

Sanction funds for training cell

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Association of Contract Research Organizations (ACRO) is an independent, non-profit organization with a global perspective and has 23 companies as members. It recommends the following reforms urgently:

- 1) For any study approval, CROs need to undergo a tiresome array of processes and paperwork. Single-window clearance from the office of Drug Controller General of India would be efficient, effective and timely. This would prevent undue red tape and bureaucratic hassles.
- 2) The government should sanction funds to establish a cell to conduct training sessions across India to spread awareness on the benefits of conducting ethical clinical research. Doctors, clinicians, ethics committee members and other stakeholders would benefit from such sessions. The cell would also be responsible for regular updates of ethics committee's resolutions and audits of the CROs to grade their expertise and ensure compliance.

These twin measures would permit timely approvals, shorten the time-to-market for drugs by reducing time and cost overruns, and thereby facilitate the government's efforts to ensure lower drug prices. Since clinical research is imperative and indispensable to enhance the quality of life for patients, ACRO India believes the above reforms will go a long way in making the lives of patients more comfortable.

Mr Apurva Shah

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