

## Patients back-out from clinical trials fearing AV consent

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The discussion was led by Ms Suneela Thatte, president, ISCR, and Dr Bapsy, senior consultant and head of department, oncology, Apollo Hospitals.

During the discussion, Dr Bapsy revealed that Japan leads in clinical trials followed by China, Taiwan and Korea. "The population of Korea is not more than Karnataka, but they are engaged in more trials than India," she said.

Talking about AV consent of patients during clinical trials, Dr Bapsy added, "In one way the audio-video (AV) consent is appreciative. However, many patients do not want to sit before a video camera. They are extremely conservative. Women are especially reluctant, and they hesitate to participate if it requires an AV consent."

Also, the AV consent is said to add heavily to the clinical research costs. "With our infrastructure the AV consent is not suitable. Later, when we advance, our hospitals will be able to afford it. Many patients are fleeing clinical trials not because of the harm that maybe caused by the drug but due to the AV consent," she emphasized.

Currently, only in the case of difficult surgeries or transplantations, corporate hospitals execute AV consent of patients and their families as they are a one-time crucial activity.

"Taking the portrait pictures of patients will involve a third person who are professional photographers which brings the issue of confidentiality, since doctors and researchers are not qualified in taking pictures. This is not possible in government hospitals," Dr Bapsy opined.

At this point, the onus is expected to be with the ethical committee who can be the best decision makers.

"Clinical research should be done with proper regulatory and trained investigators together with an efficient committee. If these three are in place, then there is definitely no harm caused to the patients," she concluded.