

## Rethinking Accountability in Clinical Research: Building a Culture of Ethical Confidence

31 October 2025 | Views | By Dr Shekhar Dawkhar, Executive Committee Member, Indian Society for Clinical Research (ISCR)

**India's CROs are growing fast; sustaining trust requires strong ethics, transparency, and collaboration. Ethical integrity will be India's key differentiator and global advantage**



India's contract research organizations (CROs) are at a defining moment. Globally, the CRO services market was valued at \$85.54 billion in 2024 and is projected to grow to \$175.53 billion by 2032, at a compound annual growth rate of 9.6 per cent. Within India, the opportunity is equally strong. The Indian pharmaceutical CRO market generated almost \$2.5 billion in the previous year and by 2030 is expected to grow \$4.4 billion, growing at about 9.9 per cent yearly. These trends reflect not only growth but also India's rising image as a trusted partner in clinical development.

To encourage this momentum, credibility and ethical integrity must also evolve alongside scale. A single ethical failure can undo years of progress and weaken the confidence and trust of participants, regulators and stakeholders placed in our ecosystem.

### Why Ethics Matters More Than Ever

As trials are becoming more complicated and virtual, the ethical environment is growing more complex. In India, varying diversity of trial locations, ranging from large cities to small centers, results in differential training, infrastructure, and monitoring. Together with this, the advent of decentralised trials, digital consent, data sharing, and AI raises new frontier

issues requiring careful regulation and watchfulness.

India is now no longer playing the cost-only game. International sponsors now assess the credibility of data, safety of participants, and openness as essential criteria in their alliances. Ethics and compliance, in such a scenario, are not only responsibilities but also differentiators that dictate trust.

### **Building Ethical Resilience in Practice**

Ethical leadership should begin at all levels of a CRO. Organisations can create ethical promoters who encourage open conversation and help teams understand that ethics are values that improve science, not just rules to follow. Regular scenario-based training, reviews of informed consent, and practical conversations about everyday problems can help people turn guidelines into actions.

Oversight needs to change as well. Digital traceability, real-time monitoring, and strong data governance can all help make sure that the whole process is accurate and accountable. Reviews shouldn't just look at papers; they should also understand the purpose, process, and effect. When teams and participants feel secure enough to voice their concerns, organisations can act swiftly to prevent harm and protect their reputation.

### **Partnerships That Build Trust**

Ethical excellence cannot happen in isolation. Regulators, sponsors, academia, and ethics committees must work together to provide consistency, capacity, and shared responsibility. The ethical guidelines of the Indian Council of Medical Research (ICMR) create a strong foundation that needs to be strengthened through uniform standards, collaboration, and continuous education.

The Indian Society for Clinical Research is partnering with stakeholders to promote ethical knowledge and standards across the clinical research value chain. Transparency and shared learning are vital to build trust among participants, regulators, and the global community.

### **Ethics as India's Global Advantage**

India's CRO industry has traditionally been renowned for scientific manpower, diversity of patients, and operational effectiveness. In the future, its real differentiator will be trust. Excellence in ethics will determine which organisations succeed in a progressively competitive, globally transparent world.

By integrating ethics into every decision and every test, India can set the standard for ethics in research. Clinical trials, fundamentally, are about people and their desire for improved health. With ethics informing every move, progress not only accelerates but also becomes fairer and more meaningful.

Dr Shekhar Dawkhar, Executive Committee Member, Indian Society for Clinical Research (ISCR)

**Disclaimer:** *The views expressed in this article are personal and do not represent the views of the member's organisation. The article has been written on behalf of ISCR.*