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## 'Clinical Trial Norms Should Change'

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**BANGALORE:** Medical experts feel that the country's regulatory mechanism on clinical trials is very reactionary and needs to be changed.

Members of the Indian Society for Clinical Research (ISCR) say that in the last one month, there have been at least 15 new orders on various aspects of clinical trials passed by the Central Drugs Standard Control Organisation (CDSCO), the regulatory body on pharmaceuticals.

Because of the regulatory uncertainty, there has been a drastic slowdown in clinical trials and many companies are shifting their research to other countries. "This is detrimental to clinical research prospects in the country and we need trials because they benefit the likes of cancer patients," said Dr P P Bapsy, oncologist and former director of Kidwai Institute of Oncology.

Stating that clinical trials help discover drugs, she recalled how, in 1985, the first trial on cancer patients was held in the country. "And we had a drug for breast cancer out of the trial. If India was not a participant in that trial, we would have gotten the drug 10 years later," she said.

### What Bogs Them Down

She said two clauses — on audio-visual consent and compensation — complicate the process. "Patients may come forward only for the money and this can lead to skewed data as some companies misuse the clause. There is also a clause for audio-visual consent and many patients are reluctant to have themselves recorded," she said. She added that the compensation and the recipient should be decided by an ethics committee.

Dr Viraj Suvarna, a member of ICSR's executive council, said if clinical trials are not encouraged, patients will not have access to new and improved treatment. "Doctors and researchers will not get to be involved in medical breakthroughs. Our health statistics will not improve," he said.

### How It Helped This Patient

Prem Roop Alva is a haemophilia patient. Whenever he suffers an injury, he bleeds for hours. He used to take medications every eight hours to stop the bleeding. But in 2012, he participated in a clinical trial by Dr Cecil Ross of St John's Medical Hospital, for a drug called 'Long Lasting Factor'. He said, "I tried a hundred drugs. This was the best. I continue to take that drug whenever I need it. I am on an extended trial."