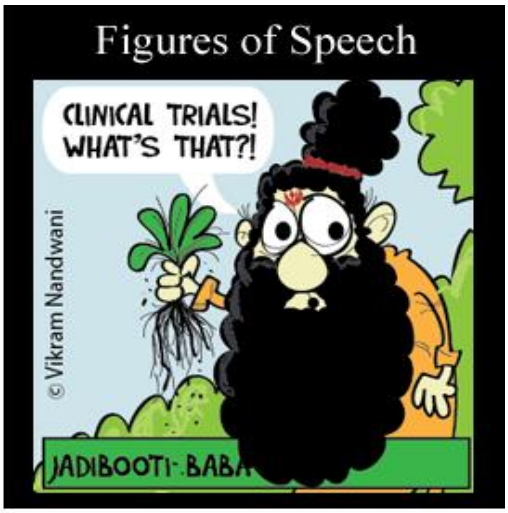
Empowering TIMES

Inspire . Aspire . Achieve . Grow

August 2015

Thinking Aloud	Podium	We Recommend	Standing Ovation
Clinical Trials Industry in India: The Drift Continues - **Jay**	Interview with **Dr. Pramod Kabra -** Managing Director & General Manager at Fisher Clinical Services	**Triggers – Sparking Positive Change and Making it Last, By Marshall Goldsmith**	**Abhinav, Uttar Pradesh**

Dear Reader,



Globally, the Clinical Trials industry has come a long way in testing new and promising drugs to treat various serious conditions. Chalking out India's journey in the Clinical Trials industry, regulations in India were amended in 2005 - India introduced patent protection laws in a bid to liberalise the conduct of global drug trials. Since then, companies have flocked here because of the country's diverse population, and reducing R&D costs by nearly 60% in phase II and III trials.

However, trials in the country have been plagued by various concerns. According to official figures, more than 2,600 patients participating in Clinical Trials in India lost their lives between 2005 and 2012, due to the irregularities in the government's framework for conducting such trials in India. The negative outcome after treating the survivors of the Bhopal gas tragedy for Clinical Trials without their knowledge or consent further exacerbated the sorry state of affairs of this industry, while bringing to the fore the irregularities and ethical violations in some trials conducted by clinical research firms and pharma companies in the country.

Such challenges, among many others seem to wash out any other opportunity for this industry to progress. Recent research from the Associated Chambers of Commerce of India reveals that such trials in countries like India are cheaper to run. Coupled with this, when Clinical Trials are conducted ethically, India's poor also stand to gain, given that only 20% of India's overall population are covered by health insurance.

Though the country has a huge potential for Clinical Trials, the industry faces a lot of resistance both from Rights groups and from regulators. It is about time that the country streamlines its regulations - government and regulatory

bodies have to take matters into their own hands to fix the roadblocks that challenge clinical research, so as to seize opportunities of this still under-achieved arena. ET this month looks at the theme - Clinical Trials Industry: Services & Solutions.

In the **Thinking Aloud** section, Jay delves into the world of Clinical Trials, constituents of this industry and the current state of the same in India. This industry is plagued with various challenges and because of the fact that bringing new medicines to the market is very slow, the consequences continue to impact not just firms in the industry, but its stakeholders, especially patients longing for a cure for their ailments.

On the **Podium**, Dr. Pramod Kabra, Managing Director & General Manager at Fisher Clinical Services, states that the Clinical Trials industry in India is going through a phase of consolidation, despite the various concerns that it faces. This segment, according to Dr. Kabra, has a lot to offer and has got growth potential in the future.

In **We Recommend**, Prasad reviews Marshall Goldsmith's book, 'Triggers - Sparking Positive Change and Making it Last'. Triggers play a pivotal part as it defines the way we behave. Goldsmith suggests that we start with structure and discipline to overcome negative Triggers. The environment in which we operate can also affect our lives. Goldsmith offers tool and tricks in becoming the person we would like to be.

In **Standing Ovation**, Uttar Pradesh based Abhinav is an NGO that supports the cause of women, children and youth in India, working alongside the government, UN organizations, NGOs and corporates for elevating the livelihoods of less privileged and marginalized communities. Abhinav has wide-spread interventions in agriculture, health & hygiene, water & sanitation, and child education. The organization also works to promote entrepreneurship for employment and self-employment.

In **Figures of Speech**, it's back to basics for Vikram's toon!

