

Clinical Trials: Realities and myths

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The conference on the first day hosted a session titled, *'Myths and Realities - How Patients Benefit from Vaccine Trials'*, which was presented by Dr Temsunaro Rongsen Chandola, Research Scientist, Centre for Health Research & Development, Society for Applied Studies, New Delhi.

In her presentation, Ms Chandola emphasized that the biggest challenge faced today by the research community is earning the trust of the public.

She said, "We need to gain the public trust by building an enterprise of trust by encouraging the community that we are working with, and create a network of stakeholders community and get the dialogue going with them. This communication

must be transparent and coherent between the stakeholders. Once that's in place, we need to conduct the trials, and walk-the-talk while conducting the trials."

To successfully conduct clinical trials, Ms Chandola feels that, first, the right community has to be identified and accessed. "After gaining their confidence," she said, "we need to get to know the community and interact with local leaders, physicians and have adequate data on the disease burdens that you want to study."

She further added, "It is imperative to understand the socio-cultural context of the study population, what they do for a living, their geographic location and immunization centers, and the distance between their health facilities, and conduct formative research activities before you start a trial."

Dr Chandola also spoke about the significance of creating a community support while conducting clinical trials. She expressed, "We must educate the population in this regard. Just because they don't have college degrees doesn't mean they don't understand."

"We need to be consistently and readily be accessible to the communities. This system will work since it is transparent, thereby gaining the communities confidence. Accessibility has to be centered around the subjects and their families and never be compromised throughout the study," she explained.

To build an enterprise of trust, Ms Chandola said that the pillars of ethics and competence has to be inculcated. She said, "Don't ever take shortcuts. It will eventually slow things down and it is not worth it. The best of clinical studies lay on the foundation of ethics and good clinical practices (GCP)."

Dr Chandola culminated her presentation by saying, "Communication must be open, honest, timely and very clear. Good clinical practices without values is heartless. Value for the patients life and safety matters a lot at the end."

Ms Chandola also presented the ROTAVAC Phase III clinical trial case study in her presentation.