way these children were perceiving laboratories. Even the medical equipment and medicines are different than those used with adults.

Our thalassemia initiative is indeed one of our CSR activities. We have observed a growth in thalassemia cases, without a real significant change in public behaviour. In some areas of Indonesia, it has nearly become endemic. We are therefore supporting the Foundation for thalassemia in their efforts. We help make people aware on how to prevent the disease, and what the treatment options are. This activity started around five years ago and is ongoing.

Prodia Group has diversified its activities in recent years. What is your vision of the future of Prodia Group and the role it should play within the Indonesian healthcare landscape?

Historically, we have been active in areas that have not yet developed, though there is a need in the market. Our diagnostics business, for instance, is not exactly new to the laboratory. However, Indonesia has never really been able to produce diagnostics. We were the first clinical laboratory striving for exceptional quality, we were the first ISO certified laboratory, we were first for MGSP certification, we were the first local independent CRO, we launched the first occupational health institute, we were the first in diagnostics, we were the first in stem cell research, and so forth. We are not active in areas where other companies are already active.

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