EXPRESS PHARMA

'ACRO agenda is to minimise headwind, take advantage of tailwind '

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D A Prasanna**, Founder Chairman, Ecron Acunova has taken over as the Chairman of Association of Contract Research Organizations (ACRO INDIA) at a time when the Indian CRO industry is facing multiple challenges. He plans to strengthen the industry base and create healthy interactions with the DCGI and Ministry of Health (MoH). He reveals more details of his strategies to **Usha Sharma

Your appointment as the ACRO Chairman comes at a juncture when the Indian CRO industry is facing tough times. How will the current scenario increase your responsibilities?


D A Prasanna

It is true that the CRO industry in India is facing challenges from multiple fronts. Global clinical trials have dried up in India, from 500 approvals in 2010 to less than 50 approvals in 2013. Strictures of US FDA on Ranbaxy and Wockhardt is largely focused on GMP compliance in manufacturing. The overall image of Indian CRO services has suffered.

On the other hand, there are positive aspects in the environment for clinical research. These include outsourcing of back office in PV/ safety services, clinical data management (CDM) which continue to enjoy healthy demand. ITES companies benefit more than CROs. There is also a new demand for remote monitoring of global sites from India.

Indian companies do have new chemical entities (NCE), new biological entities (NBE), new cell therapies, new medical devices in the pipeline and these have shown ways for them to grow. Registration in the Indian market will be the key for these products.

Similarly, biosimilars from Biocon, Zydus Cadila, Amneal Pharmaceutical etc. are all keen to launch biosimilars in the Indian market.

Another growth driver is the fact that generic companies are racing against the July 2014 deadline for ANDA filing. So also, they are differentiating with clinical benefits under 505 b (2) pathway. And since demonstration of benefits needs clinical studies, this will be a growth driver for the CRO industry.

What agenda have you set and how will you accomplish it during your tenure ?

ACRO's agenda is to minimise headwind and take advantage of tailwind!

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Due to various factors, the total number of clinical trials conducted in India have declined and some of them have shifted to other countries as well. How will your experience assist in stabilising the industry's position?

Root cause of headwinds is the concern raised by NGOs that attention is not given to patient safety in clinical trials and the regulator (and the Ministry of Health and Family Welfare) is not taking adequate steps. Inadequate response by stakeholders and government forced NGOs to go to the media and litigate through PIL in the Supreme Court. This resulted in global clinical trials coming to a halt, the Ministry of Health (MoH) and Drug Controller General (India) (DCGI) reacting with very stringent regulation and global pharma companies backing out of India due to uncertainty. There is uncertainty on the time it takes to get approval of applications from MoH, holding meetings of the New Drug Advisory Committees (NDAC). Also, the rules related to compensation of clinical trial injury and medical management are onerous. While officials agree (on this point), they have not changed the onerous rules.

Which will be your top five priorities and why?

a) Demonstrate that CRO services are delivered with highest attention to patient safety. Reduce the trust deficit related to patient safety with NGOs and media. And changes related to the clinical research regulations should be in line with uplifting the industry responsibly without disturbing the growth of the industry.

b) Actively engage with DCGI, MoH and Parliamentary Advisory Committee on health, to ensure that uncertainties are reduced on timeliness and NDAC meetings.

Ensure that the New Drugs and Cosmetic Act enables sound decision making and is passed soon.

c) Instill global best practices in Indian CRO service, to deliver highly credible research data to regulators under safe conduct of clinical studies.

d) Based on actions in the above three areas, improve the image of Indian clinical research among national and global stakeholders.

e) Ensure that the interests of ACRO is aligned to Indian pharma, biotech and device companies and increase co-operation for a better clinical research environment in India.

What new programmes/ initiatives are you planning to roll out for the CRO industry's brand building globally?

Brand can be built when we take action. ACRO has been working quietly in the last few months and a few actions are revealed below.

- **Patient safety:** We have worked with global insurance companies to cover new compensation risks in a new policy. This will prove to be helpful to all stakeholders. We have shared with members, a CRO's best practices to identify patient risk, fire and electrical risks and how to mitigate them. These would improve India's pharmacology units to highest global safety standards. We have set up a national database and software to prevent cross participation in studies, improve safety. These are a few initial steps.
- **Advocacy:** With quality time given by Health Secretary, DCGI and MPs to our problem, we contributed to DCGI publishing timelines for decision on 18 types of applications. Now DCGI's timeline for decision on global clinical trial application is 180 days and BE NOC is 45 days! The timetable for NDAC meetings in 2014 is on the CDSCO website. This reduces uncertainty and is welcomed by all stakeholders.
- **Best practice:** First best practice seminar run by highly credible faculty from pharma companies and CRO leadership was held in Mumbai in January this year. There is more to come.
- **Improving image:** We plan to publish a quarterly newsletter and distribute it amongst stakeholders. The ACRO website is being transformed into a clinical research portal. As we do more work, we will engage communication channels.
- **Co-operation:** We plan to work closely with IPA, ABLE and Pharmexcil to promote India in the clinical research arena.

Tell us about your mission and vision for uplifting the Indian CRO industry.

Our mission and vision is: responsible clinical research with high attention to patient safety, delivering credible data to regulators and helping to bring new medicines to patients fast.

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