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ICMR launches report to strengthen first-in-human Phase 1 clinical trials in India

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Operational guidelines for single ethics review of multicentre research launched



The Indian Council of Medical Research (ICMR) recently organised the “1st ICMR Annual Clinical Trial Meet 2026”, under the theme “International Clinical Trials Day: Focus on Integrative Medicine Clinical Trials.”

The national-level event served as a significant platform for deliberations on strengthening India’s clinical trial ecosystem and advancing evidence-based integrative medicine research in the country.

The meet brought together policymakers, scientists, clinicians, researchers, regulatory authorities and experts from diverse fields to discuss emerging opportunities, ethical frameworks, regulatory pathways and innovations in clinical research.

One of the major highlights of the event was the presentation of findings from the ICMR-CCRAS multicentric Phase III Randomised Controlled Trial (RCT) on Iron Deficiency Anaemia. The study evaluated integrative approaches for managing anaemia, a major public health concern in India.

The event also witnessed the launch of the report titled “Advancing First-in-Human Phase 1 Clinical Trials in India: A Delphi Study on Regulatory Pathways and Opportunities.” The report was developed through a two-round consultation involving 37 experts from the pharmaceutical industry, Contract Research Organisations (CROs), academia and national regulatory agencies.

The study identified major bottlenecks affecting the advancement of early-phase clinical trials in India and recommended measures including strengthening regulatory capacity, streamlining approval processes and enhancing coordination among agencies to support innovation-driven clinical research in the country.

Another important milestone during the event was the release of the “Operational Guidelines for Single Ethics Review of Multicentre Research in India,” aimed at strengthening and harmonising ethical review mechanisms for multicentre research studies nationwide.