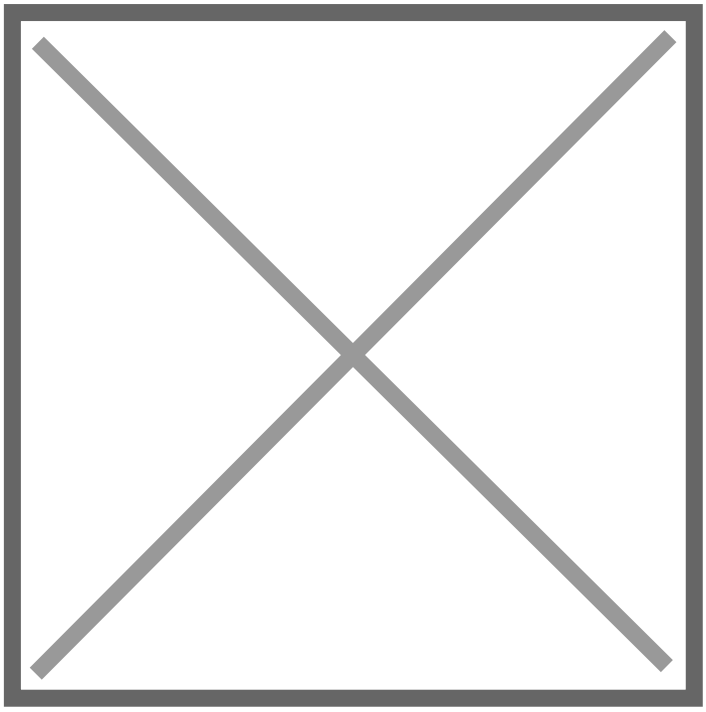
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Data Manager

12 February 2004 | News



India has all the ingredients to conduct clinical trials to tap the $70 billion opportunity in clinical trials and clinical data management system. Providing the right inputs for the subjects is very essential as is doing good trials.

India promises to become a world center for testing new medicinesÃ¢â?¬â??Economist, London, January 2000

India can capture approximately $1 billion worth of global clinical research spending by 2010Ã¢â?¬â? McKinsey 2002

Today India is identified as a major resource center for conducting clinical trails and data management servicesÃ¢â?¬â?•Applied Clinical Trials, February 2003

These are the testimonies to India's potential in clinical research services. If properly harnessed, the above gains could translate to make India an important clinical research organization (CRO) destination in the world, said Dr Satish Bhatia, president Wellquest Clinical Research. According to Shruti Shukla, senior manager, business development, Synchron Research Services Pvt Ltd, "We require at least another 20 CROs to meet the requirements of the internal and external clients. There exists no competition among the CROs."

But the reality Ã¢â?¬Â¦

"India has a potential to bring in $70 billion in clinical trials as a major industry. We have all the ingredients to conduct clinical trials and clinical data management system. Providing the right inputs for the subjects is very essential. Institutes decide to develop infrastructure that will help in developing manpower needed for the sector. The industry is finding it difficult in finding out the talents to carry out the drug discovery process and conducting clinical trials," said Prof. AS Kolaskar, vice chancellor, University of Pune.

The Indian CRO industry

The Indian CRO industry is small and fragmented but growing by 20 percent per annum. Many companies including the leading pharma firms are setting up CRO units. The companies already working in the field include Lamba Therapeutic, Synchron, ClinInvent, Quintiles, IGATE Clinical Research International, ClinWorld Inc, ICON Clinical Research, Vimta Labs, SIRO Clinpharma, Apothecaries Clinical Research Clingene. Many pharma companies like Ranbaxy, Novatis, Wellquest, Pfizer, Wockhardt, Dr Reddy's Labs, Panacea Biotec, Reliance Clinical Research Services, Lupin are also working on clinical research sector.

IT companies such as Infosys, HCL Technologies, TCS, IBM India, and Persistent Systems are looking at the opportunities in clinical data management, a module in clinical research.

A few CROs and pharma companies have established a track record of conformance to good clinical practices and good laboratory practices (GCP/GLP) guidelines by getting approvals by Europe, UK, MHRA, Latin America and US FDA in the last few years. The Indian CROs are currently poised for international recognitions and alliance. The CROs give the Indian medical fraternity a chance to participate in the international research programs and this brings latest advances in medicine to India.

A solution exists in bridging the gap between academia and industry. Both have to work together. University of Pune recently conducted a symposium on clinical data management. It was the first step to know what's relevant and what is not. It was set to review the new skills, the changes to existing processes, the direct influence of international regulatory guidelines, and validation methodologies.

Guljit Chaudhri, convenor of the symposium informed, "The symposium aimed to create a forum for European, Asian and US Life Sciences organizations and academia to interact, exchange, learn and implement the latest advances in clinical data management as per ICH-GCP standards. And we were looking at offering excellent opportunities for exchange of ideas and experience on the campus between participants and international practitioners and it was designed to reinforce the learning from the sessions, tutorials and work on case studies and to address common problems faced in every day situations."

"Based on the response to the program we will come out with the tailor-made courses on clinical data management. It is only a beginning. We are also planning to conduct a few more symposiums to understand the needs and areas into which we should focus at before proceeding, " said Prof Kolaskar.

