

Changes in Chinese regulations stimulate market for CRO

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A recent circular issued by the Chinese State Drug Administration (SDA), has opened up a large market for Contract Research Organizations (CROs) across the world.

The circular (referred to as No. 52 of 2018) allows Chinese pharmaceutical companies to use clinical trial data from studies conducted outside China for their drug submissions to the SDA.

Global CROs have long been keen to enter the growing Chinese market for pharmaceutical drug testing. Sharing his views on the development, Dr. Satish Sawant, the Founder and CEO of Accutest Research Laboratories, Mumbai said, "In the current market context, it is critical for pharma companies in China to accelerate their speed-to-market. This is a challenging problem given the high cost of clinical studies in China and the shortage of high-quality CROs. Accutest has successfully partnered with leading pharma companies in China to achieve these goals. With this announcement, we will finally be able to collaborate with Chinese pharma players for their pivotal study submissions to the SDA."

This announcement is especially beneficial for CROs like Accutest which have an early mover advantage in the Chinese market. Dr. Sawant outlined Accutest's work experience in China, "Over the past 5-6 years, Accutest has conducted more than 250 Bioequivalence (BE) clinical trials for Chinese clients, including 150+ pre-BE studies for the SDA."

"Accutest has also supported Chinese clients by conducting BE studies for global submissions for regulators like the US Food & Drug Administration, the World Health Organization and the European Medicines Agency. With more than 30 active clients in China, we are definitely a preferred choice as a strong and reliable CRO for SDA submission studies." He stated further.