As always, we value your opinion, so do let us know how you liked this issue. To visit our previous issues you can visit the Resources section on the website or simply Click Here. You can also follow us on **Facebook**, **Twitter**, **LinkedIn** & **Google+** - where you can join our community to continue the dialogue with us! For smartphone and tab users, please Click here to continue reading Empowering Times.

Thinking Aloud

Clinical Trials Industry in India: The Drift Continues - Jay

The news that Sprout Chemicals has been cleared by the US Food & Drugs Administration (FDA) to launch Addyi (chemical name Flibanserin) has created excitement not just in the Pharmaceutical world but also all around. Loosely touted in the Press to be the 'female Viagra', all eyes will be on the drug once it actually reaches the market and gets acceptance.

But that one clearance was sufficient to bring to fore a fairly unknown firm into the limelight. Enough, in fact, to be

quickly acquired a few days later by Valeant Pharmaceuticals International in a US$ 1 bn deal!

For the moment let us keep the commercial aspects of the deal aside, and focus on the medical side. What is largely unknown is that before this magic drug (as some believe it to be) could reach a patient, there have been many pulls & counter-pulls behind the scene.

The drug has been in the wings for a long time. Originally developed by Boehringer Ingelheim, the German firm, Flibanserin lost favor with the company after it failed to pass muster with the US FDA in 2010. Later, Sprout Chemicals acquired the drug and continued Clinical Trials turning to subjects who had found the drug to be an answer to their medical needs. According to reports, what followed was a lot of lobbying with the FDA & in fact the prescription drug has now finally been cleared with conditions attached.

This tale is illustrative in multiple ways. There are a number of patients with a variety of ailments that are crying out for cure. And the challenge of bringing new medicines to them is frustratingly slow. And, why is this so?

While there is some merit in the argument that drug development is skewed to the needs of the western world, the fact is that the process involves a deep investment of resources (chiefly, time, talent, and of course, money). For instance, current estimates are that new drug development requires investment of over a decade and nearly a billion Dollars. No small change this!

The crucial input to the final decision by the FDA to permit launch of a new drug is its efficacy and safety. The primary way to establish the 'go/no-go' parameters is the outcome of the Clinical Trials. And, until recently, this industry was viewed as a growth business in India.

The sad downturn of the Clinical Trials industry in India has been caused by a number of factors. From the days when India had over 250 Global Clinical Trials approved for conduct (in 2010) to less than 100 approvals in 2013, the slide reflects the fact that the industry is itself ailing and in urgent need for rehabilitation. While there cannot be two views on the need for protecting the interest of patients undergoing trials, it is also important to note that due to the action of a few unscrupulous firms, the brush of venality has tarred the whole industry, and what you now have is a quagmire of regulations that test the will of most companies. The result is the exit of many global players and a sharp drop in opportunities of employment for many aspiring Clinical Researchers.

The sorry consequence is not just faced by firms in the Industry but impacts all the stakeholders (first of all patients, then others, including doctors, researchers, potential employees, vendors, etc.) who had all put their faith on the growth of this industry as the next sunrise business in India.

The unfortunate conclusion of most of the industry experts is that the government's desire to provide ease of business does not seem to extend to the Clinical Trials industry. And, thereby hangs a tale – how a promising industry that could have leveraged the technical expertise in India at a globally competitive price – and benefitted distressed patients - has been allowed to wither away.

back to top ^

Podium

Dr. Pramod Kabra - Managing Director & General Manager at Fisher Clinical Services

Dr. Pramod Kabra is a qualified Internist (MD, Internal Medicine) with over 17 years of experience in the field of business management, strategy deployment, drug development, clinical research and sales processes. He has been responsible for managing businesses at different levels, in both Indian and global organizations. Currently, he is based out of Ahmedabad and responsible for managing Fisher Clinical Services' business, encompassing Clinical Trial packaging, logistics management and comparator sourcing, in the capacity of Managing Director and General Manager of the EU regulatory approved facility.

Dr. Kabra is well aware and updated about the constantly changing Indian and international regulatory scenario in drug development and well versed with local and international regulatory guidelines, including Schedule-Y, ICH GCP, ICH GMP, etc. He successfully faced various audits by USFDA, MHRA, ANVISA, MPA Sweden and several other regulatory agencies.

ET: How would you describe the current status of the Clinical Trials industry in India?

PK: The Clinical Trials industry in India is going through a phase of evolution/maturing – especially with reference to the regulatory process. Personally, I feel that we are at the cusp of rapid growth, and are currently going through a phase of consolidation.

