

SPOTLIGHT

Believe in the best

Within a year and a half of its operations, **Manipal AcuNova** has achieved success that very few companies can. **Vanessa Mahapatra** analyses the factors that set it apart from its contemporaries

In times when Indian CROs are being criticised for compromising on quality to maintain their cost edge, one CRO that stands tall is the Bangalore-based Manipal AcuNova. Ethics and quality of services are the ingredients of its success recipe. Despite the business being risky, the company has grown phenomenally in less than two years and has established a firm base of clients across the world.

How it began

Nothing happens in a day. Every successful venture involves a lot of critical thought and planning. Similar is the story of Manipal AcuNova. Manipal Group, which is an important player in higher education and healthcare sector, entered the biotech and clinical research space by promoting Manipal AcuNova. This CRO is a collaborative venture between the Manipal Education and Medical Group International India as well as the US based AcuNova LifeSciences.

The Manipal Group comprises of a number of teaching hospitals and medical colleges, which had been undertaking clinical research and clinical trials since 1995. By 2004, the group realised that over 100 clinical trials had already been conducted at existing centres. Moreover, there was a larger opportunity that could be banked upon. That is when the Manipal Group decided to expand their operations in a professional manner. "We decided to do it the way sponsors would want us to. Typically, that required us to know the needs of the pharma industry better and conduct trials with more rigour so that we could confidently report our findings to regulatory agencies," says D A Prasanna, Managing Director and Vice-Chairman, Manipal AcuNova. Consequently, Manipal

AcuNova, the CRO, came into being in January 2005. It is co-promoted by the Manipal

Group and AcuNova and is driven by investments from private equity and strategic

investors. "We wanted to have the advantage of the group's experience in research activities and AcuNova's knowledge of clinical technology and the



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pharma industry," reveals Prasanna. The management of clinical trials was initially transferred from the group to the new company. Phase I trials, bio-availability and bio-equivalence services were sourced from the group until Manipal AcuNova built its own delivery centres. Sooner than imagined, steered by revenues from the clinical research activities, a central lab and a data man-



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Managing Director and Vice-Chairman
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agement centre came up in Bangalore and the bio-availability and bio-equivalence capacity was expanded in Manipal and Mangalore. Following this, business development operations were set up in Europe and US.

Here we are

Two years is not enough time to judge a company's performance, one would say. After all, how much can a company achieve in such a short period. Yet, Proximare, a New Jersey based strategic management consulting firm that develops and implements growth strategies for pharmaceutical and biotech companies, awarded Manipal AcuNova the title of 'India's No 1 Emerging CRO'.

Beginning from a small team of seven to eight people, today the company boasts of a team of 170 professionals. It is their contribution that has enabled the company climb the ladder of success rapidly. "Of the numerous trials that we have been involved in this short period of time, an oral oncology drug recently got a marketing approval," informs Prasanna. Currently, the company is conducting 56 trials and has been entrusted with key trials involving recombinant drugs, monoclonal antibodies and diagnostic agents. In addition to this, Prasanna reports, "Recently, we got projects from DBT worth more than Rs 87 lakh."

Essence of Manipal

Driven by values like ethics and quality, Manipal AcuNova has been able to make its presence felt at the onset itself. In the CRO business, quality is one of the major factors that give a company a brand image. Manipal AcuNova has made conscious efforts to maintain quality standards

at every step by rigorous planning and delivery. "We have deployed international quality infrastructure and employed internationally approved and accepted processes. Since the technology and processes have to be run by people, we have recruited high quality people and provided motivation to them to deliver," elucidates Prasanna.

Moreover, all operational efforts of the company conform to global standards. This has rendered them a dependable name in the CRO industry with successful client audits by global majors and regulatory agencies. "Auditors have said that our quality standards are very high," remarks a proud Prasanna. The company has also received global certifications like ISO 27001 for data management by Underwriters Laboratory and ISO 15189 by the National Accreditation Board for Testing and Calibration Laboratories for their central labs. Additionally, it is the first CRO in India to be awarded the ISO 9001:2000 certification by UL and its research sites conform to ICH GCP guidelines.

In the highly competitive environment ethics are mostly overlooked. But for this committed CRO, ethics come foremost for creating a name and reputation worldwide. This being a business which involves great risks to patients under trial, doctors, sponsors and the company itself, unless there is a basic ethical value in the endeavours, it could jeopardise the business.

"The pros and cons of our trials are conveyed to our participants and reported results are disclosed accurately to the researchers, participants, regulators and sponsors. If anything is compromised, it can create serious problems," Prasanna says. Thus all communication involved with clinical procedures is complete and absolutely transparent.

Just a start

In spite of all the achievements, it is just the beginning! Prasanna believes that the company is yet to achieve high targets that have been set for it. "We intend to come under the top three CROs in India and at least among

the top 10 companies in a particular segment, across the world."

He further believes that though they provide end-to-end solutions and services, the company is yet to develop a core competency, which would make it further distinguishable. The company is still at a nascent stage and has a long way to go. ■

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Initial hitches

The beginning of any venture always poses numerous challenges and is the most difficult phase. Similarly the team that initiated Manipal AcuNova's functions encountered a few hurdles. The experience of setting up the global quality infrastructure and attaining right approvals happened at a snail's pace. "It takes time to set up the globally accepted infrastructure, get global certifications and also for global companies to audit you. The whole process is very long and time taking."

The idea of research is very conservative in the Indian industry, observes Prasanna. He felt that, "Getting the recognition of a research institution is not easy in India as the concept of research is very orthodox. People look for a building, a laboratory and a lot of instruments. The idea of providing an integrated service is still not understood in this industry."

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