

SHRI B. V. PATEL EDUCATION TRUST

(TRUST REG. NO. E-2571, AHMEDABAD)

August 5, 2016

Essay Competition - 2016

Shri B. V. Patel Education Trust invites entries for the essay competition for the year 2016. The subject for the essay is :

“Clinical trials in India and China-Advantages and Disadvantages”

In the last few years, Asian countries have emerged as top clinical trial destination and offer an alternative to traditional regions. The average costs of conducting phase I/II/III drug trials in US is around \$20/50/100 million respectively, whereas in Asian countries like India, it is 50-60% of the same in addition to being 75% faster.

India and China are expected to have tremendous growth potential in clinical research due to their huge disease prevalence and treatment-naïve patient pools. India has the added benefits of vast genetically diverse population, well-equipped hospitals, and highly qualified English-speaking investigators making it one of the preferred destinations for conducting global clinical trials. The contract research and manufacturing services in India was expected to increase from \$3.8 billion in 2010 to nearly \$7.6 billion in 2012. Similarly, China's registered interventional studies have increased almost 90% between 2008 and 2013. As of June 2016, China was ranked 13th globally with an estimated 5,628 commercial clinical trial sites. However, conducting clinical trials in India and China has its own advantages and disadvantages. Both countries are facing the challenge of creating a stable and predictable regulatory environment and developing government agencies that are able to uphold quality in the application process, implementation and scrutiny of the trials. In India, the regulation of clinical trials is uncertain compared with other countries where everything is on the website, the timeline and the procedure. The under registration of trials, ignorance and fear among the patients regarding the participation and lack of training on legal aspects are some of the loopholes exist in conducting clinical trials. As a result, the number of active clinical trial sites in India has decreased over the last 5 years, estimated at 1,884 in 2016. Irregularities occur in China too and there have been cases where the implementers of trials have manipulated results and documentation.

Economic uncertainty, regulatory barriers and clinical trial quality are key concerns for the conduct of trials. Expansion of clinical trials requires detailed understanding of country specific dynamics in order to maximize the benefits.

It is expected that the Essay will highlight the advantages and disadvantages of conducting clinical trials in India and China.

