



Mr D A Prasanna, Vice Chairman & MD, ECRON AcuNova, India

Mr DA Prasanna, Vice Chairman & Managing Director, Ecron Acunova, has been instrumental in the formation of the company, by combining the strengths of two regional CROs. As Executive Chairman of the Manipal Group, his focus was on developing a research thrust for the Group. Considered a thought leader in healthcare and life sciences, he has worked in global leadership positions in GE and was Vice Chairman of Wipro. Mr Prasanna is acknowledged in the healthcare sector as the pioneer in creating a market for high technology medical equipment and delivering clinical excellence at low patient fees in Asian Hospitals, through innovative strategies.



Dr Antal K Hajos, Executive VP, Strategic Operations, Europe, ECRON AcuNova

Dr Antal K Hajos, Executive VP, Strategic Operations, Europe is based out of the company's European HQ—Frankfurt, Germany. Dr Hajos has over 15 years of experience in Clinical Development and Medical Writing. He has developed his expertise with companies like Merckle GmbH and Altana Pharma AG. Prior to joining Ecron AcuNova, he was working as Managing Director and Chair of the Board with Nycomed Pharma's Indian R&D center based at Mumbai. He is a member of the European Medical Writer's Association, ICRS, and founding member of the All India Medical Writer's Association to name a few. He has completed his PhD in Biochemistry from Louisiana State University, USA, where he was awarded the Robert Scott Alan Outstanding dissertation award. He has also completed the Asian Executive Management Program from INSEAD, Singapore.

Speed to Market

The Relative Advantage of Geography

Cost of drug development continues to increase while output efficiency decreases driving companies to vividly explore effective alternatives for 'valuable clinical research.' Steered by the growing pressure, companies are now more than ever establishing innovative strategies to optimize and speed up drug development. Global companies have joined hands with regional CROs to leverage emerging geographies, reshaping the drug development services industry. Today, the contract research services industry comprises the entire research and drug development process including discovery research, pre-clinical evaluations, study design, clinical trial management, data management, statistical analysis, medical writing, protocol design, biomarker development, regulatory consulting as well as central lab services.

With the breadth of services and the urgency to bring the drug to market faster, many companies have sought for outsourcing large parts of their non-core activities across emerging geographies. This is aimed towards capitalizing on the regional benefits of cost viability, highly educated personnel, and ease in recruitment of subjects, well-trained investigators, and access to secure sites for trials amongst others. These companies understand the importance of passing the product through exploration, development and regulatory processes in a fast and cost effective manner. A typical development cycle involves a discovery to pre-clinical testing phase of approximately four-to-five years, followed by development, early development, and proof of concept studies and the subsequent late phase development spanning another four-to-six years. Finally, the regu-

latory submission including regulatory approval of the label claim, is followed by launch activities and possible licensing—all of which needs to be shortened in timelines.

The development phase with its clinical trials constitutes the longer and by far most expensive phase in drug development and hence is particularly in focus for cost efficiency and optimized cycle times. Further, quality is of highest priority as ultimately only the right data of highest quality will result in regulatory authority acceptance as well as market value. Utilizing regional experts may often attenuate the dilemma of global CROs processes and organization obliterating regional cost advantages. Therefore, focusing on the right geography, with a regional expert CRO, will guarantee greater speed, with quality data available at a lower cost.

The quality of data is often a key factor in decision making and evaluating the progress of the drug development. While there are various factors impacting the quality of data, market forces like EU regulation, access to the EU and the US,

the demography of the trial population as well as the location of the trial that may impact the study site, the standard of care and the type of study are some areas increasingly demanding attention. Increasing demands of regulators, such as the EU directives, and discussions on criteria for acceptance of foreign data add further pressure. The quality of CROs, their processes, systems, and people also have a tangible impact. Regulatory inspections and audit programs evaluate GCP compliance. Full service CROs, being more comprehensive in their processes and interface definitions, may be expected to be in a better position to control and monitor quality.

The primary factors impacting clinical trial speed include a defect free submission of regulatory application, the need for translation at the location, the CROs credibility with regulatory authorities as well as the investigational site- and EC process. The availability of subjects, investigators, and improved logistics in emerging countries such as in Eastern Europe, India, Latin America, have created new major geographies for clinical trials. Therefore, speed to market is the result of the right study design in the right geography partnered with the right CRO.

The CRO industry in emerging markets, relative to the mature market CROs have been less impacted by the current financial crisis. In fact, the crisis is expected to significantly contribute towards the growth of these new geographies due to cost pressures in the matured countries. For example, a joint report by KPMG and CII foresee an emerging geography like



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India to witness the clinical research outsourcing industry to grow from \$200 million as of today to \$600 million by 2010. Emerging markets such as, India provide a cost level of approximately 15-20% of the US price for basic trials and a cost level of approximately 50-60% of the US price for sophisticated trials. Research indicates that with R&D expenditure continuing to rise, companies will look for more value-add and cost efficient solutions while gaining other benefits such as faster enrollment, speed of completion,

and high compliance, amongst others. Today and in the times to come, countries like Brazil, Russia, India, China, Korea and Mexico, will increasingly become important clinical research and outsourcing markets. Not the least, the demographic characteristics and economical growth rates will make these very markets to be amongst the top 10 of pharmaceutical product markets in the coming decades. The clinical trial industry is hence an early indicator of global gravity shift that is there to stay. ■



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