ET: As a leading solutions & service provider to the Clinical Trials industry, what are the challenges presently encountered by your sector?

PK: When we are discussing issues I am facing, I reference primary issues related to the industry in India. The major issue affecting and hampering growth of the industry is a continued lack of clarity on regulations. While we acknowledge that the government is putting efforts into resolving this issue, however, this effort needs to be expedited. There are patients waiting. Once this is addressed, the industry needs to focus on building capacity to accommodate future growth prospects. The clinical research industry has high growth potential in India.

ET: How do you think the Clinical Trials industry of the future will differ from how they look today, and why?

PK: Globally, this industry in growing with increasing trends to outsource many aspects of clinical research such as packaging, labelling, storage and distribution. Major pharma companies continue to grow and invest their time, expertise and productivity in drug development, working in partnerships and outsourcing other aspects of clinical research to specialists in the field. Smaller biotech companies outsource to specialists as they need guidance on how to conduct clinical research, particularly in emerging regions.

In India, domestic pharma companies are investing in clinical development and conducting studies in clinical end points, developing biosimilar and new molecules – which necessitates for them to conduct global hospital-based Clinical Trials. Essentially in this process, capacity is being developed within domestic pharma companies, which is further propelling growth and maturity of the industry in India.

ET: As a solutions provider to the Clinical Trials industry, what are the emerging trends that you foresee?

PK: Cold chain is a high growth market, globally, with many of the leading pharmaceutical companies developing healthcare products (vaccines, biologics, large molecules) requiring temperature control across the entire supply chain. Fisher Clinical Services has the infrastructure, technology, staff and processes in place globally to support these needs. This is a highly competitive marketplace. Many other providers wish to serve this high growth market.

New researches are being initiated in Asia, South America and recently in Sub-Saharan Africa. This trend will continue to grow, which will require support for evolving regulations in these countries, import/export support, building infrastructure to serve the industry, and most importantly, training of healthcare professionals to ethically conduct clinical research as they establish clinical research processes in line with ethics committees, treatment for naive patients, etc.

ET: Please tell us about your company, Fisher Clinical Services.

PK: Fisher Clinical Services is a world leader in clinical supply chain management. For over 25 years, the company has exclusively focused on serving the packaging and distribution requirements of Clinical Trials across the world. As Clinical Trials require increasingly complex supply chain support, our purpose-built integrated facilities provides global presence, information systems, and flexibility to allow unparalleled visibility and control of Good Manufacturing Practices (GMP) activities from protocol design through to the investigator site.

Quality Assurance (QA) teams support every project to ensure Standard Operating Procedures (SOPs) are strictly implemented and that current Good Manufacturing Practices (cGMP) are rigorously executed.

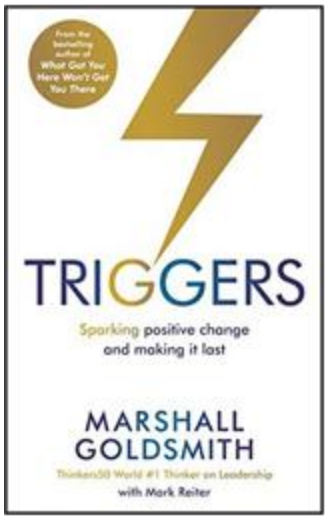
With exposure to large multinational trials and thousands of protocols every year across all therapeutic areas, Fisher Clinical Services has developed the industry's best practices in clinical supply chain management.

Fisher Clinical Services is a part of the BioPharma Services Division of ThermoFisher Scientific, the world leader in serving science, enabling our customers to make the world healthier, cleaner and safer. With annual revenues of US$ 17 bn, we have more than 50,000 employees and serve over 350,000 customers within pharmaceutical and biotech companies, hospitals and clinical diagnostic labs, universities, research institutions and government agencies, as well as environmental and industrial process control settings.

back to top ^

We Recommend

Triggers – Sparking Positive Change and Making it Last, By Marshall Goldsmith



"Triggers are what shape our behavior. Certain situations can provoke even the most rational among us into behaving differently – and in business, that can be fatal. The difference between success and failure is as simple – and as hard – as mastering Triggers."

Marshall in his inimitable style has again written a practical and sensible book that helps us answer the question "Why don't we become the person that we want to be?" Why indeed?

Needless to say, even if you are happy being who you are, this book does make you want to re-examine some of your behaviors that you may want to change.