It is not that there were no programs at all for training. The Academy for Clinical Excellence (ACE) is one such center based in Mumbai providing training in clinical research. It was set up in October 2002 at the Bombay College of Pharmacy through the initiative and financial contribution of Pfizer India Ltd. It is expected that Pfizer will be contributing to the tune of $100,000 for a period of five years for the development of the academy.

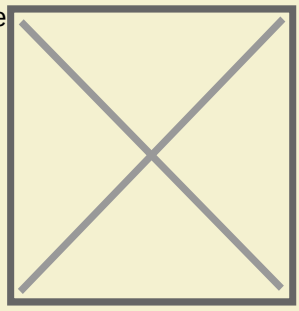
Subsequently, the academy was opened up for industry collaboration and Suven Life Sciences Ltd of Hyderabad has become a partner of ACE by making a financial contribution. The academy is conceived, as a one-stop-shop for all training needs of all clinical research professionals in the country. Now it is offering post-graduate diploma in clinical research. The director of the academy Samyukta Ajay said, "The diploma program has been developed and will be delivered by eminent clinical research professionals from pharmaceutical industries, CROs and academia. We have trained over 400 candidates in CRO and also conducted tailor made courses to three companies. "

Continuing Samyukta Ajay said, "Professionals are looking at clinical data management, one of the six modules of clinical research as a new avenue as clinical research needs a bit of travel for doing the trials".

But what assumes significance now is that the government of Maharashtra has prepared a blue print to develop University of Pune as a Center of Excellence in biotechnology and making Mumbai as a CRO hub. The day is not far off when this dream will be realized. The University has begun well and is taking a pragmatic approach.

Narayan Kulkarni

"Academia's support is a key for industry's growth"



Prof. AS Kolaskar, vice chancellor, University of Pune and member of the Biotechnology Task Force of Government of Maharashtra spoke to BioSpectrum about the initiatives taken by the university to introduce a course in clinical data management, an opportunity that every company is looking at. Excerpts:

What motivated you to look at clinical data management as a new course?

Looking at the opportunities, India can become a major hub for clinical trials in the world. We have enough biodiversity available here. Even people from different parts of the country stay here in Maharashtra particularly in the MumbaiÃ¢â?¬â??Pune belt. We have a very good hospital system. Many hospitals are interested to have a tie up with research organizations of the western world and many people are exposed to newer drugs and they want to do the clinical trials. What we require is a proper channel for collecting the data, organizing and analyzing the same. The problem we are facing is collection of data and how to organize it. Taking the consent of the volunteer is a must and that should be taken well in advance. Indians need a proper training in this sector.

Today if we see, clinical data management is not included in any syllabus. Industry particularly pharmaceutical and Clinical Research Organizations (CRO), international organizations and foundations look at clinical data management in different approaches. Within and outside the country the environments are different. It needs to be put in an organized way. In the first phase we brought international experts to sensitize a topic like which practices are used to collect the data? How it can be organized and retried for the benefit of the human kind? As different sectors like information technology, pharmaceuticals, academia, research organizations are involved in this we want to interact closely with each other before formalizing the final and regular course.

When did you get the idea to start a course in clinical data management?

I got the idea while we were preparing the biotechnology policy of Government of Maharashtra that was launched in 2001. And started collecting data on the topic. We learnt that our strength lies in biodiversity, good English speaking people and good hospital infrastructure. We also discussed at the Biotech Commission meetings to put Maharashtra on the clinical hub of the world. As an educator it gives me an opportunity to look at clinical data management as a new course. However we can download the stuff from websites and design the course. But I am not looking at that. I feel downloading won't work. Therefore my focus is to develop a proper system that should support the industry.

Do you have any fixed time frame for introducing the course?

We have just finished one workshop. The next one will be after three months. Based on the support we get from the industry we will go for the third one. Then formulate the necessary course program as a long-term policy. As the course is to be well accepted by the industry we have to have a tie up with international certification agency like CIDSC. It shouldn't become another regular course. I am looking at making it purely a job-oriented course, which will give India a global advantage. We want to create a proper environment to provide the right knowledge to the candidate in clinical data management both in quality and quantity.

When the programs of the university have been well accepted by the industry why are you looking for certification from an external agency?

There is a predetermined mindset among the industry people. We don't want to try and break these mindsets and take some time in that. I don't want India to loose valuable time in developing proper environment for clinical data management program. But the question is how we can develop India as a hub for clinical trials? There are many professionals working individually in this sector. They have experience. But they don't have the infrastructure and certification. That is why Indians are not gaining acceptance in the international market. In clinical data management authentication is a key.

What is the course design that you are looking at?

Normally it is the academia, which takes the initiatives. My interest is to take an early edge in this sector after understanding the needs of the users. Be it manufacturers, CROs all should come together and say all we need is these things from academia. Therefore we had organized the international symposium on clinical data management in mid- December to bring together the people who are actually in the field and those who are looking at this as a new upcoming sector.

The first workshop was to sensitize and to tell the industry what the university can do in this area? And how useful the program is? The second workshop should be a focused one, where we have to go in depth on each of the topics. We have to collect enough material and take the best suited. I am not in a position to hurriedly take decision by bringing some topics by selecting few from the US, UK and EU. It is a difficult task. The candidates need tailor-made courses. We can't give one course for every one. This is what Indian students are missing. Looking at the paying capability of the students and needs of the industry we are looking at short-term courses of 10-15 days, even part time courses. We have to look at various things.

Narayan Kulkarni