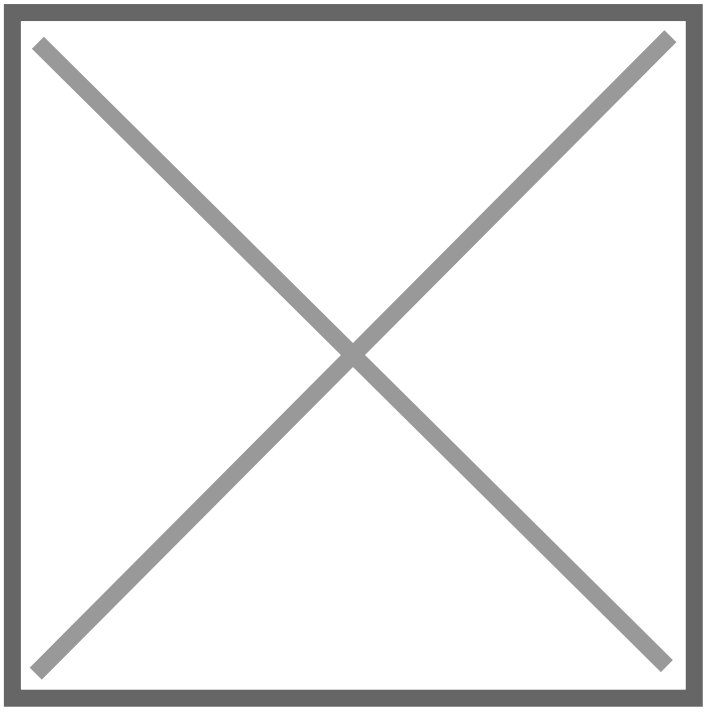
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Success sure with CRO-KPO combo

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Dr Ajoy Kumar, chief executive officer, Max Neeman International, New Delhi

Dr Ajoy Kumar, currently the CEO of Max Neeman International, has over 19 years of experience with Apollo Hospitals; Cummins Diesel as CEO and manging director; and Tata Sons as general manager (group human resources). At Apollo Hospitals, Dr Kumar was responsible for overseeing operations of the group hospitals, and other businesses of Apollo. He initiated Apollo Clinical Excellence Model, Emergency Network, and development of common corporate database. An MBBS holder from Jawaharlal Nehru Institute of Postgraduate Medical Education and Research (JIPMER), Pondicherry, and post-graduate diplomas in business administration, hospital administration and preventive and promotional healthcare; Dr Kumar conceptualized and implemented the disease management program for the Apollo Group, and was leader of the nationwide Apollo Heart Plan

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Contract research organizations (CROs) have to consider a hybrid of CRO and knowledge process outsourcing (KPO). The business model should offer solutions to small-and-mid-sized biotechnology, device and pharmaceutical companies in paving the way for success of a research molecule, from the lab to the market. The CROs have to understand the need to move up in the value chain, and evolve into a solution provider, rather than being just a CRO.

The CROs from India and China are being tapped by the global pharmaceutical, biotechnology and device companies. Clinical research in India is expected to grow to a huge business opportunity, as pharmaceutical companies abroad find it attractive to outsource clinical trials to India.

India advantage

- Lower cost of trials
- Increasing ICH GCP-trained investigators
- Faster patient recruitment
- Disease diversity
- Highly-qualified clinical research professionals
- Several hospitals with state-of-the-art equipment and infrastructure

It’s time we think out-of-the-box and implement ideas from different practices in the field.

Using the six sigma methodology for faster recruitment, we can reduce the cycle time in completion of the clinical study report and generate a statistical analysis plan. The investigators, clinical research professionals, project managers, safety and medical monitors, can help in developing, materializing and implementing the strategy generated from the piece of concept in the sponsor’s mind. This can be exemplified by a case study given below:

Scientists worked on a peptide for 10 years in the lab, and were ecstatic that the molecule gave the intended results in acute

wounds, but the difficulty was in designing a study. They conceptualized a 10mm incision on which the investigational product should be applied, and the usage procedure. New incisions were definitely not the option. They decided to use hernia patients who were ready for a surgery. After deciding the criteria, the team was assigned the whole project from protocol development – study design, inclusion and exclusion criteria, making a statistical analysis plan – to conducting the study, handling the monitoring and data management and writing the clinical study report.

This is how we can add a new vertical for offering solutions, and helping in making a road map for the success of a molecule, rather than offering only services to conduct these trials. This will help in adding value to the sponsor's research, and at the same time, will become India's USP.

The hybrid developed has the potential of becoming a massive success as the sponsor will get a cost-effective solution by outsourcing the designing and implementation work to the same company, along with an added benefit of process transparency. The industry has a large pool of knowledge workers and with the passage of time we change the myth that Indian companies can only 'implement the ideas' and not 'generate such ideas'. Our focus should be on bringing a molecule from the lab to bedside in the fastest and cheapest way and not let the research effort go into trash.