As Marshall asserts, meaningful behavioral change is the toughest thing to do, primarily because of belief Triggers and the environment. The environment nudges and influences us in powerful unseen ways to behave in ways that we might regret later. Whether you are a powerful executive, a 'master of the universe' or someone who could behave in a kinder way with customers or colleagues, the environment can exert a pernicious hold on us, far more than we are aware of.

A Trigger is any stimulus that impacts our behavior and is the other element in the mix that makes behavioral change so tough for us. Triggers can be encouraging, discouraging, productive or counter-productive depending on what goal we would like to achieve. To put the impact of Triggers in perspective, Marshall makes use of a simple grid - what we need versus what we want. Encouraging Triggers when we are pursuing that what we need and want moves us towards our goal and the same Triggers when we are pursuing something that we want and don't need would make us ease a bit and set us back.

Marshall reminds us that we always have a choice when it comes to our behavior. The environment and our Triggers can influence us positively, when we make wise choices between our wants and needs, the short and the long term, in the pursuit of meaningful change of behavior.

Marshall's explanation why we are such superior planners and inferior doers is insightful. He uses the theory of 'Situational Leadership' to show us that there is a leader and follower inside all of us. The leader plans our desired behavioral change and the follower in us has to execute that plan. We think that they are both part of who we are. But we are wrong. We often start the day as bifurcated individuals, part leader and part follower, but as the day progresses, the two grow further apart.

Marshall is a fervent advocate of getting better with structure. So much so that he only wears a green polo and khaki trousers! He offers multiple structures such as the daily questions and the hourly questions. Structure not only increases our chances of success, it makes us more efficient at it.

As always, Marshall's many examples peppered throughout the book make for a very interesting, easy read. His use of a few tools like the AIWATT (Am I Willing At This Time, to make the investment required or to make a positive difference) and the Wheel of Change will appeal to experienced executives, coaches and all of us who are interested in becoming the person we would like to be.

back to top ^

Standing Ovation

Abhinav, Uttar Pradesh

Abhinav began operations in 1993, with the aim of assisting the poor and downtrodden segments of the society. Abhinav prefers the role of a facilitator rather than an operator or implementer. Its main objective is to develop farmers, women, and unemployed youth to make them stand on their feet. The main stress of the organization has always been on generating employment oriented opportunities. Since its inception, Abhinav relentlessly works at the grass root level and has trained more 17,000 people including men, women, children and youth.

Mission

- Creation of self-reliant communities by adoption of a participatory approach.
- Acquainting with the country's rich tradition and heritage and imbibing the spirit of using efficient use of modern resources.
- Make provision for opportunities to the disadvantaged sections of the community for their all round development.
- Creation of awareness of social, economic and political incidences, which have kept the rural masses poor and deprived.
- Emphasis on women empowerment.
- Slum development.

Major activities include:

- **Safe drinking water & sanitation program**: The NGO has achieved milestones in the provision of safe drinking water & sanitation, implementing 96 projects in 8 districts of Uttar Pradesh and over 100 well known government schemes under the Swajaldhara project.
- **Health and family welfare**: Distributed over 2,000 health and hygiene kits, provided more than 19,070 vaccinations to mothers and children, rendered family welfare services to 15,788 families, provided more than 21,741 curative treatment to rural people and 5,916 referral services.
- **Training and employment generation**: Imparts training to self-help groups in Bareilly under various schemes. **Abhinav** has established a post-harvest technology center and a food processing and training center so as to help rural people to be self-independent by learning the various techniques involved in food processing, post harvesting.

- **Awareness programmes**: Various social awareness programmes to educate against dowry system, superstition, and other social evils are imparted at **Abhinav**. Road safety awareness and other rural awareness programmes are also conducted.
- **Advance Level Information & Satellite Technology Center**: **Abhinav** runs an Advance Level Information & Satellite Technologies Training Center in the village Nayagoan, Block Jansath of District Muzaffarnagar (UP), for the purpose of introduction & dissemination of cutting edge Information technologies in the deep rural areas with the assistance of Indian Space Research Organization (ISRO).

The activities of **Abhinav** have been evaluated by IIM, Lucknow. Besides this, the organization along with the State Family Welfare Institute, Lucknow has been appraised by various departments of State and Central governments. In all these evaluation studies, **Abhinav** ranked highly.

To know more, please visit their website http://www.abhinavindia.org

For its noble cause, **Abhinav** deserves a Standing Ovation!

back to top ^

Empowered Learning Systems Pvt. Ltd.

101, Lords Manor, 49, Sahaney Sujan Park, Lullanagar, Pune – 411040, Maharashtra, India