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"I don't see any reason why India cannot emerge as a major center for clinical trials"

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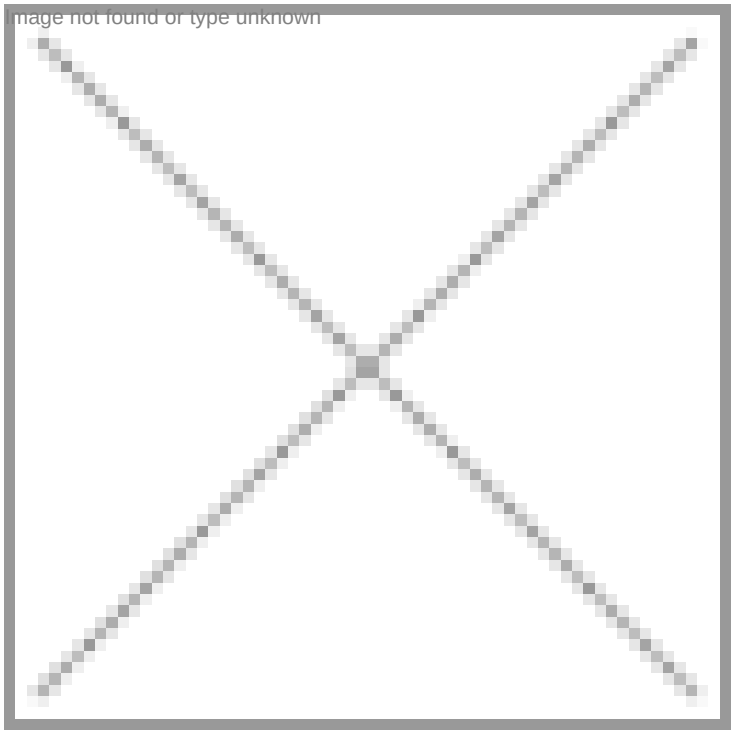

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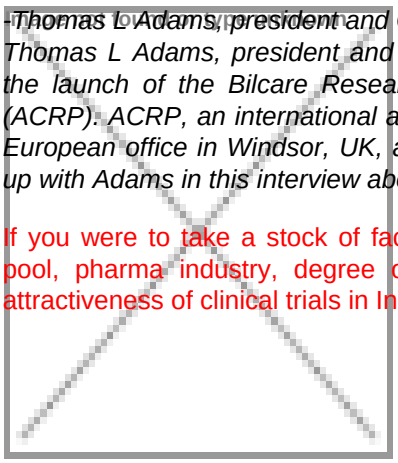

-Thomas L Adams, president and CEO of ACRP

Thomas L Adams, president and CEO of ACRP (Association of Clinical Research Professionals), was recently in India for the launch of the Bilcare Research Academy set up in partnership with Association of Clinical Research Professionals (ACRP). ACRP, an international association with more than 20,000 members, is headquartered in Alexandria, Virginia with a European office in Windsor, UK, and starting its Indian chapter in Pune. Pratima Harigunani from CyberMedia News caught up with Adams in this interview about whether the Clinical Trials syringe has hit the right vein here or not? Excerpts:

If you were to take a stock of factors like regulatory environment, medical infrastructure, certifications, gene pool, disease pool, pharma industry, degree of specializations, patient consent system and costs, how would you rate the overall attractiveness of clinical trials in India?

I don't see any reason why India cannot emerge as a major center for clinical trials. You have a well respected medical establishment and a pharmaceutical industry that is all ready recognized as a major player in the generic marketplace. Many of the diseases in the general population are the same as in the rest of the world and while certification is not currently prevalent in the country with appropriate education and training it can be. I believe certification is the yardstick by which India can assure that trials conducted here meet the same stringent standards that occur in the US and EU.

How practical and fertile is the outsourcing concept for the CT industry? How does the Indian environment for CTs stand in comparison to countries like China, Vietnam and Thailand?

The movement of CTs to an outsourced model by pharma is underway. It will be the preferred model in about five years if not sooner. Because the medical establishment is so highly regarded, growth in CTs will progress faster than in the other countries you mention. Additionally that English is universally used is a huge jump-start compared to other countries that you mentioned.

Are the enrolment numbers and mix of volunteers satisfactory so far?

Less than one percent of CTs are currently conducted in India. There is room for substantial growth.

What made you come to India and where are you heading next in the subcontinent? What's your set of criteria about a country's selection?

India and China were high on ACRP's list for expansion due to the reasons above and our belief that India is in an important place due to the art of medicine, strong experience with generics and reliance on English as a primary language. The main criteria that we use in determining when to enter a new market is our comfort level with finding a partner to oversee our affairs in the new country. Bilcare's commitment to ethical training and education made them a logical partner for us. We believe that together we will grow quickly here and in Southeast Asia. Other countries on the map include China and the Bilcare Academy expansion countries.

Is the industry successfully tackling the issues of placebos, role of sponsors in CTs, futility terminations, registration and reporting of CTs to medical journals, CT registry, etc? How serious are these issues?

The entire issue of CT registries and what they should contain are up in the air. ACRP has been on record as supporting a centralized registry for all clinical trials. The interest is there on the part of FDA and others but no one has stepped forward to design and pay for one and its maintenance. Perhaps with India's strong IT community this is something that could be undertaken here and exported over time.

Any observations on the implications of human genome project?

It opened the door for designer drugs. Now how do we afford them and what should the priorities be, is the next point.

What is the latest hot spot in CTs in view of ethical debates across the globe?

The two areas I'm asked about most often are: How do you insure informed consent when large portions of a potential population do not read or write? How do you insure global standards for CTs are met?

So, what's the biggest challenge that you and your peers are currently dealing with?

The need for education and certification exceeding our ability to provide it.

What are the challenges, in particular, from the perspective of CR Professionals in the US and globally?

Education and certification. If I sound like a broken record on this subject, it is intentional. Those are the only two methods to insure that people who are doing the trials know what they are doing and insure that patients have the protections they need and deserve.