

KEY TRENDS TRANSFORMING THE CLINICAL TRIAL INDUSTRY

Day: Saturday

Date: May 2nd, 2015

Time: 12:15 p.m. to 1:15 p.m.

Venue: Convention Hall, Symbiosis International University, Lavale campus, Pune

Speakers: Dr. Nimita Limaye

The lecture was about recent trends in the field of clinical trials in India. The speaker talked about some areas of concern in the pharmaceutical sector (expiring patents, evolving regulations, disconnected interfaces, manual processes, limited standardization, and customization method). These problems lead to records and quality issues, missing information, high costs, and quality issues relating to EBM. She discussed SMACK (Social Media Cloud Computing) and robotic customization in pharmaceutical industry.

The Indian pharmaceutical industry is the third largest in terms of volume and tenth largest in terms of revenue. It is growing at the rate of 8.9% CAGR. However, it is all about generic drugs. New trends of biosimilars and biobetter drugs are increasingly gaining attention. Pharmaceutical industry is dealing with two types of innovations: incremental innovation and disruptive innovation.

The speaker talked about various trends in the pharmaceutical industry:

1. As of now, 140 drugs have been developed in India and only 28% are available in the market.
2. Cancer drugs have been exempted from clinical trials because these drugs are approved by DCGI.
3. The compensations that are given for mishappening during clinical trials is \$100000.
4. The CDSCO has received Rs. 900 crore grants.
5. Mergers and acquisition are common.
6. Nowadays, 70% of the “big pharma” revenue are for patents.

She also discussed clinical analytics, which involves dealing with identification of disease, drug target assessment, social media, clouding, SMACK, situational analysis, licensing assessment, and predictive analysis.

The presentation included the following themes: “printing tissue;” HOMO- MINITUS; ETHENA; personalized medicine; transcelerate biopharm; and robotic automation.

She concluded by stating the two stages of clinical trials:

- a. **I- Spy 2 Trial**: It is used for cancer patients and is used in third phase trial. It is based on bio marker and is based on adaptive design and trial wherein the researchers have used 12 different investigational drugs and saved 35% cost in clinical trials.
- b. **Virtual Clinical trial**: It was done by Pfizer in phase 4 clinical trial wherein they used audio video consenting and saved \$2500 per patient..