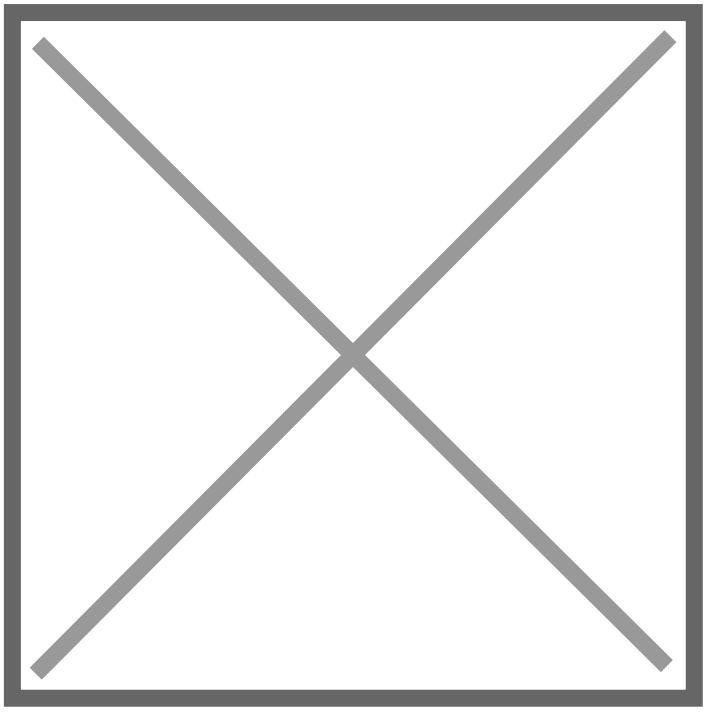
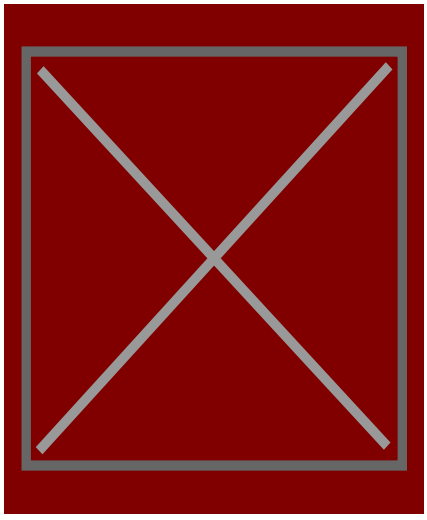
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Clinical Trials, A Peanuts Business: Vasireddi

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Dr SP Vasireddi

Dr SP Vasireddi, chairman and managing director, attributes the success of the company to team effort and vision. He strongly believes in turning adversities into advantages. CyberMedia News caught up with him in a brief chat to voice his opinion on the status quo of clinical contract research activity globally and the role of India.

What's the focus of Vimta Labs?

Vimta has been the leader in the fields of chemical, biological, and mechanical testing and validation of various materials. The present focus is on research and testing of water, food and agri-products, nutritional labeling and drugs and pharmaceuticals.

When Vimta was started in 1984 with contract testing facility, it was then an evolving activity and so we maintained R&D in different segments. And when we moved to our present facility at Cherlapalli (Hyderabad) in 1992, we focused on biological testing. Today, we are looking more at health elements like water, food, drugs and clinical testing.

We have consolidated our operations. It was started with focus on almost all the sectors of the industry. But today, we are focusing on important sectors and importantly we are dealing with comprehensive contract research and testing services.

Currently, what are the areas that you are working on? What are your plans in the near future?
We are concentrating more on the life sciences activity. Molecular biology is one key substitute. For clinical research, we are using several molecular biological testing. We are the first to offer neonatal screening service commercially a year ago. And we would be offering more such genomic features in the days ahead.

But most of the laboratories in our country are not really designed to conduct this type of tests, as we need bio-safety levels I, II and III. We can't alter existing facilities and carry on the operations. Keeping this in view, we are now constructing a facility in SP Biotech Park, Genome Valley, Hyderabad. The 160,000 sq. ft. facility with an investment of Rs 40 crore would be ready by April-June 2005. The lab with its 24/7 operations would accommodate 300 employees per shift. Addressing all biological safety requirements, the building would be fully automated and energy efficient.

Also, the molecular biology lab at TICEL Biopark in Chennai is ready for commencement of the operations. This would primarily extend support to occupants in the biopark.

What are the key bottlenecks you are facing as an industry?
I don't buy the theory that there are too many bottlenecks in the industry. One has to take risks and overcome hurdles to attain success. However, quality and price is a hurdle. Quality can't come at a cheaper price. But this is evolving as volumes and technology are making it easier. With increase in volumes, the process costs could be absorbed and the benefits can be passed on to the customer. Equally, technology is contributing by less usage of manpower and fast access.

India is said to be emerging as the new destination for clinical trials. How real is this view?
It's an unnecessary hype on clinical trials prospects. A simple analysis based on commonsense can prove this. The US market for the year 2003 is about $10.7 billion. And what cost advantage does India have for clinical trials? Some predict it to be 50 per cent, some 70, 80 and so on. Even if we assume that the rest of the world stops contributing, India's amount could sum up to less than $5 billon. But why will the existing players stop their functions?

Assuming that we are exceedingly doing well and if a miracle happens then we can do at the most $1 billion. Clinical trials itself is a peanuts business and globally it's a monopoly market. The top five CROs themselves contribute 54 per cent of the total market share. Of the rest 46 percent, 63 percent of the revenues are shared by third world countries like India that has a market size of anything between $1-3 billion. It's doubtless that the rest of the world has to close down so that India will twinkle as the new destination for clinical trials.

What are the reasons that are hindering the forward movement of India as the new destination for clinical trials?
Reasons are many. Independent committees are still to be registered in our country. There is no national monetary mechanism. Regulations are yet to become favorable for conducting phase I, II and III trials. Besides, uninformed patient pool, naÃ?Â¨ve insurance companies, which are not ready to offer all the professional coverage's are few others.

There are so many issues and everything boils down to environment factor. And when we talk of future, we are talking about the next three-four years or maximum of five to seven years. Keeping the above factors in view, I don't see a glorious opportunity for clinical trials.

Further, it is being touted as Maharashtra emerging as a clinical trials hub. Do you intend to move there?
These are all proprietary statements. I don't want to make it controversial. Everyone has their own claims but as I was mentioning earlier that clinical trials itself is a peanuts business. Considering this, where does the question arise of Maharashtra being a hub? It's awkward to talk on such statements.

What is the cost arbitrage involved with clinical trials and contract research testing in India?
Most global CROs have Phase III trials as their core business. A phase III clinical trial involves anything not less than 500-1000 patients and could cost Rs 50 lakh to Rs 1 crore or more with about 30 percent margins. The Indian drug controller does not allow Phase I and Phase II trials unless the molecule had been developed here.

Now considering that Indian clinical CROs get a project for Phase III trials for about Rs 1 crore, how can Indian clinical trials market reach the touted billions target?
There are several companies like Elli Lilly etc, which are doing a lot of contract research. How do you foresee the opportunity and competition from such companies?

They are all established global players. They have efficient systems in place and they know what they are doing. They have their own programs above all. We are third party CROs and they are not our competitors.

How has your business grown in the last few years?
We have a long-term vision to be one among the top 10 contract research and testing organizations globally by 2010. In an

effort to reach our ambitious goal, we are targeting aggressive growth rates. Our 80 percent Compounded Annual Growth Rate (CAGR) in the last financial year exemplifies this.

Sunitha Natti, CyberMedia News, Hyderabad